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ERRATA

- p iv Chapter Five title: "Conducting" for "Conduction"
- p 13 para 1, 8th line: "pubic" to "public"
- p 17 last line: "to be health law" for "to health law"
- p 34 box: "HIV virus" to "HIV"
- p 53 para 2, 4th line: "per-son" to "person"; para 3, 3rd line: "con-sent" to "consent";
para 4, 3rd line: "out-side" to "outside"
- p 54 para 1, 6th line: "inter-national" to "international"
- p 107 para 2, 2nd line: "1962" to "1862"
- p 108 para 2, 7th line: "o" to "to"
- p 110 para 2, 11th line: after "in" insert "the developing world. It was erroneously
thought that"
- p 112 para 3, line 1: "Exert" to Expert"
- p 122 Chapter Five title: "Conducting" for "Conduction"
- p 127 1st para, 1st line: "specific be" to "specific attention be"
- p 165 No. 4, 1st line: "should project" to "project should"
- p 170 para 1, 4th line: "cure STDs" to "cure to STDs"; para 2, 4th line "inun-dated"
to "inundated"

Health and Human Rights:

Case studies in the potential contribution of a human rights framework to the analysis of health questions

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Abstract

Simply stated, this thesis is a collection of case studies which examine the potential contribution of a human rights based framework to the analysis of health concerns. These case studies include an examination of: sexual health; intellectual property and access to pharmaceuticals; ethical questions that arise when research is conducted in developing countries; the application of Australian health law; and issues pertinent to specific populations including Indigenous Australians. Finally the relationship between human rights and international humanitarian law is explored.

Statement of Authorship

Declaration for thesis based or partially based on conjointly published or unpublished work

In accordance with Monash University Doctorate Regulation the following Declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes eighteen original papers published in peer-reviewed journals and four book chapters. The core theme of the thesis is that benefits may be made to the health of populations by considering health policies and programmes within a human rights framework. The ideas, development and writing up of the papers and chapters in the thesis were the principal responsibility of myself, the candidate, working within the Department of Epidemiology and Preventive Medicine under the supervision of Associate Professor Flavia Cicuttini and Associate Professor Beth Gaze of the Law Faculty.

The inclusion of co-authors reflects the fact that the work arose from active collaborations. My contributions to the published works are as follows:

	Thesis Chapter	Publication Title	Publication Status	Nature and Extent of Candidate's Contribution
1	2	"Public Health, Health Promotion and the Law" in Hands-on Health Promotion eds Rob Moodie, Alana Hulme. IP Communications. Melbourne 2004	Published	100% Conception and Execution
2	2	"Learning a culture of respect for human rights" Lancet 1998; 352: 1800	Published	80% Conception and Execution
3	2	"Getting serious about the right to health" Lancet 2000; 356: 435	Published	50% Conception and Execution
4	2	"Do human rights have a role in public health work?" Lancet 2002; 360: 1880	Published	50% Conception and Execution
5	2	"Are human rights good for your health?" Lancet 2001; 358: 1901	Published	33.3 % There were 3 authors. Each contributed equally.
6	3	"Prostitution, public health and human rights law" Lancet 2000; 356 1764	Published	90% Conception and Execution
7	3	"Can health programmes lead to mistreatment of	Published	70% Conception and

		sex workers?" Lancet 2003; 361: 1982-1983		Execution
8	3	"Sex, Morality and the Law" in Sexual Health Medicine – A clinical approach. Eds Christopher Fairley, Davis Bradford, Darren Russell	In Press	100% Conception and Execution
9	3	"Distortions and difficulties in data for trafficking" Lancet 2004; 363: 566,	Published	70% Conception and Execution
10	3	"Compulsory detention: limits of the law" Lancet 2001; 358: 146	Published	60% Conception and Execution
11	3	"Japan's comfort women" Lancet 2001; 357: 02	Published	50% Conception and Execution
12	4	How much is patent protection threatened by drug costs? Expert Opin. Pharmacother. (2004) 5(9):	In Press	100% Conception and Execution
13	4	"Patents on Drugs: Manufacturing Scarcity or Advancing Health" Journal of Law Medicine and Ethics 2002; 30: 621-631	Published	50% Conception and Execution
14	4	"Patents and access to essential drugs" Transactions of the	Published	100% Conception and Execution

		Royal Society of Tropical Medicine and Hygiene 2003; 97: 6-9		
15	5	"The Declaration of Helsinki and research on vulnerable populations" MJA 2000; 172: 292	Published	80% Conception and Execution
16	5	"The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations" Nature Medicine 2000; 6: 615	Published	33.3% There were 3 authors. The paper was based upon a lecture of mine delivered at a Symposium. This is noted in the paper
17	6	"Health Law and Human Rights" in Human rights in Australian Law: Principles, Practice and Potential, editor David Kinley, The Federation Press, Sydney 1998	Published	50% Conception and Execution
18	6	"Healthcare, rationing, patient rights and the law" Medical Journal of Australia 2001; 174: 472-473	Published	70% Conception and Execution
19	7	"Aboriginal reconciliation still a long way to go" Lancet 2000; 355: 2070	Published	50% Conception and Execution
20	7	Voices Lost Indigenous	In Print	30%

		Health and Human Rights in Australia Lancet		Conception and Execution
21	7	Detention of Asylum Seekers in Australia Lancet 2002; 359: 792	Published	100% Conception and Execution
22	8	International Humanitarian Law and International Human Rights Law – a brief overview “The Encyclopedia of Forensic and Legal Medicine” Elsevier Ltd. Oxford	In press	50% Conception and Execution



Beatrice Loff

August 2004

FOR MY PARENTS, SALEK AND KALCIA

FOR WHOM EDUCATION WAS ALWAYS

THE MOST IMPORTANT THING

*"THEY CAN TAKE AWAY EVERYTHING ELSE BUT WHAT IS IN YOUR HEAD
CAN NEVER BE TAKEN AWAY."*

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Prologue

There comes a need to stop writing and put materials together in the formation of a doctoral thesis. Yet in this area, health and human rights, which is not a discipline, there remains so much that is yet to be said, so much yet to be considered and analysed. So, though my ideas are constantly in flux, I have stopped and collected some of my publications and put these forward as a body of work – a small contribution to this emerging field.

These publications consist of book chapters, articles and commentaries. These publications do not have the appearance of epidemiological research or reports of clinical trial outcomes. Neither are they publications drawn from law, which is my background. Yet they are meaningful contributions to the field of endeavour which many of us engage in – that of improving the lives of our fellows – and these contributions have been thought worthy of publication and discussion. Although this work is not drawn from any singly discipline, the need for a rigorous approach to research and development of ideas remains and hopefully it has been demonstrated here.

Except where otherwise indicated, the articles, commentaries and book chapters in this thesis have been peer reviewed.

Chapter One: Introduction

Health and Human rights – a new beginning

In 1994 a new journal was launched. Its title was "Health and Human Rights: An International Quarterly Journal". Its editors announced

"We have created this new journal, Health and Human Rights, to inform and expand the space within which ideas about the intersection between health and human rights can venture forth into the world, to be cited and criticized, debated and discussed, torn down and built up. For it is in the nature of pioneering work -in this case, exploring the frontiers of health and human rights - that some new paths will lead forward, and others will be found, later from afar, to have only been byways and meandering trails."¹

The laudable aim was an indication that much was yet to be discovered about the contribution human rights jurisprudence could make to the theory and practice of public health and vice versa.

The first article of that edition went on to propose what was described as a three part provisional framework for "exploring the potential collaboration between health and human rights".² The aim of this collaboration was to enhance human well being by utilising an interdisciplinary approach, each discipline enriching the other.

The first proposition was that where health policies and programs impact upon human rights, the optimum balance must be struck between public health goals and human rights norms. The next proposition called for recognition of the impact of violation of rights upon health. Finally, and most importantly, is the idea of the interdependence of and inextricable linkage between health and human rights.

¹ Mann J. A new journal: a new beginning. *Health and Human Rights*. 1994;1(1):1-2. at p 1

² Mann J, Gostin L, Gruskin S, Brennan T, Lazzarini Z, Fineberg HV. Health and human rights. *Health and Human Rights*. 1994; 1:6-23. at p 6

These themes have been grasped and endorsed on numerous occasions. Of particular note in this regard is the United Nations document entitled "HIV/AIDS and Human Rights: International Guidelines"³. This document creates guidelines for States to assist them in formulating a rights based response to HIV/AIDS. It also encourages United Nations human rights bodies "to incorporate HIV/AIDS issues into their monitoring functions and general mandates".⁴

The World Health Organization has also begun to integrate human rights norms and standards into its work. Various aspects of these efforts have been detailed in the written submission of the World Health Organization to the 59th session of the United Nations Commission on Human Rights.⁵ They include consideration of the impact on health of: racial discrimination; the right to development; gender; the rights of the child; indigenous issues; and the effective functioning of human rights mechanisms.

This thesis is a collection of works that span the broad interrelationship between health and human rights. The thesis begins by describing the emergence of thinking regarding health and human rights. It follows with a general commentary on public health and poses the question – why link health policies and programmes with human rights standards. The thesis then explores various health issues from human rights based perspective. These include: sexual health; intellectual property and access to pharmaceuticals; ethical questions that arise when research is conducted in developing countries; health and human rights issues in specific vulnerable populations; and health law and human rights as they apply in the Australian context. Next, and on a slightly different though related theme, the relationship between human rights and international humanitarian law is explored.

³ Office of the United Nations High Commissioner for Human Rights and UNAIDS. *HIV/AIDS and Human Rights: International Guidelines*. Geneva: United Nations; 1996.

⁴ Office of the United Nations High Commissioner for Human Rights and UNAIDS. *HIV/AIDS and Human Rights: International Guidelines*. Geneva: United Nations; 1996.

⁵ World Health Organization. *Written Submission to 59th Session of the Commission on Human Rights, Economic and Social Council*. E/CN.4/2003/122 30 January 2003.

The assertions that are made in the published works collected in the thesis, while already guiding the work of agencies such as the World Health Organization and UNAIDS, await true interdisciplinary research. Such research should involve the coming together of epidemiological researchers, clinicians, sociologists, anthropologists, lawyers, and of course the relevant communities to test the rhetoric. If the rhetoric is found to have substance and the human rights framework does indeed offer a direction for action, public health and human rights activists may come together with significant moral and legal force.

Why Health and Human Rights

The presumption that linking health policy and programs with respect for human rights will result in a better health outcome may be seen in early writing on women's health and health and race or indigenous status. Obvious connections have been noted between reproductive health and reproductive rights as they have been characterised by feminists. Health related campaigns by Australian Aborigines and other indigenous communities stress self-determination, indigenous rights and land rights as central themes.

This use of the language of rights, however, belies the fact that rights fashioned for rhetorical or political purposes are not necessarily reflected in the expression or content of international or domestic law. Further transforming a right into law does not necessarily mean that the right has been achieved in practice. However, other purposes may be served.

For example Elizabeth Kingdom notes

"...in the context of new reproductive technology, the declaration of women's right to reproduce would be understood as the mechanism for initiating research into the existing medical provisions and any legal constraints to the access to treatment, into the precise arrangements, such as funding, which are to be secured, into the

immediate popular, political and medical ideologies, and into the lessons to be learned from previous campaigns."⁶

She suggests the moulding of arguments in terms of rights may assist in determining an agenda for further investigation and activity. She presents the concept of "rights as heuristics"⁷. In this model a right may be construed as a means by which to make prominent an interest in a political context such that it facilitates the identification what must be done before it is possible to formulate policies that will truly address a problem. The expression of a right is then not an answer but a signpost indicating the direction for a series of new questions. Rights are not fixed or clear but have content continually in need of refinement.

Similarly, Scott Burris sees human rights as having a moral validity and rhetorical force not dependent upon their codification.⁸ He cites the right to health care as an example of this. Burris nevertheless asserts that the vehicle of law provides access to influential fora in which to determine conflicts and priorities impacting upon disease. These are where the traditional divisions of power are located, that is in parliament, the executive and the judiciary. Law is then, inescapably, an

"important and malleable" factor in health. It can be a useful device to further discussion about health and can provide space for the discussion to take place".⁹

Thus international and domestic legal rights may provide insights by virtue of being a starting point for a program of politically purposeful research and activism. It is this model of thinking about rights that is used in this discussion about "health and human rights". We may begin to see, at some stage in the future, epidemiological evidence concerning the relationship between health and rights, but this work has not yet begun

⁶ Kingdom E. *Transforming Rights: Feminist Political Heuristics*. Res Publica; 1996;11(1):63-75. at pp 73-4

⁷ Ibid

⁸ Burris S. Law as a structural factor in the spread of infectious disease. *Houston Law Review*. 1999;36:1755-1786. at p 1770

⁹ Ibid

(other than in the very obvious instances of gross human rights abuses such as torture and other war crimes and their impact on health).

Developing the framework

The need to address the social, economic and political environment or 'upstream' factors in public health has been known for at least the last 150 years¹⁰ and is clearly articulated in the Alma Ata Declaration (the Declaration).¹¹ Though the ink was hardly dry on the Declaration before it began to be undermined,¹² the Declaration explicitly recognised health as a human right and the underlying social, economic and political causes of poor health.

It is, however, the account of the history HIV/AIDS that provides the best articulation of the theoretical development of the approach that links together health and human rights. Discussion of HIV/AIDS and its impact also pervades many of the chapters of this thesis. Mann and Tarantola describe the history of the response to HIV/AIDS as having developed in four phases, moving from:

"a danger to be alerted about, to a problem of individual behaviour, to a societally contextualised behavioural issue, and finally to a human rights linked challenge".¹³

¹⁰ McKeown T, *The Role of Medicine, Dream, Mirage or Nemesis?*. Oxford: Basil Blackwell; 1979.

¹¹ The Alma-Ata Declaration. *WHO Basic Documents*. Geneva: WHO; 1978. agreed to by virtually all of the 134 nations represented at the International Conference on Primary health Care, held in 1978 in Alma Ata, Kazakhstan (former republic of the USSR).

¹² Walsh J, Warren K. Selective primary health care: an interim strategy for disease control in developing countries. *New England Journal of Medicine*. 1979;301:967 was the initial article which led to the famous and lively debate within international health in the early 1980s on selective primary health care as an alternative to the primary health care approach adopted only seven months before at the Alma Ata conference.

¹³ Mann J, Tarantola D. Responding to HIV/AIDS: a historical perspective. *Health and Human Rights*. 1998; 2: 5-9.

This progression in thought was, in some ways, an insightful reflection of what was being discovered about the aetiology and epidemiology of the disease.

At first little was known and there was no treatment. All that was possible was a description of the end stage of the disease, although some attempts, quite peculiar in retrospect, were made to connect the disease with certain aspects of homosexual activity.¹⁴ The identification of individual risk factors made possible an "individual-behaviour based approach to prevention".¹⁵ Programmes targeted at the disease focussed on the provision of information, education and communication; clinical services; provision of condoms; creation of sites for voluntary testing and counselling; and protection of confidentiality.

It was becoming clear that the greatest proportion of those becoming infected were and continue to be in the developing world and amongst the less privileged in the developed world¹⁶. Programmes that might have some impact in a developed world context (though not entirely helpful even in these settings) could not deal with the issues now being identified as central to the spread of HIV/AIDS: discrimination, social marginalisation, and poverty.

It was posited, with some force, that a human rights framework might offer a means by which to begin to examine and respond to issues in public health unresponsive to the more usual public health approaches. The rights framework ostensibly relied upon for this purpose was that expounded in international legal instruments and the International Bill of Human Rights¹⁷ in particular. This framework allowed

¹⁴ see Altman D. HIV, homophobia and human rights. *Health and Human Rights*. 1998; 2(4):15-22.

¹⁵ Mann J, Tarantola D. Responding to HIV/AIDS: a historical perspective. *Health and Human Rights*. 1998; 2(4):5-9. at p 6

¹⁶ It is recognised that terms such as developed/developing world, vulnerable/industrialised, north/south and east/west are all unsatisfactory being unable to convey the complexity of societal dynamics. They are used as a convenient shorthand.

¹⁷ The *Universal Declaration of Human Rights* 1948, the *International Covenant on Civil and Political Rights* 1966 and the *International Covenant on Economic Social and Cultural Rights* 1966.

UNAIDS¹⁸ to characterise vulnerability to HIV/AIDS in a non-biological fashion. Vulnerability was seen as

“exercising little or no control over one’s risk of acquiring HIV infection or, for those already infected or affected by HIV, to have little or no access to appropriate care and support.....(V)ulnerability is magnified by societal factors such as marginalisation or discrimination.... and by economic policies and other structural factors that hinder sustainable human development.”¹⁹

Global factors including: the impact of external debt and structural adjustment programmes on national sovereignty; conflict; famine; disease other than HIV infection; and natural disaster all have an impact on the spread of HIV. Domestic law can readily contribute to vulnerability. For example, in many places girls are forced to marry before or during adolescence and are forbidden from gaining independent employment, or maintaining relationships with their family and friends. In these circumstances it is far more likely that their health status will be poor.

Despite this, as noted earlier, HIV interventions have been largely directed towards changing individual behaviour. While it is clear that unprotected sex is significant in transmission of the HIV epidemic, it may be over-emphasized when attempting to explain the variation in infection rates between and within and between countries. Long-term solutions could include confronting deficient immune systems and particularly co-infection with a myriad of diseases of poverty, addressing the inability of countries to make decisions in their own interests as a result of World Bank/IMF policies, and the sometimes-stigmatising responses by the international community to

¹⁸ UNAIDS is the Joint United Nations Program on HIV/AIDS co-sponsored by UNDP, UNESCO, UNFPA, UNICEF, WHO and the World Bank.

¹⁹ UNAIDS Strategic Plan 1996 – 2000 (Revised December 1995). In: Timberlake S. UNAIDS: Human rights, ethics and law. *Health and Human Rights*. 1998; 3(1):87-106. at p 91

the HIV epidemic.²⁰ These matters are not easily addressed without recourse to, at least in part, a rights based framework.

The Requirement for Activism on Two Fronts

It is unfortunately clear that some groups described by UNAIDS as being vulnerable (women, minorities, indigenous people, men who have sex with men, sex workers and injecting drug users), do not obtain a great deal of practical benefit from international human rights instruments. The social environment conducive to vulnerability is often not responsive to a "traditional" and legalistic rights based responses premised on non-discrimination or equality, nor to public health programs. The situation is compounded for those who engage in controversial, illegal or socially unacceptable behaviours. Paradoxically, yet quite intentionally, it is these very people upon which the health and human rights movement has sought to focus.

This shortcoming of legal rights has not been lost upon human rights and other activists who have also engaged in efforts to improve the relevance, applicability and enforceability of rights instruments to improve the status of these vulnerable groups. For example, human rights activists have lobbied for protective laws and processes for abuses occurring in the private sphere (notably domestic violence) despite the failure of laws to address this issue in an effective manner in the past. Other more traditional areas of legal activity have included improving access to information and education, welfare, housing have also been disappointing in practical outcome. Human rights activity is about both giving a worthwhile meaning to rights and the struggle to make real that meaning.

Writers promoting a health and human rights approach have suggested that

"(h)uman rights should not be considered simply as a rigid list of static norms and standards, but rather a discipline that is constantly evolving".²¹

²⁰ Katz A. AIDS, individual behaviour and the unexplained remaining variation. *African Journal of AIDS Research*. 2002;1:125-142.

This means, however, that for the health and human rights movement, activism must be rights based and be on two fronts simultaneously, human rights and public health.

The innovative character of a health and human rights approach should not be overlooked regardless of its difficulties. Public health was and, by and large, continues to be based upon utilitarian principles, cognisant of human rights and fair procedures only to the extent that it is necessary to disregard or overrule them. Indeed, a risk to public health may be regarded as grounds for exceptional treatment in anti discrimination law or as a basis upon which to limit many rights as set out in international instruments. A more robust implementation of human rights norms and standards would demand that other fundamental matters, often seen as opposing concerns, be given greater primacy. This divergence of approach at a foundational level means that conflicts will often be difficult to reconcile. This issue is considered further in a commentary in Chapter 2 of this thesis entitled "Do human rights have a role in public health work?"²²

The Contribution of this Framework

Undoubtedly we must learn to ask rights based questions about social dynamics impacting upon public health that might otherwise remain unasked. But these questions must not be asked naively. The failure of rights instruments to deal adequately with a human predicament must be confronted. Where there is a conflict between different rights documents, or where the interpretation of rights is arguably gendered, or racist or fails to take account of differences created in sexuality or culture, there needs to be a process by which underlying themes are articulated and addressed. The potential for public health concerns to reveal and garner support for redress of human rights problems needs to figure in the picture, as do the inadequacies of public health policy. As the debate over abortion shows however, neither health

²¹ *AIDS, Health and Human Rights: An Explanatory Manual: International Federation of Red Cross and Red Crescent Societies*. Francois-Xavier Bagnoud Center for Health and Human Rights, Harvard School of Public Health; 1995. at p 21

²² Gruskin S, Loff B. Do human rights have a role in public health work. *Lancet*. 2002;360:1880.

concerns nor arguments about rights may ultimately be persuasive in the battle over reproductive rights for example.

A further criticism of this framework is that in a human rights approach individual rights are protected at all costs--even though there may be adverse effects on the public's health. Yet a rights-based approach does not privilege protection of individual rights over the public good. This apparent tension is a misunderstanding of human rights, which as a legal tool has distinct utilitarian aspects. A human rights approach mandates that any public health strategy, whether or not rights are to be restricted, be informed by evidence and be openly and transparently debated with those affected enabled to participate in a meaningful fashion.^{23 24} This approach should assist in protecting the community against unproven and potentially counterproductive strategies, even those motivated by a genuine desire to redress public health challenges.

Human rights do not conflict with restrictions, so long as the objectives and the process used to make the decision to restrict rights are clear. The introduction of human rights into public health work is about the application of fair processes and the meeting of basic needs. The chapters that follow will examine the health and human rights framework in a range of circumstances.

²³ ECOSOC. The Siracusa principles on the limitation and derogation provisions in the international covenant on civil and political rights. Geneva: ECOSOC; 1985.

²⁴ CESCR. The right to the highest attainable standard of health: CESCR general comment 14. Geneva: UN; 2000.

Chapter Two: Public health, the law and human rights

This chapter begins with a general discussion of the ways in which public health professionals might conceptualise and work with public health law. It continues with some fundamental introductory material on the potential contribution of human rights to public health.

Monash University

Declaration for Thesis Chapter 2

In the case of chapter 2, contributions to the paper "Learning a culture of respect for human rights" Lancet 1998; 352: 1800, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	80%	Conception and execution
Stephen Cordner	20%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		23.06.04
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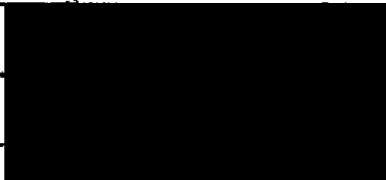
In the case of chapter 2, contributions to the paper "Getting serious about the right to health" Lancet 2000; 356: 435, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
Sofia Gruskin	50%	Conception and execution

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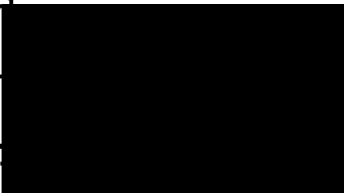
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Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
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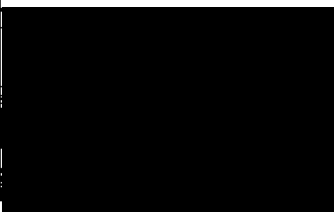
In the case of chapter 2, contributions to the paper "Are human rights good for your health?" Lancet 2001; 358: 1901, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	33.3%	Conception and execution
Scott Burris	33.3%	Conception and execution
Zita Lazzarini	33.3%	Conception and execution

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- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
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- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

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Public Health, Health Promotion and the Law

(This Chapter appears in Hands-On Health Promotion edited by Rob Moodie and Alana Hulme, IP Communications, Melbourne, 2004, pp39-49.)

Why health promotion practitioners should know about the law

Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they can exercise their authority. The law is a tool in public health work, which is used to influence norms for healthy behaviour, identify and respond to threats, and set and enforce health and safety standards. The most important social debates about health take place in legal fora – legislatures, courts and administrative agencies – and the laws language of rights, duties, and justice. It is no exaggeration to say that “the field of public health...could not long exist in the manner in which we know it today except for its sound legal basis”.²⁵

Public health in many countries is highly regulated and the breadth of subject matter dealt with is enormous, indeed far too large to be dealt with comprehensively in a short chapter. Laws governing public health and health promotion may be draconian, enabling the detention of individuals suspected of harbouring an infectious disease, just as they may be an ordinary and unremarkable aspect of life governing matters such as the orderly disposal of garbage. Public health law is primarily law made by parliaments not courts. These laws may regulate matters such as: quarantine; acquisition of property; compulsory bodily examinations; illicit drugs, alcohol and tobacco; privacy; food standards, nuisance; the environment; injury prevention; occupational health and safety; radiation exposure; sewerage; and vermin control.

Understanding the context from which contemporary public health laws emerge, as this may enable the status quo to be articulately challenged if necessary. To operate

²⁵ Gostin L. 2000 *Public Health Law: Powers, Duties, Restraint*. California:University of California

successfully as a practitioner and/or as an advocate for change in public health is difficult without having at least some sense of the background, content and the administration of laws affecting public health. Historically public health law has been distinguishable from other areas of law in that the interests of society (as understood by the law-maker) have prevailed unquestionably over the interests of the individual.

Many bodies are involved in enforcing these laws. They include national, provincial and local governments and agencies of government, such as the police, the courts, schools, and health care organisations. The prescription of certain responsibilities to one group, such as the police, as opposed to another, say government health officers, says something about the acceptability of a behaviour and the extent to which force might be expected to be exercised.

This chapter will briefly discuss the process of law making, different ways of conceptualising public health law, infectious diseases law as a specific example, the law in general as it impacts upon public health, the law in the design and implementation of public health programs, and health and human rights. The aim is to provide you with a greater understanding of how health public health law may relate to your work, and assist in you in accessing people who can advise further in different areas of these laws.

The Process of Law Making

First a few short words on the making of law. In the domestic (individual country) context parliaments, courts and the executive arms of government may make laws. In a well functioning democracy civil society will be enabled to make a contribution to the direction and content of the law. Thus a law reform process carried out by government ought to be a reasonably lengthy process in which individuals and communities are provided with comprehensible information, consulted and responses included in government decision-making. Consultation processes about law may be one mechanism by which to educate the community, not only about the content of the law and options for change, but also about the area of public health in question.

The reality is usually otherwise. The political process often demands a timetable that serves the priorities of the day as opposed to a proper examination of the adequacy of

law. The time and resources required to undertake a true consultation are often not present. In many countries officers working in the executive arm of government who may be responsible for carrying out a law reform project may be insufficiently resourced, themselves lacking basic materials and equipment. In all jurisdictions when a new law is passed by parliament it will often have gaps or errors and need to be returned to parliament for amendment.

Jurisdictions may be civil (for example France and the Netherlands and Louisiana alone within the United States) or common law (for example Australia and Great Britain) in character. Essentially in civil law jurisdictions the law is codified, that is the laws are compiled into a collection intended to be easily accessible to the public, not determined, as in common law, by judges. However although the judiciary are bound to enforce codes as developed by parliament, considerable room nonetheless exists for the exercise of discretion and creativity. In common law countries, in addition to the enforcement of statutes, the courts follow precedents established by earlier decisions of superior courts. Of course this is an oversimplified account, however any further discussion is beyond the scope of this chapter.

Courts make an impact on the law when deciding the cases that come before them. Their impact is limited by the facts of the individual cases and the lack of ability to deal with any issue comprehensively. Nevertheless, decisions of the courts may determine crucial issues such as whether and how a service like abortion is to be available, or how information is to be made accessible, and the proper role of government according to law. The capacity of courts to impose penalties or award damages may be exercised in the furtherance of public health objectives.

As some countries are arguably becoming more litigious, the scope for court involvement in public health will grow. This may or may not be a good thing. Public policy is not always best made in courts who are bound to deal with the facts arising out of cases that will come before them in an arbitrary fashion. Nevertheless, courts have a significant and crucial contribution to make, particularly when redressing wrongs committed against individuals or balancing the powers exercised by government.

Different ways of conceptualising public health law

Laws exemplify contemporary social, cultural and political trends in both their style and content. The citizen as consumer or customer has been a dominant theme of the latter part of the 20th century and this has been reflected in law. Governments have tended to take a deregulatory approach, seeking stronger justification for intervention in the marketplace. This has meant that much of what was previously thought to be a responsibility of government has been privatised and been made subject to contract.

Traditionally public health law has been thought of simplistically as being a subset of the body of law administered by ministries of health. The law is developed according to what the government agrees are key health issues to be addressed and legislation may appear as a mixed bag responses to particular diseases such as typhoid or syphilis or issues relevant to health such as waste disposal or tobacco, without clear objectives or a sense of structure.

In trying to create a unified conceptual approach some have suggested that public health might be seen as a matter of risk management. The law may be drafted in general terms rather than addressing specific health topics. It might include, for example, the functions of a health ministry and the framework of the responses to be taken to address a public health risk of any sort. The law may require that a public health risk be identified and assessed, that the risk be evaluated according to its social and economic costs, including costs to individuals of a personal nature and the range of responses that might be adopted. Some additional detailed attention may be given to issues such as privacy and access to information. Specific details to give such framework legislation structure will often be left to subordinate legislation developed by the executive arm of government. It is clear that assessments of risk and the balance to be struck between the individual and the community will be value laden.

Gostin provides a table in which he systematically evaluates public health activities according to the public benefits they produce and the private interests and rights that may be affected.²⁶ This type of exercise is most useful when attempting to identify

²⁶ *ibid* Gostin pp 86-87

what the law ought to address in order to strike the right balance between community and individual interests.

Gostin, Burris, and Lazzarini have devised a useful three-part framework describing public health and the legal responses to it, none being mutually exclusive.²⁷

First they describe the **microbial** model of public health. Disease here is a result of a microbial infection or exposure to toxic substances. The legal response to this classification may be the identification of infected people by testing or screening and reporting to a central authority, ensuring they are treated or are unable to infect others and conducting epidemiological surveillance. The enforcement of these measures may be controversial.

Their second model is a **behavioural** model. This assumes that human behaviour can contribute to disease. Here lifestyle may be the issue or behaviours that may lead to disease or injury. The state may intervene to ensure that seatbelts are worn or provide needle exchange services. Dependent upon the action taken, the state may be seen to be too interventionist or not sufficiently so. The same legislative response might be seen to be approving of illicit behaviour on the one hand or causing increased stigmatisation on the other. An example of this might be the provision of a methadone program in a coercive environment.

The third model is an ecological model, examining social institutions and conditions. This may include how society produces and distributes wealth, provides access to education, or subsidises industry creating environmental damage. Many legal avenues may be used to underpin social institutions such as taxation law, laws creating industry subsidies, environment protection laws, laws forming the structure of our educational bodies and anti discrimination laws, to name but a few. These laws are not considered to health law, though there is little doubt of their impact on health.

²⁷ Gostin LO, Burris S, Lazzarini Z. The Law and Public Health: A Study of Infectious Diseases Law in the United States. *Columbia Law Review* 1999;99:59 - 128

Infectious diseases law

It is undoubtedly the area infectious diseases law that raises some of the more controversial issues. These include immunisation, disease reporting to government, quarantine, legislative authority to breach confidentiality, and powers to restrict or detain individuals. Fear of the theoretical risk posed by a person infected with an infectious disease has often led to responses that are unjustifiable if evidence of the real risk posed was accurately assessed. In many communities leprosy was the foremost instance in which the perceived interests of the community outweighed those of the individual. The infected person was deprived of all ordinary entitlements of citizenship and made to live outside city bounds with other lepers. Today it is the person living with HIV or AIDS who, in some communities, sits in this position.

Immunization when imposed by government as a compulsory measure is often cited as an example of the tension between those wishing to protect the public health and those who believe that society is not justified in imposing such measures upon its members without their voluntary participation. This has been true since the earliest legislation was introduced to support the work of public vaccinators. It should however be noted that during the 19th century disease was undoubtedly spread through the process of immunisation. For example William Tebb argued in 1884:

"It is well-known that 'Vaccination was made compulsory by Parliament in England, at the instance of Lord Lyttelton, through the activity and persistency of Dr. Seaton, Secretary to an obscure association of a very few medical men, calling themselves the Epidemiological Society, who issued a report on the state of small-pox and Vaccination in England and Wales, and other countries, dated 26th March, 1853, in which no mention whatever is made of the failures and mischiefs arising from the practice recorded by any of these early writers. ...

And this is the "perfectly efficient prophylactic" which Parliament, relying upon the anonymous authors of this report, forces upon the people of the United Kingdom, under pains and penalties!"²⁸

Between 1901 and 1930 New York City officials routinely deployed police officers and nurses or physicians to the homes of those suspected of carrying disease, and force or the threat of force, was commonly used to overcome vaccine refusers. In some cases, police officers pinned the arm of those who refused while a city nurse jabbed it with a vaccination needle (Garrett, 2000:299).

Much of the law was about confining individual rights in the interest of the greater good. Because during the early part of the 20th century, bacteriology-based public health was perceived as extraordinarily powerful and the background of disease was obviously grim and urgent, both public health leaders and the courts tended to tip the balance in public health far in the direction of community needs.²⁹ Historically though repressive action to limit the spread of disease often did not achieve its purpose. However governments felt compelled to take action in response to apprehended threats to health and social stability.

In our own time China threatened to execute or jail for life anyone who disobeyed SARS quarantine orders or intentionally spread the virus. The penalty for officials found guilty of negligently allowing the disease to spread is imprisonment for three years and those using violence to hinder aid workers face similar consequences.³⁰ Indeed a man in northern China was sentenced to death for killing the head of the local SARS prevention team following a prohibition on people entering SARS affected regions. Police staffed checkpoints in China and arrested patients suspected

²⁸ Tebb, W. Compulsory Vaccination in England: with incidental references to foreign states by

William Tebb Londone. W. Allen, 4, Ave Maria Lane, E. C. 1884

<http://www.whale.to/v/tebb1/conclusion.html> last accessed 6 December 2002

²⁹ Garret, L. Betrayal of trust: The collapse of global public health, Hyperion, New York. p299

³⁰ <http://news.bbc.co.uk/2/hi/asia-pacific/3030069.stm> China threatens SARS death penalty BBC

World News last accessed 23 January 2004

of having SARS who had not stayed in quarantine.³¹ Extreme reactions were not confined to China.

"In Canada, members of the Immigration and Refugee Board wore masks to hearings of cases brought by Chinese claimants. ... In Hong Kong, authorities used a police electronic tracking system used in criminal investigations for tracing contacts and monitoring compliance with quarantine."³²

For those who might have instigated policing for public health purposes there were often unanticipated outcomes. For example, analysis of past incidences of epidemics has demonstrated that, although social and political upheavals did take place during epidemics, they were not always caused by the epidemics. They were rather responses to the imposition of severe controls upon human conduct and repressive policing, as well as the failure of governments to effectively communicate their purpose (Ranger & Slack, 1992).³³

Ultimately it is the individual identified as the source of risk who is constrained, behaviourally and physically, in the interests of the community. Rights might not merely be attenuated, as might be the outcome of a conviction for a criminal offence, but may be totally denied. Rarely, even now in progressive jurisdictions will individuals who are perceived to be the source of risk be accorded even procedural justice (in brief, the right to be heard before an impartial tribunal with sufficient notice of the accusations made), fundamental in other areas of law, let alone substantive rights (such as the right to privacy). And it is primarily the marginalised,

³¹ www.news24.com/News24/World/SARS/0,2-10-1488_1363733,00.htm SARS-related death penalty cited in Loff B, Black J Principles for public health action on infectious diseases Issues in Medical Ethics Vol XI No 4 October-December 2003 at pp 113-115

³² Loff B, Black J Principles for public health action on infectious diseases Issues in Medical Ethics Vol XI No 4 October-December 2003 at pp 113-115

³³ Ranger, T. & Slack, P. (eds) 1992 *Epidemics and Ideas: Essays on the Historical Perception of Pestilence*. Cambridge: Cambridge University Press.

impoverished and possibly intellectually disabled or mentally ill person that is the focus of society's attention.

The law in general as it impacts upon public health

As should now be clear, many areas of law may make a contribution to public health. Clearly the contribution of the criminal law should not be overlooked. Laws concerning abortion, drunk and culpable driving, assault and murder pertain to public health. The criminal law has been used (often inappropriately) to respond to HIV/AIDS. It is the criminal law that makes drug use illicit. Coroners' courts whose role is to inquire into the cause of death from criminal or other causes, have often made recommendations for system changes. Recommendations might have an impact on, for example, the distribution of a faulty product, road traffic safety or hospital procedures.

Other areas of law like laws governing access to information, anti discrimination law, intellectual property law, or laws dealing with the infrastructure of institutions can all impact upon public health because they can directly or indirectly affect how people are treated and perceived, services rendered and the availability of goods.

As noted earlier the courts can have an impact in defining standards. Individual or class actions may have major ramifications for a great number of people. In some countries, litigation surrounding tobacco-related diseases in some countries are an example of this. There are many other examples. The failure to diagnose positive screens for cervical cancer has been brought before the courts and has resulted in further formal government inquiry. Actions might be brought with respect to defective products causing harm to health. Public health administrators may be brought before the courts under administrative or constitutional law.

International law and the work of international agencies such as the World Trade Organization and the World Bank can have significant local impact. Multilateral and bilateral agreements, to which a country is a party, relating ostensibly to matters unconnected with health, may ultimately impact upon health. National laws of powerful countries such as the United States can impact upon decision-making in other countries. For example the powers of the United States Trade Representative to

black list a country, and exert pressure upon it, may determine what drugs that country will be able to access or whether its goods will be allowed into the profitable US market.³⁴

Each of these matters could be (and is) the subject of texts. The purpose here is simply to alert the reader to some of the many areas of law that might impact upon a particular concern.

The Law in the Design and Implementation of Public Health Programs

Given the extent of what might properly be included within the realm of public health it is impossible to give a general picture of which law might apply to what project. Suffice to say that it is likely that law will often be a consideration, and any public health practitioner should seek advice about the nature of any relevant law and its application. Negotiation between many areas of government administration may be required to properly address a public health concern. Only one example will be provided here, that of infectious disease.

Laws that might be relevant to a public health practitioner working in the area of infectious disease might include:

domestic anti discrimination law including laws prohibiting discrimination on the grounds of sex, impairment, occupation, religious or cultural belief, sexuality;

international human rights law;

criminal law such as laws dealing with assault, manslaughter, murder, drug use, prostitution, homosexuality;

employment law;

immigration law

³⁴ See Consumer Project on Technology . Country disputes involving intellectual property and health care <http://www.cptech.org/ip/health/country/> Last accessed 20 March 2003

intellectual property law;

world trade law;

laws governing the conduct of research;

censorship laws; and

laws governing the distribution of pharmaceuticals.

There are other areas of law that could be added to this list. However this should demonstrate the centrality of law and the need for awareness of its breadth and content in both a clinical setting and in political advocacy.

As is the case in any professional discipline, lawyers have different areas of expertise. For example, it is unlikely that a lawyer specialising in criminal law will have much to say about intellectual property. It might require some searching before a legal practitioner with the relevant skills is found to assist in a specific case or to provide general information. Generally speaking, it is likely that once approached, a lawyer without the appropriate expertise will refer to a lawyer practising in the required area.

Health and human rights

Impartiality, non discrimination, a fair hearing-principles well understood in the law generally-are often not present in public health law and practice. Do these and other human rights standards and norms have something positive to contribute to public health policies and programs or are they simply a hindrance? It is sometimes assumed that a human rights approach demands that the interests of the individual always take precedence over those of the community or that these interests are fundamentally in opposition. This is not correct.

Lately it has been asserted that these two approaches are complementary and in synchrony. Although the advocacy around women's health and indigenous health clearly produced rights-based debate, it was the advent of HIV/AIDS that generated a movement for "health and human rights". In the context of HIV/AIDS it was asserted that when human rights are respected, vulnerability to HIV/AIDS is reduced. In

tracing the development of this thought it has been noted that the response to HIV/AIDS developed in four phases:

a danger to be alerted about;

a problem of individual behaviour;

a societally contextualised behavioural issue; and finally

a human rights linked challenge.³⁵

The fulfilment of rights may have much to contribute to improving health. Rights to, for example, education, information, and accommodation, and to the benefits derived from scientific progress may appear obvious in their contribution to public health. However, as should now be apparent, a transparent and accountable government and functioning judicial system are also essential to the promotion of public health. This has been recognised in a "General Comment" (an authoritative interpretation) on the right to the highest attainable standard of health, produced by a treaty body of the United Nations – the Committee on Economic Social and Cultural Rights.³⁶

The General Comment further highlights principles of "availability, acceptability, accessibility, and quality".

"These terms have concrete implications: availability--health care must be offered to the extent possible within available resources, and benchmarks need to be set to guarantee that this goal is reached progressively; accessibility—health facilities, goods, and services must be attainable for everyone without discrimination on the basis of such factors as socioeconomic status, community, or disability; and finally,

³⁵Mann J, Tarantola D. Responding to HIV/AIDS: A historical perspective *Health and Human Rights* 1997; 2: 6-8

³⁶CESCR. The right to the highest attainable standard of health: CESCR general comment 14. Geneva: UN, 2000.

health care must be the highest possible quality and acceptable, culturally and otherwise, to all groups."³⁷ (Gruskin S, Loff B. 2000: 1880)

It is only in exceptional circumstances that one should seek to limit rights. Should a question arise about the restriction of a human right such as the right to freedom of movement governments are required to consider the "Siracusa principles" adopted by the UN Economic and Social Council (ECOSOC) in 1985. The principles require that the proposed restriction be provided for and implemented in accordance with the law. The restriction must be directed towards a legitimate objective of general interest, such as preventing transmission of tuberculosis and must be strictly necessary to achieve the objective in question. It must be the least intrusive and restrictive means available to reach this objective. Finally the restriction cannot be unreasonable or discriminatory in its application. Clearly responding to these criteria requires sound evidence. When this process is followed limitations to human rights will be justifiable.

Human rights standards and norms may also be used to evaluate public health policies and programs. For example, sensitivity to underlying discrimination in a community against a certain ethnic group might suggest that, when a program is assessed, particular attention is paid to the impact of the program on this group.

Debates grounded in health may also have an impact on the interpretation of rights. In the 1992 case of *Toonen v Australia* before the Human Rights Committee of the United Nations, Nicholas Toonen, a Tasmanian gay rights activist, sought to challenge Tasmanian laws making it an offence to have "unnatural sexual intercourse", or "intercourse against nature", or "indecent practice between male persons". The laws had not been enforced for a decade. Toonen asserted that those laws constituted an arbitrary interference with privacy, contrary to article 17 of the International Covenant on Civil and Political Rights. The Tasmanian government claimed that the laws were not arbitrary but were motivated by a concern to protect public health. In response the Committee noted that:

³⁷ Gruskin S, Loff B. *Do human rights have a role in public health work?* The Lancet Vol 360

"the criminalization of homosexual practices cannot be considered a reasonable means or a proportionate measure to achieve the aim of preventing the spread of HIV...Secondly the Committee notes that no link has been shown between the continued criminalization of homosexual activity and the effective control of the spread of the HIV/AIDS virus."³⁸

These laws could not be justified by appealing to a public health risk exception. The Committee required there to be a degree of reasonableness and proportionality, but offered no further insight into what might satisfy these requirements.

Consideration of the implications of health policies and programmes for human rights has enabled those working in public health to bring a new focus to their activities: placing health in a rights framework and examining how both rights and health outcomes may be maximised instead of how health might be bettered at the expense of rights.

For simplicity the Universal Declaration of Human Rights has been utilised as the fundamental tool creating a framework within which to consider public health policies and programs, but obviously there is a wealth of international and domestic law that might be relied upon. In a similar manner legal systems may benefit from a critique from the perspective of public health.

Conclusion

For a health promotion practitioner to operate with a full armoury, he or she must develop a sense of when law is an issue, why it is an issue, and what to do about it. An understanding of human rights will bring further richness to debates in public health and health promotion. To truly derive the most benefit from law for the purposes of public health or to challenge its drawbacks, an interdisciplinary approach involving lawyers with knowledge in the area is essential. The complexity, breadth and range of issues that might arise in public health and health promotion make it

³⁸ Toonen v Australia, Communication No. 488/1992, UN Doc CCPR/C/50/488/1992 (1994),

<http://www1.umn.edu/humanrts/undocs/html/vws488.htm>

imperative that assistance be sought to maximise the positive impact of law on public health.

Learning a culture of respect for human rights

THE LANCET • Vol 352 • December 5, 1998 1853-3

"Explaining is not excusing, understanding is not forgiving" 1

The Report of the South African Truth and Reconciliation Commission (TRC) 1 notes repeatedly, in different ways, that the perpetrators of gross human-rights violations under apartheid were neither evil nor psychologically unwell (vol 5, ch 7). Circumstances common to the perpetration of atrocities are identified and dissected. At the risk of losing some of the many dimensions of the analysis, the report, in seeking to understand the actions of perpetrators, pointed to: the difference in perspective between perpetrator and victim; the historicopolitical environment (the cold war, anticolonialism, and racism); social identity and the influence of group membership in diminishing moral restraint through compliance with and internalisation of group norms; and the contribution of language in allowing the dehumanisation of others.

Clearly, the message of South Africa must be heeded by all. South African doctors, including those who participated in or supported immoral action, like doctors who cooperated in the Holocaust, merge seamlessly into the medical professions of other countries. Doctors must ask themselves whether, in similar circumstances, they would be capable of the same horrors.

Under apartheid, district surgeons (forensic physicians or police surgeons) had dual and incompatible responsibilities to provide medical care for prisoners and to protect national security. The isolation and ostracism of those doctors who worked within police and prison systems served to mould and entrench their attitudes and behaviour. The report details chilling examples of surgeons' participation in torture, the turning of blind eyes, and the failure to provide necessary care. Forensic pathologists also "omitted crucial information and falsified post mortems" (vol 4, ch 5, para 53) in collusion with police, lawyers, and courts. The report also noted that health professionals with dual loyalties are "at risk of becoming involved in overt or covert abuses of the human rights of their patients . . . Appropriate measures are needed to prevent or pre-empt the moral and ethical dilemmas that may arise for health

professionals faced with the (commonly conflicting) needs of their patients and their employers" (vol 4, ch 5, para 21).

The Report of the Royal Commission into Aboriginal Deaths in Custody (RCADIC) would seem the obvious report from which an Australian might draw some analogies with the TRC report. In the RCADIC report prison medical services attracted most criticism. Authorities fundamentally misunderstood their duty of care to prisoners, a misunderstanding compounded by poor communication between prison medical services and correctional institutions.

RCADIC identified the poor management of health conditions of Aborigines in custody. This deficiency was attributed partly to the stereotyping of Aboriginal people and others with chronic alcohol problems, and to the exaggerated impact of common infectious diseases in malnourished people (vol 4, p 237). Nevertheless, the high number of aboriginal deaths in custody (99 over 10 years) reflected primarily a glaring over-representation of Aborigines in custody. The rates of death for indigenous and non-indigenous communities in custody were basically the same. RCADIC called for the elimination of disadvantage and an end to the domination of Aboriginal people.

It is, however, the recognition of the genocidal practices in colonial Australia that is most relevant to comparisons between Australia and South Africa. Bringing them Home, the report of the National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families, makes the point that the removal of children from their families by law, ostensibly in their own interests, constitutes systematic racial discrimination amounting to a gross violation of human rights. Bringing them Home recognises this violation as genocide. Further, indirect racial discrimination continues today, despite repeal of obviously discriminatory laws. Discrimination is evident in both child-welfare and juvenile-justice systems that at worst treat cultural difference as abnormal or criminal.

Lessons must be learnt from the South African experience. There must be awareness of the incremental effect of tolerance of human-rights abuse. The TRC made recommendations for the prevention of future atrocities that are applicable to the medical profession and the teaching of medical ethics (vol 5, ch 7). Doctors must be

alert to the dangers of unquestioning obedience to authority; resist compliance with group norms; and resist the compulsion to respond to the immediate situation without reflection.

From which report did the following quote come?

"The Commission recommends that government accelerate the closing of the intolerable gap between the advantaged and disadvantaged in our society by, inter alia, giving more urgent attention to the transformation of education, the provision of shelter, access to clean water and health services and the creation of job opportunities. The recognition and protection of socioeconomic rights are crucial to the development and sustaining of a culture of respect for human rights."

It is from the TRC report—but it could have come from any of the three reports.

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1 The report of the Truth and Reconciliation Commission.
<http://www.truth.org.za/final/> (accessed on Dec 1, 1998).

2 Royal Commission into Aboriginal Deaths in Custody (Commissioner, Elliot Johnston QC). Canberra : Australian Government Publishing Service, 1991.

3 Bringing them home. National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families. Sydney, Commonwealth of Australia, 1997.

Getting serious about the right to health

THE LANCET • Vol 356 • October 21, 2000 1435

On July 4, the United Nations Committee on Economic Social and Cultural Rights published the General Comment on the Right to Health (E/C.12/200/4 number 14), the purpose of which is to ensure government responsibility and accountability for health under the human-rights framework in a structured way. General Comments serve as a guide for governments on the issues which are considered when governments determine their compliance with the obligations under the human-rights treaties they have ratified. The Comment was produced by the Committee with input from the WHO, and other governmental and non-governmental organisations with expertise in health. Article 12 of the International Covenant on Economic Social and Cultural Rights (Jan 3, 1976) recognises that "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and that the steps to be taken by the States parties to the present Covenant to achieve the full realisation of this right shall include those necessary for: provision for the reduction of the rates of stillbirth and of infant mortality, and for the healthy development of the child; improvement of all aspects of environmental and industrial hygiene; prevention, treatment, and control of epidemic, endemic, occupational, and other diseases; and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The Comment notes that the right to health is closely related to and dependent upon other rights, including the rights to human dignity, non-discrimination, equality, education, housing, privacy, access to information, and freedom of association. This adds authority to the growing health and human-rights movement, which has been increasing awareness to the direct and indirect impacts that human rights have on health and wellbeing. The Comment recognises the effect that such factors such as physical or mental disability, sexual orientation, race, or language may have on both health status and the delivery of services, and highlights the need for increased attention to gender differences, older individuals, people with disabilities, children and adolescents, indigenous people, and women. The Comment notes that the right is not a right to be healthy as such, but, for example, contains freedoms with respect to

control over what happens to our bodies—such as in the case of sexual and reproductive health, and the availability, acceptability, accessibility, and quality of the facilities, goods, services, and conditions necessary for health.

The Comment further states that the right to health extends beyond health-care services to the underlying determinants of health, including access to safe and potable water, sanitation, food, housing, education, and healthy occupational and environmental conditions. A strong focus of the document is on the need to ensure the participation of affected populations in health-related decision making. National health strategies and plans of action, “should be based on principles of accountability, transparency, and the independence of the judiciary”, and mechanisms should be established at the national level for their monitoring and implementation.

Most importantly, the Comment emphasises the obligation of all governments to move deliberately towards making this right a reality. Appropriate “right to health” indicators are currently being identified. Once in place, it is expected that each State will set their own national benchmarks in relation to each indicator. For States that are in a position to do so, this will require attention to these issues not only within their own borders but also in the context of providing international assistance and cooperation. This means not only facilitating access to essential goods and services, but also using legal and political channels to prevent third parties, such as multinational corporations, from contributing to the violation of this right in other countries.

The translation of the right to health into guidelines and other tools useful to national and international design, implementation, and monitoring of governmental and intergovernmental obligations is still in its infancy. This General Comment is, however, a significant milestone and is sure to be the focus of continuing dialogue.

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Do human rights have a role in public health work?

HEALTH AND HUMAN RIGHTS

THE LANCET • Vol 360 • December 7, 2002 • 1880

What role do human rights have in public health work? Since the early stages of the women's health, reproductive health, and indigenous health movements it has been asserted that public health policies must incorporate human rights norms and standards. Lack of respect for human rights has hampered development in such areas as mental health care and control of sexually transmitted infections.¹ Lately, however, it has been argued that "Human rights based approaches to HIV/AIDS prevention might have reduced the role of public health and social justice, which offer a more applied and practical framework . . . in Africa's devastating epidemic".²

The underlying assumption is that in a human rights approach individual rights are protected at all costs—even despite adverse effects on the public's health. Yet a rights-based approach does not privilege protection of individual rights over the public good. This apparent tension should be addressed to enable the creation of sound public health policies and programmes.

A human rights approach mandates that any public health strategy, whether or not rights are to be restricted, be informed by evidence and openly debated.^{3,4} This approach protects against unproved and potentially counterproductive strategies, even those motivated by genuine despair in the face of overwhelming public health challenges.

The introduction of human rights into public health work is not about the imposition of any preordained result, but about processes and their application towards maximum public health gains. For example, a focus on health systems requires attention to their "availability, acceptability, accessibility, quality" and their outcomes among different populations.³

These terms have concrete implications: availability—health care must be offered to the extent possible within available resources, and benchmarks need to be set to

guarantee that this goal is reached progressively; accessibility— health facilities, goods, and services must be attainable for everyone without discrimination on the basis of such factors as socioeconomic status, community, or disability; and finally, health care must be the highest possible quality and acceptable, culturally and otherwise, to all groups.

At times, public health measures are needed to curb the spread of disease, resulting in restrictions on rights. For example, if a person infected by open pulmonary tuberculosis poses a grave risk to public health by refusing treatment, it may be permissible to isolate that person, and thus lawfully restrict their freedom of movement.

Human rights do not conflict with restrictions, so long as the objectives and the process used to make the decision to restrict rights are clear. For a restriction to be considered legitimate, a government has to address five criteria spelled out in the Siracusa principles adopted by the UN Economic and Social Council (panel).³

Siracusa Principles

First, the proposed restriction has to be provided for and implemented in accordance with the law.

Second, the restriction has to be directed towards a legitimate objective of general interest, such as preventing further transmission of the HIV virus.

Third, it must be strictly necessary to achieve the objective in question.

Fourth, no less intrusive and restrictive means should be available to reach this objective.

Fifth, it cannot be unreasonable or discriminatory in its application. The burden of proof falls on those who want to restrict rights, and concrete public health evidence is needed to genuinely respond to the last three criteria.

The rights-based approaches to health, currently underway in many institutions, should be assessed and validated to ensure clarity in what are understood to be the

strengths and limitations of bringing human rights into governmental, non-governmental, and international health work.

Information should be gathered to show how human rights have been relevant in analysis of the health needs of populations or public health problems; in the ways health systems' performance assessments are done; in the processes by which countries or institutions choose public health interventions; and in the implementation and monitoring of interventions—their focus, what they do, and what they do not do.

Bringing health and human rights together in public health also allows the progress, success, or failure of a policy or programme to be assessed against public health and human rights benchmarks. Ultimately, much of the work to bring human rights into public health involves looking at tradeoffs and working within a framework of transparency and accountability towards achieving the highest attainable standard of health.

There is no one-size-fits-all approach. Rights issues and the appropriateness of policies and programmes might be of concern in one setting and one population but not in another. Central to all settings, however, are the principles of non-discrimination, equality, and, to the extent possible, the genuine participation of affected communities: these principles will not undermine but further advance public health.

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Are human rights good for your health?

HEALTH AND HUMAN RIGHTS

THE LANCET • Vol 358 • December 1, 2001 1901

"While acknowledging the tragedy of the events of Sept 11, he reminded the meeting that every day 10 000 people die because AIDS drugs are too expensive"

Twenty years into the epidemic of HIV/AIDS and more than 3 years after Jonathan Mann's death, Mann's insight that human rights and health are inextricably connected has not been fully explored. To address this challenge, Temple University (Philadelphia, USA) and the American Society of Law, Medicine and Ethics held an international conference in Philadelphia from Sept 29 to Oct 1, 2001 on "Health, Law, and Human Rights: Exploring the Connection". The conference brought together epidemiologists, social scientists, lawyers, human-rights advocates, policy makers, and activists from around the world to address two key questions that Mann left unanswered: what empirical evidence supports or elucidates the relation between health, law, and human rights? And what do we know about using human-rights initiatives and law reform as tools for public-health interventions?

Until researchers and advocates begin to answer those questions, human rights can be dismissed too easily as "feel good" rhetoric and law as a sterile province visited only by lawyers. Health problems such as AIDS that often strike the most vulnerable in society remain intractable, because traditional public-health initiatives seem inadequate to address underlying conditions, such as social inequality, that put people at risk. It is not enough to rely on assertions of a special relation between health, human rights, and law. We must begin to examine and justify our reliance on that relation with empirical evidence.

Research on law should explore its links to fundamental determinants of disease such as racism, income inequality, lack of education, and poor social cohesion. Law and human-rights practices can affect health on many levels and in two broad ways. First, they can form pathways along which broader social determinants of health have an effect. For example, criminal law and law-enforcement practices might be means

through which low social status is converted into disparities in social health. In many places, the way in which criminal-justice systems are operated results in disproportionate imprisonment of low-status people and their exposure to diseases such as tuberculosis and HIV/AIDS in prison. Second, laws or legal practices could contribute to the development and stability of social determinants of health. For example, law is one of the means through which the subordinate status of women is established and maintained. Where it prohibits women from holding property, or does not prevent discrimination, law is one of the causes of women's subordination.

Good law does not necessarily lead to good health. Research must also address whether human-rights initiatives and law reform are effective tools of public-health advocacy. Three health catastrophes were used in the conference to investigate this issue: the epidemics of tuberculosis and HIV in Russian prisons, the effect of structural-adjustment policies on health and health care in Zimbabwe, and racial disparities in access to health care that have persisted in the USA despite civil-rights laws forbidding such discrimination. These cases illustrate dilemmas often faced by those who use human-rights instruments and other law to promote health. What happens when human-rights laws exist, but are unenforceable? Or when countries adopt human-rights rhetoric but do not provide resources for realisation of those rights? What can health workers do when the legal system, or any government institution, cannot serve the population? Despite these challenges, the conference yielded many positive examples of the effects of human-rights laws, from the importance of rights claims in recent legal battles for affordable access to HIV treatments to the development and application of measurement tools to measure the effect of such laws.

Ronald Bayer set the health and human-rights movement in historical context, reminding participants that an appreciation of the connection between public health and social justice was not new. Mann and colleagues, like reformers from Virchow and Engels to Jogn Ryle and Richard Titmuss, sought to harness tools for social change to bring better health.

Eric Sawyer, a founding member of ACT UP (AIDS Coalition to Unleash Power), New York, described how, as a person living with AIDS for 20 years and as an international activist for treatment, he had retained the conviction that every life

matters and deserves to be fought for. While acknowledging the tragedy of the events of Sept 11, he reminded the meeting that every day 10 000 people die because AIDS drugs are too expensive and 16 000 people contract HIV infections. Although the USA could mobilise US\$15 billion to rescue the airline industry in the wake of the terrorist attacks, the USA and other developed nations have yet to completely fund even 1 year of the United Nations Global Fund to Fight AIDS (need estimated at \$10 billion per year).¹ Sawyer asked how AIDS, other infectious diseases, and health issues overall could be reintroduced through human-rights activism into a public discourse that seems totally preoccupied with war, security, and retribution against terrorism?

The fundamental question to arise from the conference was how can we, as members of societies (both with and without long traditions of civil institutions), use laws, policies, and human-rights doctrines to improve the health and wellbeing of all people?

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1. *Newance* FD. UN is warned on anti-AIDS strategy; drugs alone might fail poor nations, panel says. *Baltimore Sun*, Nov 1, 2001: A3.

Chapter Three: Sex, the law and human rights

This chapter deals with various aspects of the interrelationship between sexual activity and human rights. The book chapter entitled "Morality the Law and Sex" (accepted for publication) forms the introduction. It provides a general overview of the ways in which communities throughout history have responded to sexuality and sexual practices, gender and sexual health. Discriminatory and stigmatising attitudes have made promotion of sexual health problematical and challenging.

This work is following by papers dealing with sexually transmitted infections, sex work, health and human rights.

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Declaration for Thesis Chapter 3


In the case of chapter 3, contributions to the paper "Prostitution, public health and human rights law" Lancet 2000; 356 1764, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	90%	Conception and execution
Beth Gaze	5%	Conception
Christopher Fairley	5%	Conception

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The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

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In the case of chapter 3, contributions to the paper "Prostitution, public health and human rights law" Lancet 2000; 356 1764, involve the following:

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In the case of chapter 3, contributions to the paper 'Can health programmes lead to mistreatment of sex workers?' Lancet 2003; 361: 1982-1983, involve the following:

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Cheryl Overs	10%	Conception
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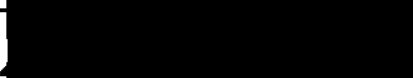
In the case of chapter 3, contributions to the paper "Japan's comfort women" Lancet 2001; 357: 302, involve the following:

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In the case of chapter 3, contributions to the paper "Compulsory detention: limits of the law" Lancet 2001; 358: 146, involve the following:

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Sex, Morality and the Law

Accepted for publication in Sexual Health Medicine – A clinical approach” edited by

Christopher Fairley, Davis Bradford, and Darren Russell

Introduction

Control of STIs has been and remains laden with moral and legal concerns that have tended to threaten rather than promote sexual health, and health and wellbeing generally. Sexual health has been confused with monogamy, marriage, the sanctity of the family, and faithfulness on the part of women. It is confused with abortion. It is confused with blame. It is confused with the wrath of God.

Despite the existence of a thriving pornography industry and sex as it is purveyed by Hollywood, from a global perspective attitudes towards sexuality have not become more liberal. As Foucault has said the purpose of sex is utilitarian and to be confined to the parent's bedroom. (1) Children and even adolescents do not have sex. And we certainly should not talk about it. Foucault notes that when we do talk about sex we know we are being subversive, challenging society's norms. (1) How might it be possible to make reasonable progress in promoting sexual health in a moral environment such as this?

The medical historian, Allan Brandt, made the point that even though we have known since the late 19th century that STIs (or venereal disease) are caused by micro-organisms there is a persistent association between STIs and dirt. (2) This was reinforced by the name chosen by those working in the area of STI control in the 20th century, the 'social hygiene' movement.

“Venereal disease came to be seen as an affliction of those who wilfully violated the moral code, a punishment for sexual irresponsibility. These infections were employed to argue for a more restricted sexuality.” (2)

The reticence that people feel when deciding whether or not to discuss matters related to sexual health is greatly compounded by discriminatory and/or ignorant attitudes on

the part of health care providers. This is particularly so in the case of those who may be seen as practising immoral behaviours and are therefore dispensable to society. Homosexually active men, transgender individuals, sex workers, fetishists, and others may resist seeking assistance unless there is a service or practitioner that they can trust and that treats them with respect. Usually though, when a person engages in the wrong behaviour they can generally expect little sympathy.

This chapter will not deal with issues like consent and confidentiality which are the bread and butter of many books on medical law and ethics, and domestic and international ethical guidelines. There are far more fundamental issues to address – issues that form the background for how we begin to conceptualise what is important and then how we choose to regulate it.

The Legacy of George W Bush

Nowhere is the mixing of morality and law in the area of sexual health more clearly demonstrated than in legislation passed by the Congress of the USA in 2003: the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act. The fundamentalist religiosity of the Bush administration is a badge borne proudly. However, its expression in legislation dealing with HIV/AIDS is both odd and alarming. It is odd because of the unusual articulation in law of one narrow set of values. It is alarming because it runs counter to years of hard come by accumulated knowledge on HIV prevention. And it equates prostitution with sexual victimisation and calls for its eradication.

The Act requires the President to establish a comprehensive, integrated, five-year strategy to combat global HIV/AIDS that strengthens the capacity of the United States to be an effective leader of the international campaign against HIV/AIDS. The strategy is to maintain sufficient flexibility and remain responsive to the ever changing nature of the HIV/AIDS pandemic and is to:

Provide that the reduction of HIV/AIDS behavioral risks shall be a priority of all prevention efforts in terms of funding, educational messages, and activities by promoting abstinence from sexual activity and substance abuse, encouraging monogamy and faithfulness, promoting the effective use of condoms, and eradicating

prostitution, the sex trade, rape, sexual assault and sexual exploitation of women and children...

Among the many funding limitations established under the Act, no funds made available to carry out the purposes of the Act may be used to promote or advocate the legalisation or practice of prostitution or sex trafficking. However, this does not preclude the provision to individuals of palliative care, treatment, or postexposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

This funding limitation is reinforced by a USAID policy directive that requires that the Standard Provisions of any grant or agreement funded with HIV/AIDS funds with a USA nongovernmental organisation or to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative, and any United Nations agency must contain a "prohibition on the promotion or advocacy of the legalization or practice of prostitution or sex trafficking". The same requirement applies to non-USA non-governmental organisations and public international organisations.

Much can and has been said about one aspect of the strategy – the promotion of abstinence and monogamy as approaches to deal with HIV/AIDS. In many countries marriage, particularly of girls under 18, marks the time of an abrupt increase in sexual activity and of greatest vulnerability to HIV. Girls will marry men, often many years their senior, and will lose their support networks and their opportunity for education and access to information. Dealing with these issues requires complex strategies, not slogans. Promotion of abstinence or condoms in the context of marriage when the premium on producing children is so high is difficult to say the least.

In the area of HIV/AIDS and sex work, experience from many programs in different regions of the world indicates that successful programs must have four core elements. They must:

build knowledge and self esteem

provide sex worker friendly health services

create an enabling environment for sex workers and their programs while promoting solidarity and social inclusion through participation of sex workers

ensure maximum coverage of the program through forging partnerships with many groups. (3)

None of this can be achieved in an environment that seeks to eradicate prostitution even if the eradication is sought to be achieved by 'rehabilitation' rather than by use of the criminal law.

Already some groups that have been actively supporting initiatives to improve the health and wellbeing of sex workers financed by the government of the USA have chosen to withdraw from this work. Others are rephrasing the ways in which they describe their activities. In the long term, this may well be more damaging to improving health than withdrawal of funds.

Was it ever thus?

Where do we go to identify the source of our attitudes to sexuality and to sexually transmitted infections? We can point to the asceticism, the exhortations to deny bodily pleasures that can be found within many religious groups. In Christianity (and before) the sexual act is associated with the 'fall', evil, sin, and death. Lifelong chastity and virginity were valued. Sex was reluctantly approved within monogamous marriage and was to have procreative ends. (4) Over time these forebodings were translated into secular law.

Why was and is there a need to deny sexual pleasure and to codify this denial? Instrumental answers have been given to this question, such as the need to promote sexual fidelity on the part of women so as to secure lines of inheritance. Independent of this, a sense of safety emerges when those who suffer from infection can be blamed because they have strayed from the correct path. If they can be segregated from the community, the rest of us are safe. This sense of other can be used for political purposes. In any century it has always been handy to have an identifiable group that is culpable for problems we may face.

In 1495 following the campaign of Charles VIII against Spain a pox was identified in Italy. The Italians called it the French sickness and the French called it the Neapolitan sickness. It was Girolamo Fracastoro who in 1530 first called it syphilis in a poem about a shepherd who became infected with the disease. Christians said it was divine retribution for licentiousness. Others identified astrological causes. In any event sufferers were isolated like lepers of earlier centuries. In France diseased migrants were given money so that they could return to their homes. Sex workers came under stricter regulation. In Edinburgh the sick were taken to the island of Inch to remain there until cured, otherwise they faced exile and the branding iron. (5)

It is still the case that we focus on categories of people such as homosexually active men, injecting drug users, and sex workers as being the most likely to become infected with HIV and spread it to the 'general' community. It is simply too hard to confront issues like malnutrition, lack of sanitation, and of medication facing sub-Saharan Africa, India, and other places; all such matters having a significant impact on immune systems and therefore vulnerability to STIs. (6)

The Law

There have been and are laws about how, where, and with whom sex can take place, and there are laws concerning the spread of STIs. Among the most significant sins that societies have identified are sodomy and incest. In addition the law has dealt with, in one way or another, adultery, having children out of wedlock, sex work, obscene or offensive behaviour, and public nudity. The sexual overtones in rape, paedophilia, and incest have meant that the policing of these issues has often been difficult and has been compromised. Issues of aggression and exploitation inherent in these crimes have gone unrecognised until quite recently and are still not well addressed. Spreading of STIs has tended to be dealt with independently of other infectious diseases.

Putting to one side the American legislation referred to above which will no doubt be referred to in the future with wonderment, the most notorious legislation dealing with STI in more recent times has been the English Contagious Diseases Acts of the mid 19th century. This legislation was an effort to limit the spread of venereal disease in the armed forces. Magistrates in garrison towns and ports were empowered to detain any

woman suspected of being a sex worker, examine her compulsorily and if infected she was to be detained in a lock hospital and treated. (7)

Why protect only soldiers and not all men?

Only the exceptional conditions of military life, requiring the effective 'celibacy' of enlisted men, justified state protection of sexual promiscuity. In the case of the 'civil fornicant' who was freer to make social choices (that is to marry) in keeping with moral responsibility, the effective state subsidy of 'male vice' would violate the enshrined laws of economic, political and moral individualism. (8)

This law had a serious impact on the civil liberties of working class women generally and created such uproar that it was eventually repealed.

In the USA some of those same people responsible for the Tuskegee Syphilis Study were attempting to legislate for a uniform approach to venereal disease across the then 48 States of America. (This Study began in 1932. Its aim was to follow the natural history of syphilis in African-Americans. Approximately 400 men (and 200 controls) were recruited from Macon County, Alabama. Despite the discovery of penicillin the men were left untreated until the study became public in 1972. President Clinton formally apologised to the survivors of the study and their families in 1996.)

The National Venereal Diseases Control Act of 1938 provided for federal grants to state boards of health to develop anti venereal measures. As part of the requirements of the legislation, each state submitted to the surgeon general a comprehensive summary of current venereal control activities as well as plans for improving services on both state and local levels. ... In addition, the Act called for research into the prevention and treatment of diseases. ... In the first year, the Act mandated the PHS (Public Health Service) to spend \$600,000 to conduct field studies, and develop educational programs for public health officials. (2)

The American Medical Association did not object to the legislation, as it did not really interfere with fee for service medicine. However, other groups were concerned that with the adoption of this new public health approach the greater goals of preservation of morality and of family would be lost. (2) States enacted laws forbidding marriage if

prospective brides or grooms were infected with a venereal disease, some of it nonsensical as all that was required was a declaration. Some states required the bridegroom only to be tested as such a test would be insulting to a pure woman. In places where testing was mandated and the rate of marriage decreased it was argued that this might lead to "free love, illegitimacy and common law marriages". (2) Many such laws in whichever country they were enacted have not been enforced and simply became obsolete. Yet a recent Supreme Court case in India in which it was decided that a person infected with HIV did not have the right to marry is a potent reminder that these attitudes are very much with us. (9)

In more recent times in many places STI laws have been largely incorporated with infectious diseases law generally, HIV being the exception to this. The reasons for this have been various. First, HIV is a new disease and legislators did not know what to make of it. Fortunately in developed countries where the disease first came to public attention gay lobbyists demanded that there be reasonable consideration of the issues they were facing. The stigma associated with HIV demanded a specific response. In some cases this response – laws prohibiting discrimination on the basis of infection with HIV, laws mandating pre and post test counselling, strengthening confidentiality requirements - was generalised to all infectious diseases. Debates arose over contact tracing, anonymous or identified notification of cases of HIV to government, the potential to isolate and detain those posing a risk to others, and to criminally prosecute those who attempted to or who infected others with HIV. These debates generated a rethink and rewriting of infectious diseases law in many countries. Given the impact of HIV in the developing world some countries have drafted national strategies that involve every area of government administration and occasionally this is reflected in law. The protection of the human rights of a person infected with HIV is a theme common to many of these strategies and is encouraged by United Nations agencies such as UNAIDS and the World Health Organization.

Conclusion

There are few better encapsulations of the relationship of societies to the ways in which people express their sexuality than the Monty Python skit, "Mouse Problem". A television interviewer is examining the social phenomenon in which men choose to

dress up as and behave like mice. A person who indulges in this perverted behaviour is asked how he realised that was what he wanted to be. Then a number of different people are interviewed, each having different attitudes, from the accepting to the extremely hostile and violent. There are so many different groups to which this skit might apply. Here is a very much shortened excerpt.

Series 1, Episode 2: Mouse Problem

Sketch starts with a policeman leading a man in mouse costume into a police station. Photo of headline: Mouse Clubs On Increase. Cut to: photos of neon signs of clubs: Eek Eek Club; The Little White Rodent Room; Caterphilly A Go-Go. Cut to studio: ordinary grey-suited Linkman.)

Linkman: Yes. The Mouse Problem. This week 'The World Around Us' looks at the growing social phenomenon of Mice and Men. What makes a man want to be a mouse.

(Interviewer, Harold Voice, sitting facing a confessor. The confessor is badly lit and is turned away from camera.)

Confessor: (very slowly and painfully) Well it's not a question of wanting to be a mouse...it just sort of happens to you. All of a sudden you realise...that's what you want to be. ...

Linkman: A typical case, whom we shall refer to as Mr A, although his real name is this:

Voice Over: (and CAPTION) ARTHUR JACKSON 32A MILTON AVENUE, HOUNSLOW, MIDDLESEX.

Linkman: What is it that attracts someone like Mr A to this way of life? I have with me a consultant psychiatrist....What makes certain men want to be mice?

Kargol: Well, we psychiatrists have found that over 8% of the population will always be mice. I mean, after all, there's something of the mouse in all of us. I mean, how many of us can honestly say that at one time or another he hasn't felt sexually attracted to mice. (Linkman looks puzzled) I know I have. I mean, most normal adolescents go

through a stage of squeaking two or three times a day. Some youngsters on the other hand, are attracted to it by its very illegality. It's like murder - make a thing illegal and it acquires a mystique. (Linkman looks increasingly embarrassed) Look at arson - I mean, how many of us can honestly say that at one time or another he hasn't set fire to some great public building. I know I have. (phone on desk rings; the Linkman picks it up but does not answer it) The only way to bring the crime figures down is to reduce the number of offences - get it out in the open - I know I have...

Linkman: But what is the attitude...

Viking:...of the man in the street towards...

Linkman:...this growing social problem?

Window Cleaner: Clamp down on them.

Off-screen Voice: How?

Window Cleaner: I'd strangle them.

Stockbroker: Well speaking as a member of the Stock Exchange I would suck their brains out with a straw, sell the widows and orphans and go into South American Zinc.

Man: Yeh I'd, er, stuff sparrows down their throats, er, until the beaks stuck out through the, er, stomach walls.

Accountant: Oh well I'm a chartered accountant, and consequently too boring to be of interest.

Vicar: I feel that these poor unfortunate people should be free to live the lives of their own choice.

Porter: I'd split their nostrils open with a boat hook, I think.

2nd Man: Well I mean, they can't help it, can they? But, er, there's nothing you can do about it. So er, I'd kill 'em.

Linkman: Clearly the British public's view is a hostile one. ... But perhaps this is because so little is generally known of these mice men. We have some film now taken

of one of the notorious weekend mouse parties, where these disgusting little perverts meet. ...(10)

It has been argued here that attitudes towards sex and sexuality are and have been subject to long standing powerful, pervasive, and insidious influences. This has created an environment that is often far from conducive to the acceptance, respect, and frankness which are a necessary basis for sound research, prevention program, and satisfactory treatment. When it is the attitude of international agencies, government, and religious institutions that is wanting, the battles to be fought are potentially overwhelming. Let us be optimistic and hope that it is possible to develop both a moral and regulatory environment that is based upon sound public health research and attitudes accepting of the rights of those with diverse genders and sexualities, and where stigma is no longer attached to the presence of an STI.

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Prostitution, public health, and human-rights law

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HEALTH AND HUMAN RIGHTS

The Optional Protocol to the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), created in September, 1981, is now open for signing and ratification by nations. Should the protocol come into force, women will be given the right to complain to the United Nations (UN) about breaches of the Convention and, in particular, discrimination in the provision of health services. For women who are prostitutes, however, and whose legal status is uncertain, it is unlikely that the Convention will be of substantial benefit. Prostitutes are entitled to enjoy universal human rights. Because their legal status is complex, and compounded by international human-rights law, prostitutes are rarely in a situation where health protection or promotional activity could be expected to succeed. The view that linking health policy with respect for human rights will result in a better health outcome is gaining acceptance. But when human-rights instruments are applied uncritically, in ignorance of the larger social picture, measurements of improved health outcomes may be less certain. Rights-based questions about public health should be asked and failings in rights instruments must be confronted.

Prostitutes overwhelmingly work outside the law. This has implications for their health that are hard to quantify. In one Australian study carried out in 1998, the prevalence of sexually transmitted bacterial infections was 80 times greater in 63 illegal street prostitutes than in 753 of their legal brothel counterparts. All the illegal street prostitutes with infections were in the group who had not been screened for infections in the past 3 months, whereas none of those screened in the last 3 months were infected. In legal brothels women are given a strong legal incentive to be screened monthly, and the use of condoms is compulsory. Legally sanctioned encouragement of prostitutes to use condoms or access screening services, both major determinants of the prevalence of sexually transmitted diseases, is impossible because of their illegal

status. Occupational health and safety law is applied to prostitutes in lawful brothels but not to their counterparts on the street.

Vulnerability to contracting HIV has been characterised as "exercising little or no control over one's risk of acquiring HIV infection...vulnerability is magnified by societal factors such as marginalisation or discrimination". This account encapsulates the situation of most prostitutes. In this context rights-based objections to individual programmes such as compulsory testing, for example, have some, but limited, worth. A failure to acknowledge a background of general deprivation of rights undermines the impact of these objections.

International law that deals with prostitution targets trafficking in women for the purpose of prostitution, and counterpoises prostitution with human dignity. The 1949 Convention for the Suppression of Traffic in Persons prohibits the exploitation of prostitution of a person even with the consent of that person. CEDAW asks States to suppress trafficking in women and exploitation of prostitution. Nowhere is trafficking defined.

In May this year the Council of Europe adopted a recommendation which stated that trafficking in human beings for the purpose of sexual exploitation includes the procurement of individuals, even with their consent. Prominence is given to the rehabilitation of the prostitute and punishment of those responsible. This is despite the comment in February this year from Radhika Coomaraswamy, the UN Special Rapporteur on violence against women, that lack of consent should be an element of trafficking.

In a 1998 International Labour Office (ILO) study on prostitution in southeast Asia investigators noted that for adults it was possible to distinguish between forced and voluntary prostitution. But, they asserted, "It is outside the purview of the ILO to take a position on whether prostitution should be legalized. The question of legalization is thorny because the human rights concerns are difficult to disentangle from concerns over morality, criminality and public health threats".

Many prostitutes would not find it difficult to disentangle the human-rights issues. Social history explains the legal emphasis on trafficking and rehabilitation, and constructed similarities to slavery. But this is no longer a sufficient explanation.

Perhaps the prohibition of exploitation of prostitution is a protective measure necessary when prostitution is illegal, but substitutes poorly for labour rights. This is not a basis upon which to carry out a health programme for prostitutes. No international treaties promote the rights of willing workers. The failure to recognise the distinction between forced and unforced prostitution allows the claims of prostitutes' rights groups to be ignored. This expression of inter-national law undermines efforts to reduce the incidence of HIV and AIDS and discriminates against prostitution on the basis of occupation. Anti-Slavery International and the Network of Sex Work Projects argue that the redefinition of prostitution as work is vital if prostitutes are to enjoy equal human rights, in particular, their rights as workers.

If it is possible to conceive that a person can enter prostitution voluntarily as the best of available options, then it is evident that there is a problem in international law. This problem contributes to the vulnerability of prostitutes to disease. It is therefore within the remit of health practitioners to advocate for a critical review of human-rights law. Rights instruments should not contribute to the vulnerability of populations to disease, they should aim to diminish this vulnerability.

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Can health programmes lead to mistreatment of sex workers?

HEALTH AND HUMAN RIGHTS

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The 100% Condom Use Programme (100% CUP) is aimed at female sex workers and, as its name suggests, promotes increased condom usage. Supported by both WHO and the Joint United Nations' Programme on AIDS (UNAIDS), the programme was initiated in Thailand in 1989. 100% CUP has been regarded as a success story in the campaign to limit the spread of HIV infection. However, the international Network of Sex Work Projects (NSWP), an informal alliance of sex worker groups with constituent Asian, African, Latin American, and European networks, does not share this view.

It seems obvious that health promotion programmes funded by international agencies ought not to contribute to mistreatment of sex workers. Because sex work tends to be regarded as a behaviour not an occupation— who you are, not what you do—sex workers are often not recognised as legitimate parties to discussions of their conditions of employment. Sex workers are often treated as the object of programmes rather than contributors to them. Yet discussions about sex work without sex worker representation result in an incomplete understanding of the social dynamics of the occupation. It is, therefore, not surprising that programmes such as 100% CUP, developed without consultation with sex worker advocates, have had and continue to have negative repercussions for sex workers.

UNAIDS describes 100% CUP as follows: "The main strategy of the programme is to gain the agreement of the owners and managers of all commercial sex establishments to enforce condom use as a condition of commercial sex. Sex workers should be instructed to refuse sex to any customer who refuses to use a condom. If all sex establishments enforce this policy, clients have no choice—they either use condoms or they don't have sex."¹

At first glance the logic of this approach seems unassailable. However, at the very least, the language of 100% condom use ignores the importance of encouraging non-penetrative sexual activity. 100% CUP discourages the building of more comprehensive sexual skills. This shortcoming is substantial, but there are further concerns. Typically, control of the programme rests with local authorities, police, and brothel owners and managers. A UNAIDS Best Practice publication notes: " 'Safer sex' is promoted by introducing protective measures such as consistent condom use and modification of risky sexual practices and by reinforcing behavioural change towards adopting these practices . . . Modifications in the way sex work is organized must be encouraged and, in some cases this may be supported by policy enforcement. Possible approaches to building such support include enlisting sex establishment owners and managers to protect their workers' health and physical safety, working with police to reduce harassment, and promoting self-esteem and workplace solidarity among sex workers." ²

What has this meant in reality? Some developing country governments now make it compulsory for brothels to register every sex worker they employ, instruct her to use condoms, and ensure that she attends mandatory checks for sexually transmitted infections (STIs). Police and other local authorities can be authorised to enforce this policy, inspecting brothels, sex workers, and documents to ensure compliance. Although free condoms should be provided, this rarely happens in practice. Sex workers have been taken to clinics under military or police escort. They have paid fees to obtain certification showing that they are free of disease, or kickbacks have been paid directly to the authority responsible for inspection of brothels. In some cases, photographs of women are displayed in brothels allowing clients to identify which worker agreed to have unprotected sex. If workers are then dismissed they may continue working in the more hidden sections of the industry. High-risk services can always be purchased.

From the perspective of the NSWP and their members, claims that the policy empowers sex workers in their interactions with clients are unfounded. In frustration, the NSWP protested at the 2002 Barcelona AIDS Conference (figure). This action prompted research on 100% CUP in Cambodia that showed its adverse effect on respect for the human rights and health of sex workers.³

There are alternative approaches to promoting health in sex workers, such as the Sonagachi project in Kolkata, India. The project began in 1992, and initially was a survey examining social demography, sexual behaviour of sex workers, their clients, and partners, and the prevalence of STIs and HIV infection. Subsequently, an intervention programme was initiated to control the spread of these infections.⁴ An understanding of the sex trade was developed and used to devise strategies to "win friends and neutralise enemies".⁵ Sex workers are now involved in management of the programme. Strikingly, the prevalence of HIV infection among the sex workers in Sonagachi has remained at 5%.⁵

Enabling strategies that build social capital among sex workers, allowing them to organise and lobby for better working conditions, would seem to be a more effective approach than creating new means of abuse, especially in environments prone to corruption. Unfortunately, abuse seems to have been the outcome of 100% CUP. Ultimately, the sex workers' rights movement seeks resources to enable sex workers to participate in civil society and in decision-making that concerns them. However, as long as commercial sex is seen as degrading and workers as tainted, efforts to improve their working conditions and lives will not succeed. Until this attitude begins to change nothing else will.

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Distortions and difficulties in data for trafficking

HEALTH AND HUMAN RIGHTS

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Research into issues related to trafficking is hampered by a lack of clarity in the way we think about and act with respect to trafficked people. Work in the area is made even more difficult by the paucity of accurate data on the topic.

Despite the definition given to trafficking in international law¹ the term and issues surrounding it remain confused both conceptually and in government policy and practice. Several issues contribute to this confusion. First, researchers, law-enforcement agencies, and non-governmental organisations usually focus on a subset of trafficked people—women and children in sex work. Second, trafficking is rarely discussed without mention of coercion. But what constitutes coercion in the trafficking context? There is no universal, or even readily arrived at, position, which creates difficulties in contextualising and responding to many dilemmas raised by trafficking. Third, the definition of trafficking is complicated by a frequent failure to differentiate between women and children. Issues pertinent to children are sometimes incorrectly applied to adults. Even the Palermo Protocol¹ adopts the indiscriminate phrase “especially women and children” (panel). Further, trafficking is sometimes confused with people smuggling and illegal immigration.

That accurate data on trafficking in all its forms are difficult to obtain is not surprising. Such data, as exist, are often contaminated with ideological and moral bias. UNESCO notes that “(w)hen it comes to statistics, trafficking of girls and women is one of several highly emotive issues which seem to overwhelm critical faculties. Numbers take on a life of their own, gaining acceptance through repetition, often with little inquiry into their derivations. Journalists, bowing to the pressures of editors, demand numbers, any number. Organizations feel compelled to supply them, lending false precision and spurious authority to many reports.”²

A definition of trafficking: the Palermo Protocol ¹
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"Trafficking in persons" means the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs

The consent of a victim of trafficking shall be irrelevant

The recruitment, transportation, transfer, harbouring or receipt of a child for the purpose of exploitation is considered "trafficking in persons"

"Child" is any person under eighteen years of age.

Emotive factors, used effectively since the days of the white slave trade campaigns, make funding easier to obtain for research on trafficking than for the full range of circumstances that exist for migrant workers. Laura Agustin D'Andrea³ makes the point that researchers wanting to study migrant sex workers find funding difficult to obtain for work outside the themes of trafficking, HIV/AIDS, or violence against women. She attempts to show how working only within these frameworks distorts the multiplicity of realities that exist for women and the range of responses that might be offered to them. If prevention of abuse and promotion of health in the context of trafficking is to be achieved, then we should work to address difficulties faced by other trafficked people such as domestic servants, workers in the carpet and garment industries, organ harvestees, agricultural labourers, and camel jockeys. Arbitrarily picking out one subset of trafficking as an issue of greater worthiness has a distorting effect.

In the past few years, there has been an upsurge in concern about trafficking, and reports that the crime is growing. Such anxieties have flourished in the post-September 11 climate, which is marked by deepening apprehensions about transnational crime, terrorism, and border security, and a hardening of attitudes to illegal immigrants. Yet,

accurate data do not exist to support or refute the concern that the number of people being trafficked has suddenly increased. In fact, many of those post-September 11 worries and corresponding restrictions are increasing the difficulty of coordinated research between countries. Paradoxically, as the need for accurate information becomes more pressing, the chances of obtaining good data are fading.

Discussions about trafficking should be considered against a background of global inequity in which people may make rational decisions to act in ways that might be illegal, socially unacceptable, or self harming.

Trafficking is the result, in part, of actions by "victims" who sensibly seek a better life for themselves and their families in another country. It is also a response to needs in the labour market in countries of destination.

What should the contribution of health-care professionals be to this issue? First, to ask trafficked people themselves about the problems they face and involve them in finding solutions. Second, to be aware of the health risks that come from being a non-citizen or illegal alien. People in this position may fear deportation and avoid health services in case their status is revealed. Surely the role of doctors and health workers is not to reinforce trafficking myths, but to fully enter into debates about migration and health that are properly located in the setting of human rights and global inequity.

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Japan's "comfort women"

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It was not until 1993 that the Japanese government stopped denying its involvement in the creation of comfort stations—establishments that saw the systematic rape, torture, and in some cases murder, of approximately 200 000 so-called comfort women. Women from Asia and the Netherlands, many of whom were girls at the time, had been a gift from Emperor Hirohito to his troops during the Second World War. Numerous attempts by the women to claim justice for their abduction and brutal treatment through the Japanese courts have failed, including a recent case brought by 46 Filipino women. Last month, to continue to put pressure on the Japanese government, the Violence Against Women in War Network (VAWW-Net Japan), the Korean Council for the Women Drafted for Military Sexual Slavery by Japan, and the Asian Center for Women's Human Rights (ASCENT) convened the women's international war-crimes tribunal on Japan's military sexual slavery. At this symbolic hearing in Tokyo, 78 former comfort women from countries including North and South Korea, Peoples Republic of China, Taiwan, Philippines, Malaysia, Indonesia, and the Netherlands gave evidence and demanded accountability.

The evidence-gathering process took many forms. In Manila in the Philippines, 30 elderly women told their stories through an interpreter. With tears rolling down their faces they exposed the pain and humiliation of their experiences more than 50 years ago. As young girls they had been forced into army brothels where they were raped by as many as 60 soldiers from the Japanese imperial army each day. Their stories were stark testimony to the horror experienced by those forced into sexual slavery. The women had recently been rejected by their families for speaking out. One woman told of her devastation after her 30-year-old daughter refused to speak to or see her on learning the details of her sexual abuse by the military for 5 months during the 1940s. One survivor from Korea told of how she became pregnant as a result of multiple rapes. The soldiers cut her fetus out with a bayonet and removed her uterus. Another, an Indonesian woman, was 16-years old when taken from her home with 80 others and kept in one room to "service" the soldiers. She explained to interpreters that every Friday a doctor would examine her, and that once the examination was complete the

doctor would rape her. The tribunal was told that at the end of the war, in order to hide evidence of one of the stations, women had been grouped there and the station bombed. Two Japanese veterans and six expert witnesses also provided testimony. Prominent international lawyers including Gabrielle Kirk McDonald, previously president of the International Criminal Tribunal for the former Yugoslavia, served as judges and prosecutors. The judges indicted Emperor Hirohito for these war crimes.

In addition, on Dec 11, there was a 1-day public hearing in Tokyo on crimes against women in recent conflicts. This hearing, coordinated by Women's Caucus for Gender Justice, brought together women who have survived violations in recent and ongoing wars and conflicts. Women presented testimonies from many countries including Sierra Leone, Burundi, Colombia, Vietnam, Somalia, and Korea. One 25-year-old woman from Chiapas, Mexico, spoke of going to a public hospital to give birth in August, 1999, where the doctor advised her that a caesarean section was necessary. She later found that she had been sterilised. A widow with five children from Sierra Leone told of how her town was attacked by rebel forces in December, 1999, and how she had escaped into the bush with her children. They were without food for 3 days and on the fourth day ten masked men raped her while swearing their allegiance to the rebel leader. They left her bleeding, helpless, and separated from her children. It is clear that impunity for violence against women continues.

Sexual assault has always occurred in armed conflict and for many years was seen merely as an inevitable consequence of war. In the last few years the ad hoc international criminal tribunals for Rwanda and the former Yugoslavia have set a strong precedent that rape is a war crime and a crime against humanity. By contrast, the Second World War international prosecutions in Nuremberg and Tokyo were almost silent on sexual crimes against women. Current developments in the ad hoc tribunals are welcome and it is heartening that the proposed international criminal court includes ample reference to sexual crimes.

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Compulsory detention: limits of law

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On March 16, a man was convicted for the first time in the UK for intentionally infecting his partner with HIV. He was sentenced to a 5-year term of imprisonment. The prosecution was criticised by AIDS groups who suggested that it would not deter similar behaviour in the future, and could well lead to unwarranted complacency among people engaging in risky sexual behaviour. Elsewhere, criminal prosecution for actual or attempted HIV transmission has also been criticised for unfairly targeting racial and sexual minorities and for its potential to further marginalise people with HIV. Those opposed to the involvement of the criminal law have not necessarily considered the sometimes less transparent, though potentially equally draconian, activities of public health officialdom. In the now 20-year-old debate on HIV and human rights, some civil libertarians have preferred the use of criminal law to the application of public health powers. Criminal law commonly requires a public trial and procedural protections for an accused. These requirements are found less often in public health law.

The power to isolate and detain carriers of infectious disease is a traditional feature of public health law. In many jurisdictions, the powers remain largely as they were more than a century ago, giving full decision-making authority to a public health bureaucrat. Some have argued that granting the authority to isolate carriers entails great risks to civil liberty. We suggest that protecting others from serious harm is a sufficient justification, in principle, for detaining an individual until the danger can be eliminated. Where a serious disease is still low in prevalence, or is approaching elimination, the case is even stronger because the benefits of preventing each case are quite high. In practice, the crucial issue is whether the conditions that would justify detention are actually present. Unfortunately, those who are detained under these laws are often at the social margin—the homeless, street workers, intravenous drug users, the mentally ill, and intellectually disabled. These populations have more exposure to disease, fewer resources for coping, and are more likely to be perceived as uncooperative. The focus of coercion on the poor and mentally ill also accounts for the fact that criminal and mental health laws have been used to achieve detention. It may

be more convenient to prosecute a sex worker under criminal law and keep him or her out of circulation for a while than to initiate what may be a cumbersome public health process. This is particularly so because many jurisdictions have done away with their infectious disease hospitals, and sanatoria thus have no place to detain an individual. Criminal law may sometimes be used because neither public health nor mental health authorities want charge of a difficult individual, and so pass on the case to the police.

Not surprisingly, HIV and tuberculosis have provided occasions to rethink the criteria and process for detention. Some jurisdictions have amended their laws to explicitly require that there is a significant risk to others involved—ie, a person cannot be detained at the discretion of an official solely because they are infected with a disease. These jurisdictions will often require graded responses to the risk posed. The least restrictive approaches must be used to deal with behavioural threats—for example, support in the community in preference to isolation and detention. The individual is provided with legal counsel and the right of review before a neutral judicial officer. Legal procedures that afford the detained individual an opportunity to present facts, and that are transparent to the public, are desirable developments. Although sometimes resented by health professionals, such systems can effectively harmonise human rights values and public health needs.

But even in these jurisdictions, legal and public health systems may cooperate too well. The chief source of evidence to the court will be a physician or health official. Decisions will turn to medical determination of the risk to others. Judicial officers will usually defer to this evidence, and will often share the cultural biases of fellow professionals in assessing the risk posed by a person of significantly lower social status. Properly seen, the issue is not whether compulsory detention can be justified in theory, but whether it can be fairly deployed in practice. Where an HIV-positive homeless and mentally ill person comes to the attention of health officials and the courts there is the danger that the risks will be overstated, the recalcitrance of the individual exaggerated, and the range of less intrusive responses ignored. In these cases, the principle of protecting the many from the serious risks of the few is sound, but misapplied on the facts. Clear legal criteria and fair transparent procedures are vital for a just public health detention system. Equally necessary is continued awareness of

the social distance between those most at risk of disease and those in charge of controlling it.

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Chapter Four: Intellectual property, access to pharmaceuticals and human rights

This chapter consists of three papers. The first paper is a recent paper commissioned by Expert Opinion in Pharmacotherapy. The second two were formulated and written in the early stages of the discussion about the relationship between patent law, world trade law and access to drugs. The second paper written with Mark Heywood of the University of Witwatersand in South Africa provides examples of the ways different countries have attempted to deal with these issues. The paper published in Transactions of the Royal Society for Tropical Medicine and Hygiene examines the historical development of this area. I have also included a short description of one set of deliberations of the World Trade Organization which was not peer reviewed.

When these papers were written the human rights mechanisms of the United Nations had not really begun to address this issue, nor was it thought appropriate to bring human rights dialogue into trade discussions. Efforts of groups such as Oxfam, Médecins Sans Frontières, the Treatment Action Campaign of South Africa and the Consumer Project on Technology have raised rights linked issues have created an environment where these issues cannot now be avoided. Even the United States recently agreed to use some of its \$15 billion commitment to fight AIDS on the purchase of generic drugs. Of course the challenge to provide access to treatment to those in need remains as urgent as ever, but at least there is growing acknowledgement that a right to treatment exists and there is a duty on all who are able to contribute to the fulfilment of this right.

Monash University**Declaration for Thesis Chapter 4**

In the case of chapter 4, contributions to the paper "Patents on Drugs: Manufacturing Scarcity or Advancing Health" Journal of Law Medicine and Ethics 2002; 30: 621-631, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
Mark Heywood	50%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		21/5/04
Signature 2		

How much is patent protection threatened by drug costs?

In Print

Expert Opin. Pharmacother. (2004) 5(9):

A recent article in the Wall Street Journal began by stating

'As public-health groups urge wider use of generic drugs to lower the cost of treating AIDS and other diseases in developing countries, US trade negotiators – prodded by the drug industry – are taking the opposite stance in new trade pacts, seeking to strengthen protections for costlier brand-name drugs.' [1]

As the impact of AIDS deepens, the demand for treatment will continue. The use of patent law in limiting access to drugs is now continually subject to challenge by civil society, governments and international organisations. In the face of an incomprehensible number of humans confronting untimely death as a result of AIDS and other treatable diseases, there is no doubt that something must change. The questions are simply what, when and how.

Analogies with the Holocaust of the Second World War are striking. As with World War 2, and the millions murdered in the concentration camps, to those in the industrialised world, it is impossible to grasp the immensity of what is happening. To say millions are dying is meaningless. Yet the story of one person or a few is intelligible. If a current affairs programme were to follow a mother in Africa each night from the moment she was diagnosed to her death, this would probably generate more sympathy and pressure for change than any horrific mortality report published by UNAIDS.

Controversy generated over the impact of patents is centuries old. Countries have swung between promotion of the implementation of intellectual property laws and revoking them. Although to some, laws may appear immutable, in fact, regulatory environments change regularly, sometimes in advance of public opinion but more commonly in response to it. It is probably naive to suggest that a single factor, such as

drug costs, will result in significant reform of patent law. In any social or legal controversy there are always a great many questions to consider.

In the case of the future development of patent law, the practices and image of the pharmaceutical industry will naturally be at issue. Anticompetitive activities ranging from excessive secrecy regarding a product (something patents were intended to remedy), to conspiracies between companies to price fix have been continuing problems[2]. Current concerns about off-label use, such as in the case of GlaxoSmithKline and Paxil ® (and potential civil litigation and criminal prosecution) have and will contribute to damaging perceptions of the industry [3]. Amongst other related issues is the failure to publish unfavourable studies regarding a product, and the practices of drug company employees in wooing medical practitioners, in order to promote their product.

Although it receives less publicity other criticisms of the industry involve the lack of development of new drugs and the inattention to the diseases of the developing world. For example, in 2000, even though the US Patent Office granted 6730 pharmaceutical patents, the FDA only registered 27 new chemical entities [101]. In addition as a germane article in the New York Times noted

'The pharmaceutical industry earns nearly two-thirds of its profit in the United States, as drug prices in the rest of the industrialized world are largely controlled by governments. Those profits rely almost entirely on laws that protect the industry from cheap imports, delay home grown knockoffs, give away government medical discoveries, allow steep tax breaks for research expenditures and forbid government officials from demanding discounts while requiring them to buy certain drugs.' [102]

It is not well understood that governments (not only that of the US) provide a range of different supports and protections, such as those described, for the pharmaceutical industry. Patents are merely one of these.

The same article went on to note that 57% of respondents to a poll conducted in the US said that drug prices are 'unreasonably high' and an equal share said that the drug industry should be increasingly regulated by the federal government. Some respondents equated the pharmaceutical industry with the tobacco industry. A former researcher for Bristol-Myers Squibb was quoted saying that surging prices invite

government controls. In response, Pfizer Inc. has said that it will provide discounted drugs to the working poor and anyone without health insurance [102].

At an international level, it is possible to see compromises on patent law and access to drugs being reached then undermined. The Doha and Cancun World Trade talks concerning intellectual property, were a breakthrough of sorts but were rendered less so with the US embarking upon a series of 'free trade' negotiations. In summary, the Doha Ministerial meeting resulted in a consensus that the multilateral agreement on

Trade Related Aspects of Intellectual Property Rights (TRIPs) should be interpreted in a manner that allows government members of the World Trade Organization (WTO) to protect public health [4]. The right of WTO members to fully use the provisions in the TRIPS Agreement, which provide flexibility for this purpose, was affirmed. Such flexibility includes compulsory licensing and parallel importing (Box 1).

It was recognised that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Therefore, the Council for TRIPS was instructed to find an expeditious solution to this problem before the end of 2002. In Cancun, in 2003, it was agreed that member countries could export pharmaceuticals made under a compulsory licence provided numerous requirements were met [5]. The decision has force until such time as TRIPs is formally amended. Although Canada has amended its law to permit this, and Malaysia and Mozambique have said that they would be issuing compulsory licences, benefit from this new arrangement has yet to be demonstrated.

Despite these negotiations, to which the US was party, the US has exerted pressure on countries during the 'free trade agreement' negotiations to reform their intellectual property laws in order to provide greater protection for the pharmaceutical industry. In its bilateral negotiations with Thailand, for example, the US raised concerns regarding Thai intellectual property law [103]. As was noted by Kamon Uppakaew of the Thai Network of People Living with HIV/AIDS:

'Scaling up access to treatment in Thailand will be challenging enough without additional barriers to obtaining generic versions of newer, patented medicines for HIV and other diseases.' [104]

Similarly, so-called TRIPs plus standards are being demanded in 'free trade' negotiations with Ecuador, Colombia and Peru. The US has also stipulated that systems regulating drug availability and pricing be made more open to challenge by the industry such as in the case of Australia [6].

As mentioned earlier, responses to the present situation now emanate not only from activist groups such as Medecins Sans Frontieres, Oxfam and Health Gap but also from the World Health Organization, UNAIDS and the United Nations Office for the High Commissioner for Human Rights. In its latest report, UNAIDS noted that

'access to antiretroviral treatment and other HIV-related disease care remains abysmally low. Five to six million people in and middle-income countries need antiretroviral treatment immediately. However, the World Health Organization (WHO) estimated that only 400,000 people at the end of 2003 had access to it. This means that nine out of ten people who urgently need HIV treatment are not being reached.' [7]

The report further acknowledges that some gains have been made in the affordability of drugs, and attributes this largely to the work of advocates. United Nations Secretary-General, Kofi Annan is quoted

'People no longer accept that the sick and dying, simply because they are poor, should be denied drugs that have transformed the lives of others because they are better off.' [8]

Prof. P Hunt, the Special Rapporteur of the United Nations Commission on Human Rights on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, issued a statement after a recent visit to Peru. It was almost entirely concerned with the trade negotiation between the US and Peru. He said

'I am deeply concerned that the US-Peru trade agreement will water-down internationally agreed health safeguards, leading to higher prices for essential drugs that millions of Peruvians will find unaffordable ...The US-Peru trade agreement must not restrict Peru's ability to use the public health safeguards enshrined in TRIPS and the Doha Declaration ... If the final agreement has the effect of restricting access to essential drugs it will be inconsistent with Peru's national and international human rights obligations' [105].

Box 1. Flexibility of the Trade Related Aspects of Intellectual Property Rights agreement.

Compulsory licensing: during a national emergency a government may issue a licence for the production or purchase of a drug for domestic use without the approval of the patent holder. Patent holders will normally receive compensation

Parallel importing: drugs will be imported from a country where they are available at a cheaper price rather than from the patent holder

Despite recognising that patent regimes are not the sole source of difficulty, United Nations human rights bodies are increasingly cognisant of the impact of patents in either driving up prices for pharmaceuticals or in ensuring their unavailability to those most in need. In June 2004, the Committee on Economic, Social and Cultural Rights strongly recommended that Ecuador take its human rights obligations into account when negotiating the US-Ecuador trade agreement. The Committee on the Rights of the Child recently adopted a similar position when recommending that El Salvador

'systematically consider the best interest of the child when negotiating trade-related intellectual property rights' [105].

Pressure to reform the patent system is mounting. Pharmaceutical companies know they have an image problem and are not entirely impervious to pressure. However, responses in the form of charity are not regarded as being sufficiently reliable so as to be satisfactory. Initiatives, such as the Global Fund on HIV, Tuberculosis and Malaria and the World Health Organization 3X5 Campaign, attempt to meet treatment needs. But this also relies upon willing donors, and is far from sufficient. The undermining of international agreements such as those reached in Doha and Cancun must

eventually lead countries to question the benefit of being party to organisations, such as the WTO. Why have international agreed standards for patent law been placed in a negotiating position that requires the imposition of a more restrictive standard? Furthermore, no democratic government, not even that of the US wishes to be seen to be in the pockets of any single force regardless of their influence. Balances must always be struck. History has demonstrated that the powerful do not relinquish their power voluntarily. It must be wrestled from them. Drug prices, among other concerns, have already resulted in some reform of the patent system. It may be that more is to come.

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Patents on drugs: Manufacturing scarcity or advancing health?

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Respect for and promotion of the human rights of people with HIV/AIDS is now an entrenched component of the global response to HIV. However, as the global HIV epidemic has turned into a global AIDS epidemic, and as the death toll mounts, one area of human rights - the right to health care - has become fiercely contested. In particular, the degree to which patents on medicines impede what the United Nations High Commissioner for Human Rights has described as the "human right" of access to essential medicines is receiving close scrutiny.¹ The controversy generated by a recent article that argues, "in Africa patents and patent law are not a major barrier to treatment access in and of themselves," is indicative of the intensity of the debate.² But more importantly, advocacy for the human right to health, and to treatment in particular, is pitting developing country interests against those of the rich world and research-based pharmaceutical companies. Advocacy for access to treatments is leading to careful moral and legal scrutiny of patents taken out on medicines, new attempts to define the boundaries to intellectual property, and calls for a renegotiation of world trade rules.

However, in the hullabaloo, the need to present practical evidence of the impact of patents on health and access to medicine is sometimes neglected. This article attempts to fill that gap by examining some of the consequences of international trade law and intellectual property law for the prophylactic or curative treatment of ill health in general and HIV in particular.

The fact that AIDS and later HIV were first diagnosed in industrialized countries, such as the United States, and the relatively rapid development of treatments for HIV has helped to bring these issues to the fore in a way that arguably other illnesses have not. This is because while treatments for HIV were designed in and for a profitable first world market, the greatest need for them is now in developing countries where they are largely unaffordable. Treatments for HIV have also suddenly created a new group of patented "essential medicines"³ (particularly antiretrovirals) that are still

highly profitable in rich countries but desperately needed in poor countries. Early this year this contention was borne out by the addition of all the current antiretroviral drugs to the World Health Organization's Model Essential Drugs List.⁴

In the context of drugs needed for the treatment of HIV we attempt to illustrate how, despite the acknowledgment of other factors named by the World Health Organization (WHO) as influencing access to medicines (such as reliable health infrastructure and supply systems, sustainable financing, and political commitment), the effect of price in limiting access to life-saving drugs is significant. This article argues that the patent status of a medicine (as well as other essential medical technologies including diagnostic tools that measure viral load and CD4 counts) is the major determinant of that medicine's price - not traditional economic factors such as demand, active ingredient costs, or even research and development costs. Once again, we reiterate that there is absolutely no doubt that there are other significant factors that can limit access to treatment, but the purpose of this article is to address the consequences of patents and the commercialization of intellectual property related to human health. Medicines and political commitment to a public health-care infrastructure that can deliver them are obviously linked. But rather than pitting one against the other, we would argue for an analytical separation of the two issues, and a recognition that the demand for upgrading public health-care systems (and properly appreciating the obstacles to this) may represent a separate agenda both politically and developmentally.

PATENTS AND PHARMACEUTICALS

Patent law is a "rather artificial, highly complex and somewhat refined subject."⁵ Patents are a legal reward provided by the state for the disclosure and working of a new and useful invention. They result in monopoly rights over a process or product for a given period. In the words of the United Nations Committee on Economic Social and Cultural Rights, the legal recognition that is given to intellectual property is a "social product" that has a "social function" - namely, "to provide incentives for inventiveness and creativity from which society benefits."⁶

The debate over the consequence of patenting essential products, including medicines, is not new. Historically, some inventors and courts have deemed certain discoveries in the fields of medicine and surgery too valuable to be subject to a patent, recognizing the inherent inconsistency between monopoly rights and goods that might have significant health effects. This is true of ether and its effect in surgery, penicillin, medical applications of radium, and the polio vaccine. In the recent case of *Bristol-Myers Squibb v. FH Faulding*, Justice Finkelstein stated, "The important question: 'is it ethical to patent a pharmaceutical substance or a method of medical treatment?' admits of no satisfactory answer."⁷ He noted that Dr. Squibb is reported to have said, "I do not myself think that anything should be patented by either physician or pharmacist."⁸

This dilemma led to the development of divergent approaches, with some countries choosing to exempt medicines from all or part of patent law. In countries like Canada and Australia, patent regimes were moderated by mechanisms to control prices, or to facilitate local production under compulsory licenses.⁹ In countries such as India, Thailand, and Brazil, other legal means were found to allow competitors to circumvent the negative effects of patents by allowing the patenting of medical products but not processes, or vice versa. In Brazil, for example, Bermudez and colleagues note:

Pharmaceutical products and processes were patent-protected until 1945, when a change in legislation excluded inventions that contained food or pharmaceutical substances obtained by chemical means or processes. Additionally, another change in 1969 excluded patent protection completely for pharmaceuticals.¹⁰

Such approaches had dramatic effects on the capacity of local industry to manufacture medicines, albeit with different effects on the actual availability of medicines to people in need. In India, for example, 20 years after the enactment of the Patents Act of 1970, the share of Indian firms in the domestic pharmaceutical market had risen from 25 percent to 70 percent of bulk drugs and 80 percent of formulations. According to Lanjouw:

Of the top ten firms by 1996 pharmaceutical sales, six are now Indian firms rather than subsidiaries of foreign multinationals. Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country.¹¹

Two rationales underlay these approaches, both arguably rooted in governmental acceptance of its responsibility for protecting and improving health. The first was to make medicines affordable, the second to stimulate local industry (sometimes state-owned) in order to move toward greater self-sufficiency in medicines.

INTELLECTUAL PROPERTY LAW, ITS INTERNATIONALIZATION AND ENFORCEMENT

Regrettably, this pluralistic approach to the patenting of medicines, possible under treaties of the World Intellectual Property Organization (WIPO), is now being sacrificed. During the nineteenth century, countries became increasingly interested in international cooperation in the field of intellectual property and negotiated bilateral treaties. These agreements laid the foundation for the Paris Convention of 1883, resulting in a union for the protection of industrial property, including patents, and numerous treaties. Eventually, WIPO was formed in 1967, becoming a United Nations agency in 1974.

Nevertheless, significant domestic variation in intellectual property law remained. The enforcement mechanism for WIPO treaties was ultimately to bring an appeal to the International Court of Justice.¹² However, countries placed reservations on dispute resolution clauses, meaning that in reality there were no effective means of international enforcement of patent law.

Faced with the impossibility of enforcing its intellectual property rights under the WIPO treaties and the growing economic value of intellectual property, the United States began to look for an alternative system for more effectively policing intellectual property entitlements. In 1974, the U.S. Congress established a private sector advisory committee system to ensure that its trade policy reflected its commercial and economic interests. The Advisory Committee for Trade Negotiations, chaired by the chief economic officer of Pfizer in 1981, was critical in promoting the

idea of linking trade negotiations and implementation of intellectual property law. This led to the United States amending its own trade legislation in 1984, enabling it to impose sanctions on countries that did not respect U.S. intellectual property.

During the 1980s, the U.S. government, under fierce political pressure from U.S.-based pharmaceutical companies, directed resources to internationalizing its domestic standard of patent law, thereby giving its companies the possibility of truly global markets. But for over a decade, as efforts were turned to negotiating a new international patent agreement, concurrently this stick was wielded with great effect to protect the "property" of U.S. companies in foreign markets.¹³

In Thailand, for example, the 1979 Patent Act, which allowed pharmaceutical processes to be patented, but not products or ingredients, led to sustained threats of trade sanctions from the United States over a number of years, eventually leading to the Act's amendment in 1992 and 1998. Under the first amendment to the Patent Act, pharmaceutical processes became patentable, patent protection was extended from 15 to 20 years, and powers of compulsory licensing were weakened. Under the second amendment, local working requirements were removed and the Pharmaceutical Patent Review Board was abolished.¹⁴ Brazil faced similar pressures.

PATENTS AND THE WORLD TRADE ORGANIZATION

At the end of the Second World War, the idea for an international trade organization emerged, along with a proposal for a conference to discuss multilateral reduction of trade barriers. The first proposal was not pursued, but the second resulted in the General Agreement on Tariffs and Trade (GATT). The purpose of GATT was to promote trade liberalization and a number of "rounds" of GATT negotiations took place.

By the time the Uruguay Round of discussions commenced, GATT was regarded as insufficient to meet the needs of the world trade environment. From 1986 to 1994, the United States, supported by Europe, Canada, and Japan, examined how trading principles could be extended into areas not previously included, such as (and completely inappropriately) intellectual property. In contrast to WIPO, where

developing countries had a greater impact due to their number, industrialized countries, because of their economic power, dominated the GATT negotiations.¹⁵

Between 1986 and 1989, developing countries refused to negotiate a trade agreement on intellectual property. Industrialized countries argued that such an agreement would result in more foreign investment, technology transfer, and the promotion of local research and development. It was also erroneously thought that the United States might limit the unilateral imposition of trade sanctions and rely on the international system, but this was belied by continuing threats of sanctions against countries such as South Africa and the Philippines after the World Trade Organization (WTO) agreements came into effect. Eventually, there was a trade-off in which developing countries were to obtain access to markets for their textile and agricultural products and intellectual property was to be incorporated into the world trade regime.¹⁶

The result of this process was the Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations, signed April 15, 1994 at Marrakesh, Morocco.¹⁷ The Act established the WTO and included the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).¹⁸

Thus, trade law was significantly expanded, covering not only goods, but also services and intellectual property. TRIPS will, no doubt, have its greatest impact in the area of pharmaceutical products.

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY

The law contained in TRIPS is in its embryonic stage and the next few years will be crucial in determining the balance between the competing interests of health and profits. The TRIPS agreement creates minimum standards to be observed in drafting national law, but its overall result is the expansion of U.S. standards of intellectual property law to developing countries, where its benefits are questionable.

Defenders of TRIPS point out that the agreement's stated objectives are to enforce intellectual property rights in the interests of both producers and users "in a manner conducive to social and economic welfare, and to a balance of rights and

obligations."¹⁹ In this regard, Article 8 states that WTO members may adopt measures necessary to protect public health consistent with the terms of TRIPS.²⁰

In a mechanism known as compulsory licensing,²¹ third parties may exploit patents for a limited period if the proposed user has made efforts to obtain a license to produce the product on reasonable commercial terms and these efforts have been unsuccessful. The patent holder is to be given adequate recompense. Article 31 waives the requirement of obtaining authorization from the patent holder on reasonable commercial terms in cases of national emergency.

These are two potentially important windows that can be kept open in the interests of public health. However, the lack of skilled intellectual property lawyers in some countries will most likely result in law that does not take full advantage of the provisions of TRIPS and in unworkable patenting systems. This will be to the advantage of more powerful nations and to the detriment of health - a conclusion that is shared by the United Nations Commissioner on Human Rights, whose report recognizes:

The various links [in TRIPS] with the subject matter of human rights - the promotion of public health, nutrition, environment and development - are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement.²²

A matter that was not stated but is of exceptional importance is the 20-year period of market exclusivity now required by TRIPS. Professor Jagdish Bhagwati of Columbia University and Special Adviser to the United Nations on Globalization noted in an interview on Australian radio that this lengthy period is supported by very few economists.²³ Indeed, a growing number of prominent economists, including Joseph Stiglitz, winner of the Nobel Prize in 2001, senior economists from the World Bank, and Jagdish Bhagwati, have begun to see "patent protectionism" as unfair, inefficient, and inconsistent with a free trade agenda.²⁴

The World Health Organization believes that "an infectious disease crisis of global proportions is today threatening hard-won gains in health and life expectancy."²⁵ This historical coincidence between the globalization of patent protection on medicines and the globalization of certain diseases, driven by the HIV/AIDS pandemic, has meant

that the early years of TRIPS have been fraught with conflict.²⁶ Changes in domestic legal frameworks to make laws TRIPS-compliant (or the spectre of such changes in countries such as India) have led to greater patent protection on medicines, and higher prices, at a time when there is unprecedented demand for medicines - particularly, but not exclusively, medicines under patent that treat AIDS. In the argument about the actual impact of stronger intellectual property protection, a complex group of discussions is often conflated to the detriment of being able to arrive at firm conclusions. However, we would assert that the core conflict is between those who argue that:

the monopoly over a market bestowed by a patent harms health by making medicines unaffordable, versus

the ability to profit from research is an essential guarantee for further research into new and better medicines.

Patents, therefore, keep the wheel of research and invention in perpetual motion.

SOUTH AFRICA

South Africa has a population of 44 million people, the majority of whom live in dire poverty. However, it is atypical of poor countries because it has a sizeable middle class, previously mostly white people who benefited from apartheid, that has created a market for first world health care and brand name medicines. Consequently, medicines in this market are heavily patented and highly priced. Unfortunately, many of the medicines that are highly priced to maximize profit in the private sector are needed equally in the public sector, where ill health creates a large market based on need, but poverty restricts the market because of affordability. Consequently, the high price of patented medicines is a relative barrier to health care in the private sector, but an absolute barrier to health care in the public sector.

As in other countries, the HIV/AIDS epidemic and the price of AIDS medicines have brought this conflict to the fore. Last year, the world watched as multinational pharmaceutical manufacturers and the South African government (with vocal and visible support from groups such as the Treatment Action Campaign (TAC) and

Medicins Sans Frontieres) battled in a court case over intellectual property rights. Ironically, except for its intent to create a legal framework for parallel importation, this case actually had little to do with any real threat of depriving patent rights. The law in question (the Medicines and Related Substances Control Amendment Act, 1997) was primarily aimed at regulating other means by which pharmaceutical companies leverage prices, particularly "perverse incentives" that encourage doctors to continue to prescribe expensive brand-name medicines whose patents have expired, even when there are cheaper generic alternatives.

However, largely as a result of the successful intervention of the TAC as an *amicus curiae* (friend of the court), the media focus turned to the price of AIDS drugs and the patent power of the companies that manufacture them as justification for the South African government's duty to take legislative measures to improve access to health care. The legal arguments in *Pharmaceutical Manufacturers Association v. President of the Republic of South Africa*²⁷ are not the subject of this article. But what is significant is the manner in which the shaming of the companies led to rapid and deep drops in the prices of patented antiretroviral medicines. At the beginning of 2001, triple therapy had cost approximately 3,500 rand (U.S. \$450) per month. By June 2001, the price of the same medicines had dropped to approximately 1,000 rand (U.S. \$125) per month.

This may be indicative of the size of the surplus that was being extracted from these medicines by the patent holders before they faced a challenge. It is instructive that South Africa has not been alone in experiencing deep, but apparently arbitrary price reductions. Richard Stern, director of the Agua Buena Human Rights Association in Costa Rica, writes how in Honduras the price of antiretrovirals dropped by 85 percent in 2001, while in Nicaragua their price remained stable at approximately \$5,000 yearly for most cocktails.²⁸

As a result of price reductions, there has been a marked expansion in the number of South Africans who are being treated with antiretroviral medicines, either through medical insurance or out of pocket. Some analysts suggest that whereas the number of people using these medicines had previously been static at around 10,000, the price reductions make possible an expansion of up to 150,000 people who will be receiving treatment within the next two years. The benefits for health are demonstrated through

the records of Medscheme, South Africa's largest private medical insurance scheme, whose Aid for AIDS program shows large reductions in hospitalization costs for the patients receiving these medicines.²⁹

Here then is clear evidence of the link between price and access. Patent status is relevant because it is the primary determinant of price; and in South Africa - as Attaran and Gillespie-White demonstrate - thirteen out of the fifteen registered antiretroviral medicines are under patent.³⁰ In recent years, South Africa has gone through a torturous process of high level political denial about HIV, which has also manifested itself in governmental opposition to the use of antiretroviral medicines by people dependent on public health services. As a consequence, the primary beneficiary of price reductions so far has been the private sector. But this should not blind us to the fact that the South African public health sector has the most developed and expansive infrastructure in Africa - with the potential to scale up treatment to reach tens of thousands of poor people. If drug prices were to come down even further, it would begin to allow discussion and calculation of the opportunity costs, cost savings, and cost benefits of using the same medicines in the public health system. But further significant price reductions are unlikely unless the patents of these medicines are challenged. This requires a political commitment to the rights of people with HIV/AIDS, which is where the lessons of Brazil become instructive.

BRAZIL

It is important to acknowledge the differences between Brazil and South Africa, particularly the different scales of the HIV/AIDS epidemic and the fact that Brazil is largely urbanized, whereas in South Africa nearly 50 percent of the population still lives in rural areas.

However, there are also significant similarities: Both are middle income countries, and in certain areas, both are able to record high levels of commitment to health, indicative, we would argue, of the capacity of the public health infrastructure to treat HIV if there was political commitment and if medicine was affordable. For example, both countries have high rates of immunization against measles and tuberculosis (TB), and high percentages of births attended by skilled staff.³¹ The most relevant difference

between South Africa and Brazil is that, in the latter, there is a political commitment that has made it possible to demonstrate the relationship between patents, prices, and the number of people on treatment.

Since making a decision in 1996 to ensure access to antiretrovirals for "100 percent of identified HIV patients in the country,"³² Brazil has repeatedly asserted its right to take legal measures to ameliorate the abuse of patent powers by excessive pricing. Initially, this was done by generic production of those antiretroviral medicines that were not patent-protected locally before Brazil's intellectual property law was made TRIPS-compliant in 1996 (before this, inventions involving medicines were excluded from being patented). This included drugs such as Zidovudine, patented by Glaxo Wellcome, and Pfizer's antifungal Diflucan.

The benefits of Brazil's policy to locally produce generic medicines have been internationally recognized. According to UNAIDS, "The annual cost of double therapy with nucleoside analogues decreased on average by 80% between 1996 and 2000.... For triple therapy with two nucleosides and one protease inhibitor, the cost reduction was 36% over the same period...."³³ Similarly, the United Nations High Commissioner on Human Rights noted approvingly that generic production of antiretrovirals had saved the Brazilian government an estimated \$230 million.³⁴ Another positive consequence of generic competition in Brazil has been a drop in the prices of patented medicines as multinational companies aimed to compete with local manufacturers.³⁵

Despite pressure from the United States, the Brazilian government drafted its intellectual property law to ensure that the allowance in TRIPS for countries to use compulsory licensing was exploited.³⁶ Since the law was passed, the government has been prepared to use it, or threaten to use it, with significant results. Last year, Brazil negotiated a price reduction of almost 70 percent for the antiretroviral drug Efavirenz (patented by Merck). When similar negotiations failed to bring about a satisfactory result, it threatened to issue compulsory licenses for Nelfinavir, a protease inhibitor patented by Pfizer but licensed to Roche. This threat brought about a price reduction of 40 percent (from \$1.07 per pill to 64 cents per pill).³⁷ This elasticity in pricing is yet another example of the lack of transparency in the real costs of drug development.

Important to our argument is the way in which lower drug prices, achieved through the production of non-patent-- protected drugs or threats to implement compulsory licensing provisions in Brazilian law, made possible a bold HIV/AIDS treatment program, which - despite other challenges to its success - has quickly become the largest in the world with demonstrable health outcomes. Again, the report of the United Nations Commissioner for Human Rights deserves quotation:

In terms of the enjoyment of Brazilians' right to health, there has been a reduction in deaths due to AIDS by 50 per cent over the last four years. Further, there has been a reduction of 80 per cent in cases of hospitalization due to opportunistic diseases with a reduction in the appearance of the most serious opportunistic diseases tuberculosis (by 60 per cent), cytomegalovirus (by 54 per cent) and Kaposi's sarcoma (by 38 per cent).³⁸

A clearer illustration of the links between patents and prices would be hard to find. Finally, contrary to those who argue that where health infrastructure is lacking, treatment is not possible (and thus discussions of patents and price are irrelevant), in Brazil affordable medicines provided the incentive to create the infrastructure for their optimal use. Thus, according to the Brazilian Ministry of Health, in 2001 it was anticipated that 422,000 viral load tests and CD4 T-lymphocyte counts would be conducted.

THAILAND

Brazil is not the only country in the world where it is possible to evince this kind of evidence. In Thailand, a country relatively high on the United Nations Development Programme's Human Development Index (HDI), 95 percent of the population has access to what the WHO currently defines as "essential drugs," suggesting that both health infrastructure and political commitment to health exists.³⁹ But the contrast between general access to medicines and access to the patented medicines needed to treat the Thai HIV/ AIDS epidemic could not be starker. According to Oxfam, "Less than five per cent of people living with HIV/AIDS have access to the anti-retroviral medicines.... The main reason for this is the high cost of drug therapy."⁴⁰ Neither the government nor the consumer can afford the cost of treatment. After an evaluation of

the government program to provide antiretrovirals to the poor by the Thai Government and the World Bank, it was decided that "free treatment was not cost-effective when compared to prevention programmes."⁴¹ The scheme ended other than limited provision of AZT to prevent mother-to-child transmission.

Other difficulties related to the structure of the patent regime in Thailand - difficulties arising from pressure from the United States both before and after the TRIPS agreement - have resulted in additional and unnecessary delays in generic products getting to the Thai market.

Like Brazil, although by virtue of a different history of variations in patent law, the Thai Government Pharmaceutical Organization has been able to produce generic versions of a number of patented medicines and create price (and consequently access) differentials. Fluconazole and Ciprofloxacin, two drugs that play an important role in treating HIV-related opportunistic infections, are available as generics. In the case of the former, there is a 95 percent price differential between the brand name and the generic; in the case of the latter, the differential is 62 percent.⁴² Unfortunately, though, of antiretrovirals, only Zidovudine, Stavudine, and Didanosine are available off-patent. This allows some Thai patients to access this regimen of triple therapy, but leaves a sword of Damocles hanging over those who fail on this regimen, or cannot tolerate it and are dependent on substitution with a drug still under patent and available only at a much higher price. In the words of the President of the Thai Maw Chao Ban Foundation (Rural Doctors), "Those who can't afford treatment either take herbal remedies or pray."⁴³

DISCUSSION

Pharmaceutical companies frequently suggest that it is not patent law that limits access to drugs, but lack of funds with which to purchase these drugs - or systems to distribute them. The proof offered for this contention is that in countries with a low level of patent protection, such as India, poor people do not have access to drugs.⁴⁴

Apart from being a very selective example, this is to take a narrow interpretation of the historical and current impact of intellectual property law. It is also to take a short-sighted view of the meaning of access to drugs.

India is a country of more than a billion people, 70 percent of whom live in rural areas, with only 31 percent having access to "adequate" sanitation facilities. To equate India's intellectual property regimen with its general health crisis is simply untenable, and as we noted in our introduction, we do not assert that redressing the single issue of intellectual property law will revolutionize health care. While the price of many medicines in India is drastically lower than in many other countries, and this undoubtedly increases the possibility of access to health care for many (uncounted) people, it obviously cannot undo the general crisis of human development that exists in that country.

It should nevertheless be noted that patent law also has structural effects on the development of economies and is more suited to states with well-established industry. It is likely that strengthened patent law in developing countries may in fact deepen the crisis of development, as it causes technology and capital to flow back to patent holders - who are predominantly located in industrialized countries. The World Bank, for example, found that in 1997 patent applications in high income countries numbered more than 2.5 million, whereas in East Asia and the Pacific they numbered 290,630 "and in sub-Saharan Africa only 392,959, with only 38 of those filed by residents."⁴⁵

Intellectual property law, therefore, primarily serves to protect a handful of dominant multinational corporations. The monopoly market power provided by the grant and extension of a patent inhibits the growth of generic industries. As intellectual property law extends its reach, developing countries will be unable to copy products using reverse engineering. There is thus no obvious reason that TRIPS should lead to an investment in research and development in developing countries. There also is no obvious reason (or evidence) why TRIPS should encourage research into drugs for diseases whose main impact is in developing countries where there is no economic market for these medicines.

The examples we have provided of South Africa, Brazil, and Thailand point to a number of conclusions. Firstly, the speed at which prices have been reduced under pressure or in the face of generic competition strengthens the assumption that the price of the drug and its cost of production have little direct relationship. Secondly, significant price reductions of patented medicines in these (and other) countries have

had no visible impact on the global profitability of research-based companies. GlaxoSmithKline, for example, reported that in 2001 its sales of pharmaceutical products amounted to \$24.8 billion (a 15 percent increase measured in sterling over 2000). The antiretroviral medicine Combivir had sales of \$872 million.⁴⁶ This casts a question mark over allegations that generic competition will deplete resources for research and development. Is this argument not in reality a veiled threat of an investment strike by companies whose real losses will in fact only be negligible? Thirdly, the connection among patents, price, access to medicine, and health is confirmed by tangible evidence of larger numbers of people on treatment and improved health outcomes as prices decrease. Simply asserting that a lack of funds is the reason for limited access to drugs has other obvious flaws. As we have discussed, in South Africa, a country that could afford to provide general treatment for HIV were it not for blanket patenting, drugs are only available in the private sector.

THE DOHA MEETING

In the late 1990s, a movement to mitigate the worst effects of TRIPS and to try to strengthen and create a countervailing set of state duties emerged from developing countries, often led by Brazil, South Africa, and India. The battle has popped up from time to time in the World Health Assembly, particularly at the time of discussion of the Revised Drug Strategy,⁴⁷ and in other forums. But in 2001, it received a renewed impetus from the South African court case, leading to better coordination between developing countries, better technical support from nongovernmental organizations, and high-impact lobbying of industrialized countries. This revival of concern about TRIPS found its clearest expression at a meeting of the Ministerial Council of the WTO that took place in Doha, Qatar November 9-14 of last year.⁴⁸

It is arguable that the anthrax scares that followed the terrorist attacks in the United States on September 11 also created a changed international mood, leading to greater sensitivity to the centrality of access to medicine to health. As demand grew in the United States and Canada for drugs to combat anthrax, the pharmaceutical company Bayer was forced to sell Ciprofloxacin at a substantially reduced rate after threats that both countries would otherwise issue compulsory licenses. The parallels with the demand for AIDS medicines were unavoidable.

Consequently, by the time of the Doha meeting, it would have appeared unconscionable for the United States or Canada to deny other countries the right to determine what constituted a public health emergency. The Ministerial Declaration on the TRIPS Agreement and Public Health produced by the meeting recognized that TRIPS does not prevent countries from taking measures to protect public health and that WTO members are entitled to use TRIPS provisions for this purpose. The declaration states:

(b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.⁴⁹

The declaration extends until January 2016 the obligation for least developed countries (such as India, but not Brazil, Thailand or the Philippines) to fulfill their obligations under TRIPS. It also recognizes the difficulty countries with insufficient manufacturing capacity face in making effective use of compulsory licensing provisions. Thus, the Council for TRIPS is instructed to find an expeditious solution to this problem before the end of 2002.

This represents a theoretical advance on earlier consideration of the rights and obligations of developing countries. Whether this also facilitates greater access to drugs, particularly after 2016, is yet to be seen. Indeed, within four months of the Doha meeting, the United States already retreated from what might have been the clear intent of the meeting, arguing for a time-limited conditional moratorium on WTO challenges in these circumstances.⁵⁰

PATENTS AND HUMAN RIGHTS

In the first chapter of the World Health Organization's World Health Report 2000, a number of poignant comments are made about human health that are cause for reflection, and beg the question as to whether health - or factors that directly affect

health - should not be the subject of more explicit and enforceable human rights protections. The report notes that health is an "inalienable asset" that "is subject to large and unpredictable risks, which are mostly independent of one another." ⁵¹ Drawing an analogy between health insurance and car insurance (!), the report points out:

If a car worth \$10,000 would cost \$15,000 to repair after an accident, the insurer would pay only \$10,000. The impossibility of replacing the body, and the consequent absence of a market value for it precludes any such ceiling on health costs. Since the poor are condemned to live in their bodies just as the rich are, they need protection against health risks fully as much. ⁵²

The need to protect the "inalienable assets" of the poor from health risks as much as those of the rich goes to the heart of the crisis exacerbated by the strengthening of intellectual property law globally. The question is to what extent national human rights law has the power to do this - and to what extent international human rights law will lend support to national autonomy on this question.

On the one hand, the right to health, including medicines needed for health, as a human right that can be demanded of the state has been quite broadly established. Jurisprudence worldwide is replete with cases where this right has been asserted. On the other hand, the right of governments to take measures to make medicines more affordable and thereby allow them to fulfill their duties is more contested - even though more countries are trying to claim this right. ⁵³

The history of modern human rights law provides contrasting insight into the extent of the legal "right" to intellectual property in an international context, and which right trumps when this right is in conflict with arguably more fundamental rights. This is the heart of the question addressed by the report of the United Nations High Commissioner that we have referred to repeatedly in this article.

Article 15 of the International Covenant on Economic Social and Cultural Rights provides that states recognize the right of all:

(a) to take part in cultural life;

(b) to enjoy the benefits of scientific progress and its applications;

(c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [she] is the author.⁵⁴

The conceptual approach of Article 15 reflects an unresolved debate concerning whether intellectual property ought to be considered a right. Some states argue that no such protection is required and that intellectual property protection merely reflects the elitist privileges of the literary and scientific community. All should be able to share in the benefits derived from the advances in science. Eastern Bloc countries argue that the right to benefit from scientific advancement should not be confused with rights to property.

While intellectual property was ultimately included as a right, what exactly is protected by this right is left unclear. One interpretation is that in order to fit the normative pattern of human rights, the right to intellectual property must be rooted in the human dignity of the author of the work.⁵⁵ Such a right should be distinguished from other legally protected rights, such as commercial rights and the rights of corporate entities. Once property ownership moves from an individual to a commercial body, these rights should be sourced to secondary laws outside human rights, such as, in this case, TRIPS.

As Audrey Chapman has stated:

Ultimately, a human rights approach requires that intellectual property protection serve the objective of human well-being, to which the international human rights instruments give legal expression. Human rights are inalienable and universal claims belonging to individuals, and in some situations, to communities, but never to corporations. Human rights are understood to exist independently of recognition or implementation while intellectual property rights are granted by the State according to criteria defined by national legislation. In contrast with human rights, which establish permanent and irrevocable entitlements, intellectual property rights are temporary; they exist for a limited period and can be revoked, licensed or assigned to someone else.⁵⁶

These debates received renewed impetus last year as a result of the actual clashes between intellectual property rights and rights to health. In April 2001, for example, the United Nations Human Rights Commission approved a resolution, sponsored by Brazil, titled Access to Medication in the Context of Pandemics Such as HIV/AIDS (from which the United States was the only country to abstain).⁵⁷ In June 2001, the High Commissioner for Human Rights published a report on The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, and in December 2001, the United Nations Committee on Economic, Social and Cultural Rights issued a statement on human rights and intellectual property, which includes the unambiguous assertion that "[a]ny intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party."⁵⁸

Human rights bodies inside and outside the United Nations now argue that the regulation of the global economy must not be divorced from global social problems. Intellectual property law should be considered within the body of international human rights law and be implemented consistently with human rights such as the right to health, to nondiscrimination, and to development. A new international legal architecture could be constructed that both makes bodies like the WTO accountable for their actions and builds within them a consciousness of human rights. Thus, citing Chapman with approval, the United Nations High Commissioner points out that "a human rights approach ... would explicitly place the promotion and protection of human rights, in particular those in ICESCR [International Covenant on Economic, Social and Cultural Rights], at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement."⁵⁹

CONCLUSION

There is no doubt that many factors contribute to health. These include access to food, clean water, general sanitation, and shelter. Social measures to reduce vulnerability are equally crucial. Both prevention and treatment programs and services are necessary, as is research directed toward diseases affecting those in developing

countries. To suggest that any of these measures may be sacrificed is to take a simplistic view of a highly complex world.

But it is equally simplistic to suggest that intellectual property law as now partnered with world trade law is not a significant factor in determining who has access to what drugs. This law was clearly designed to ensure that control over patented drugs would rest in the hands of their manufacturers, predominantly American pharmaceutical companies. This has, in general, not been balanced by other considerations, such as health and development. Under present world trade law, patent laws cannot be structured to suit the requirements of domestic economic conditions. The impact of patent law on health is significant and needs to be addressed. However, it must not be considered in a vacuum. It must be judged against and made accountable to other arguably more pressing ethical and legal considerations.

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2. Attaran and L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatments in Africa?," JAMA, 286, no. 15 (2001): 1886-992. For replies, see M. Boelaert et al., Letters, JAMA, 287 (2002): 7; E. Goemaere, Letters, JAMA, 287 (2002): 7; M.J. Selgelid et al., Letters, JAMA, 287 (2002): 7.
3. The term "essential medicines" is used here to connote the necessity of particular medicines to the survival of a large proportion of people in the developing world. It is not intended in the specialized way that "essential drugs and medicines" are defined for purposes of the list generated by the World Health Organization (WHO). A broader definition, with the Essential

Drugs List criteria based on health need rather than current prices, is advocated. This is in keeping with the recommendation of the WHO Expert Committee on Essential Drugs in November 1999, which stated, "Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford."

4. Expert Committee on the Selection and Use of Essential Medicines, Summary of Recommendations, 12th Expert Committee on the Selection and Use of Essential Medicines Meeting, Geneva, April 15-19, 2002, available at <<http://www.who.int/medicines/organization/par/edl/expertrecommend.shtml>>.
5. Commissioner of Patents v. The Wellcome Foundation [1983] N.Z.L.R. 385, at 398.
6. Committee on Economic, Social and Cultural Rights, United Nations Economic and Social Council, Human Rights and Intellectual Property, Statement by the Committee on Economic, Social and Cultural Rights, E/C.12/2001/15 (December 14, 2001): paras. 4 and 6.
7. Bristol-Myers Squibb Co. v. FH Faulding & Co. Ltd [2000] FCA 316, available at <<http://www.ipcr.gov.au/SUBMIS/docs2/Sub11AttA.pdf>>.
8. Id
9. In an affidavit filed in support of the Treatment Action Campaign in Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998), Professor Colleen Flood of the University of Toronto mapped how patent law in Canada evolved since 1923 with the "expressly stated goal of making food and medicine affordable to the public" (at para. 4). To facilitate this, various legal devices, including compulsory licensing and administrative mechanisms (a Patented Medicines Prices Review Board), were established. However, in common with

developing countries, Canada has been pressured to strengthen intellectual property protection. In Australia, the government negotiates with industry as a monopsonist purchaser and is thus able to provide drugs to the community at greatly reduced prices under a Pharmaceutical Benefits Scheme.

10. Bermudez et al., Access to Drugs, the WTO TRIPS Agreement, and Patent Protection in Brazil: Trends, Perspectives, and Recommendations to Help Find Our Way, paper prepared for the Medicins Sans Frontieres Drugs for Neglected Diseases Working Group (February 20, 2002): at 2 (citation omitted).
11. J.O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering'?", Oxford Intellectual Property Research Centre, Electronic Journal of Intellectual Property Rights, WP 07/99 (originally published August 10, 1999), available at <<http://www.oiprc.ox.ac.uk/EJWP0799.html>>.
12. See, for example, Article 28 of the Paris Convention for the Protection of Industrial Property (March 20, 18 83, as amended on September 28, 1979), available at <<http://www.wipo.int/clea/docs/en/wo/wo020en.htm>>.
13. According to Audrey Chapman, Brazil, Ecuador, India, Pakistan, South Africa, and Thailand were among the countries subject to trade threats. A.R. Chapman, Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c), E/C.12/2000/12 (November 27, 2000): at para. 33, cited in Robinson, *supra* note 1.
14. S. Markandya, Timeline of Trade Disputes Involving Thailand and Access to Medicines, Version 1.0, Consumer Project on Technology (July 23, 2001), at <<http://www.cptech.org/ip/health/c/thailand/thailand.html>>.
15. M. Ryan, Knowledge Diplomacy, Global Competition and the Politics of Intellectual Property (Washington D.C.: Brookings Institution Press, 1998): at 12.
16. J. Braithwaite and P. Drahos, Global Business Regulation (Cambridge, England: Cambridge University Press, 2000): at 83. 17. Final Act Embodying

the Results of the Uruguay Round of the Multilateral Trade Negotiations, April 15, 1994, available at <http://www.wto.org/english/docs_e/legal_e/03-fa.pdf>.

17. Agreement on Trade-Related Aspects of Intellectual Property (April 15, 1994), available at <http://www.wto.org/english/tratop_e/trips_e/t-agm0-e.htm>. 19. *Id.* at Article 7.
18. One such measure might be the use of parallel importation, a legal mechanism on which TRIPS allows countries to determine their own law. Parallel importation means that once the patent holder has sold its product, it has exhausted its rights over the product and the new owner may sell it to others. As pharmaceuticals vary dramatically in price internationally, this is a useful provision that is widely used in the European Union. It has also been exploited successfully by the Philippines government to buy patented medicines from India at prices lower than they were being sold in the Philippines. However, in 2016, when all countries are to become members of the WTO, there will be limited benefit to parallel importation as there will be less variation in the price of patented medicines between countries as a result of the elimination of generic competition.
19. Compulsory licensing involves the licensing of companies that are not the inventors (patent holders) of a medicine to produce and sell that medicine. It means a deprivation of certain rights ordinarily granted to patent holders. Its benefit in the context of medicine is drastically lower prices. Compulsory licensing is of no effect when there is no domestic industry, as TRIPS does not allow the export of medicines produced under compulsory license. This leaves poor countries without their own industry at the mercy of donor agencies and multilateral organizations. Contractual agreements sometimes suggested as an alternative legal route for obtaining pharmaceuticals would be subject to the contingences created by unequal bargaining power.
20. Robinson, *supra* note 1, at para. 22.
21. Jagdish Bhagwati, interview by Geraldine Doogue, Life Matters, Australian Broadcasting Corporation (March 12, 2002). 24. M. Weisbrot, Center for

Economic and Policy Research, Rich Country Protectionism Puts WTO on the Slow Track (November 16, 2001), at <http://www.cepr.net/columns/weisbrot/rich_country_protectionism.htm>. James Love, director of the Consumer Project on Technology, states simply, "market incentives for health care R&D are not efficient." See J. Love, Paying for Health Care RED: Carrot and Sticks, paper prepared for the Medicins Sans Frontieres Drugs for Neglected Diseases Working Group (January 2001): at 1.

22. World Health Organization, Removing Obstacles to Healthy Development, Report on Infectious Diseases, WHO/CDS/ 99.1 (Geneva: World Health Organization, 1999): at 5 1.1, available at <<http://www.who.int/infectious-disease-report/pages/textonly.html>>.
23. Id. In this context, it is often argued that the difference between (a) the cost of producing the developed drug and (b) the cumulative costs of research and development that go into bringing a successful new medicine to the market make downward pressures on drug prices (by whatever means) unsustainable and ultimately counterproductive to the future development of new drugs. However, this argument is difficult to dissect because of the dearth of transparency regarding the actual costs of research and development, marketing and the costs of providing the developed drug alone. Typical of the rhetoric on the cost of development is a recent claim by PhRMA that \$800 million is required to bring a drug to market, where only one product results from a pool of more than 5,000 new chemical entities. See PhRMA Special 301 Submission, Priority List Watch Countries, 2002. These claims by pharmaceutical companies are, to put it mildly, contested. Actual costs are difficult to obtain. James Love, for example, has pointed out how these claims originate from a 1991 study by Joseph DiMasi, which estimated the cost of new drug development at \$231 million. But Love points to "several misunderstandings" regarding subsequent estimates based on DiMasi's work, including the fact that these figures were: estimates of the costs of doing both the early discovery and pre-clinical work, the clinical trials and FDA regulatory approval. For many drugs, the U.S. government paid for either the pre-clinical or clinical work. In those cases the companies' costs were lower.

In addition, these figures were largely based upon adjustments for both risk and huge cost of capital assumptions, and not on actual expenditures on R&D. James Packard Love, Affidavit (April 9, 2001): at paras. 37-38, filed in support of the Treatment Action Campaign in Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998).

24. Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998).
25. R. Stern, AIDS Treatment Access in Latin America: The Year in Review, Consumer Project on Technology January 7, 2002), at <http://www.cptech.org/ip/health/aids/stern01072002.html>.
26. S. Laverack, presentation on the Aid for AIDS program, Cape Town, June 2001. "Significant sustained cost savings have been achieved primarily by reduced expenditure on hospitalisation." *Id.*
27. See Attaran and Gillespie-White, *supra* note 2, at 1892, who make the strange assertion that "the data suggest that patents in Africa have generally not been a factor in either pharmaceutical economics and anti-retroviral drug treatment access (South Africa, with its larger affluent market, is an exception.)." In addition to its "affluent market," where 22 million people live below the poverty line (?), South Africa has one tenth of the global total of people living with HIV
28. United Nations Development Programme, "Human Development Indicators," Human Development Report 2001 (New York: Oxford University Press, 2001): at 159.
29. National AIDS Drug Policy, Ministry of Health, Secretariat of Health Policies (2001). Also according to the National AIDS Drug Policy of the Brazilian Ministry of Health, "Congressional Bill 9113, of 13 November 1996,

guarantees every patient access, free of direct costs, to all the medication required for his/ her treatment, including protease inhibitors."

30. UNAIDS, Report of the Global HN/AIDS Epidemic, UNAIDS/00.13E (June 2000): at 102, available at <http://www.unaids.org/epidemic_update/report/Epi-report.htm>.
31. Robinson, *supra* note 1, at para. 52.
32. See E. 't Hoen and S. Moon, *Medicins Sans Frontieres, Pills and Pocketbooks* (July 18, 2001), at <<http://www.msf.org/content/page.cfm?articleid=1A25BDD8-64D1-4B40BA2C06C23BEAFFCE>>. 't Hoen and Moon write, "Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over five years as a result of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period." See also World Health Organization, World Trade Organization, Norwegian Foreign Affairs Ministry, and Global Health Council, *Report of the Workshop on Differential Pricing and Financing of Essential Drugs* (April 2001): at 7, available at <http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wholereporthosbjorworkshopfin-eng.doc>: "It was noted that within the year prior to the workshop, a combination of corporate responsiveness, domestic production, and competition have led to substantial reductions in the price of HIV/AIDS drugs."
33. Law No. 9.279 of May 14, 1996, to Regulate Rights and Obligations Relating to Industrial Property, Article 71 states: "In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee do not satisfy such need, a temporary nonexclusive compulsory license to exploit the patent may be granted ex officio, without prejudice to the rights of the owner of the patent."
34. On August 22, 2001, the Brazilian Ministry of Health announced its intention to "break the patent of the drug Nelfinavir"; it was pointed out that a Brazilian government laboratory "has succeeded in producing the drug at a saving of 40% over that charged by Roche. This will mean a saving of 88 million reais per year." Brazilian Ministry of Health, Official Note (August 22, 2001),

available at <<http://lists.essential.org/pipermail/pharm-policy/2001-August/001410.html>>.

35. Robinson, *supra* note 1, at para. 58.
36. See United Nations Development Programme, *supra* note 31, at 159. It is also significant that Thailand occupies a relatively high position (99 out of 191) in terms of general health system attainment and performance. See World Health Organization, World Health Report 2000 (Geneva: World Health Organization, 2000): at Annex Table 1, "Health System Attainment and Performance in all Member States," at 152-55.
37. Oxfam, The Impact of Patent Rules on the Treatment of HIV/AIDS in Thailand, Thailand Country Profile (March 2001): at 1.
38. *Id.* at 2. 42. *Id.* at 5. 43. *Id.* at 3.
39. See Attaran and Gillespie-White, *supra* note 2.
40. Robinson, *supra* note 1, at para. 25, citing World Bank, World Development Indicators 2000 (Washington, D.C.: World Bank, 2000): at Table 5.12.
41. J.P. Garnier, presentation at the Lehman Brothers 5th Annual Global Healthcare Conference, Orlando, Florida, February 26, 2002, available at <<http://corp.gsk.com/financial/lehbrothers26feb2002.htm>>.
42. World Health Assembly, Revised Drug Strategy, WHA52.19 (May 24, 1999), available at <http://www.who.int/gb/EB_WHA/PDF/WHA52/ResWHA52/e19.pdf>.
43. The Ministerial Conference is the highest decision-making body of the WTO and it can make decisions on all matters under any of the WTO agreements, including the TRIPS agreement.
44. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (adopted November 14, 2001): at para. 5, available at <http://www.wto.org/english/thewto_e/minist_e/minOe/mindecltrips_e.htm>.

45. Inside U.S. Trade, "EU and U.S. Split over Scope of TRIPS Exceptions for Public Health" (March 8 2002), available at < <http://lists.essential.org/pipermail/ip-health/2002-March/002756.html>>.
46. World Health Organization, *supra* note 39, at 4. 52. *Id.* at 4.
47. Reference has already been made to the Medicines and Related Substances Control Amendment Act, 1997, in South Africa. In 2001, the government of Kenya passed a new Industrial Property Bill which, according to Medicins Sans Frontieres, represented a landmark victory, includes rights concerning parallel importation, compulsory licensing, and a Bolar provision. Medicins Sans Frontieres, Press Release (May 10, 2001), at <<http://www.msf.org/content/page.cfm?articleid=D2BCAC7D8881-4391-83ACDSD23BDBED2A>>.
48. General Assembly, United Nations, International Covenant on Economic, Social and Cultural Rights (adopted December 16, 1966): at Article 15.
49. See Robinson, *supra* note 1.
50. Audrey Chapman, American Association for the Advancement of Science, "New Projects Focus on Intellectual Property and Human Rights," Report on Science & Human Rights, XXII, no. 1 (Winter 2002), available at <<http://shr.aaas.org/report/xxii/ip.htm>>.
51. Washington File USIS, "United States Abstains from Vote on AIDS Drugs Resolution: Measure to Increase Access Is 'Flawed,' Ambassador Says," April 23, 2001, available at <<http://www.aegis.com/default.asp?req=http://www.aegis.com/news/usis/2001/US010405.html>>.
52. Committee on Economic, Social and Cultural Rights, *supra* note 6, at para. 12.
53. Robinson, *supra* note 1, at para. 22.

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Debate that "This house believes the essential drug concept hinders the effective deployment of drugs in developing countries"

Patents and access to essential drugs

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Abstract

This paper provides a brief overview of historical developments in patent law including its recent incorporation into world trade law. The impact of patents on access to essential drugs will be discussed. The relationship between intellectual property rights and the right to health will be considered.

Keywords: chemotherapy, drugs, patent law, Essential Drugs List

Introduction

Many factors contribute to the ability of a community to gain access to drugs. These include a functioning public health infrastructure and skilled health service providers. This paper will not address these issues. In so far as patents create a monopoly over a drug for the manufacturer and contribute to the price of pharmaceuticals they are independently worthy of analysis. Elsewhere it has been argued that patents are not a significant factor in determining access to a drug (Ataran & Gillespie-White, 2001; Boelaert et al., 2002; Goemaere et al., 2002; Selgelid et al., 2002); a view not accepted here and the subject of another paper by Loff & Heywood (2002).

Controversy over monopoly rights

Controversy over patents, their morality and overly broad application is not new. Patents have been known to English law since the fifteenth century. Queen Elizabeth I consolidated their use in order to stimulate the importation of inventions and privilege industrial ventures of certain individuals whether they be new or not. General monopolies, distinguished from patents for inventions, were granted to individuals and groups under the power of Royal Prerogative. They could not be challenged under common law. It is worth noting, in the light of contemporary debates in an environment in which a patent is regarded as a right of the inventor, that patents were conceived as a privilege granted by the monarch not a right of the recipient.

Abusive monopolies, granted for all variety of odd purposes, gave rise to such discontent that in 1601 the Queen was forced to issue 'A proclamation for the reformation of many abuses and misdemeanours committed by patentees'. In her last speech to the Commons, the 'Golden Speech', on 30 November 1601, Elizabeth stated: she had granted monopolies in good faith and that they would not be permitted to harm her subjects.

In 1624 the Statute of Monopolies was passed making monopolies null and void, except those granted for inventions. It stated that, for a patent to be valid it must possess seven features:

It must be for a term of twenty-one years or under.

It must be granted to the true and first inventor.

It must be in respect of new manufactures.

The privilege must not be contrary to law.

It must not be mischievous to the State by raising the price of commodities at home ('In every such new manufacture that deserves a privilege, there must be Urgens necessitas, and evidens utilitas.' – urgent necessity and evident utility).

The privilege must not be to the hurt of trade.

It must not be generally inconvenient (for example it should not put men out of work).

The law takes into account the needs of the domestic market and notably contains a reference to pricing.

In 1846, when discussing the requirement for utility in the invention, Hindmarch on Patent Privileges stated that this '... seems also to mean that the excepted grants must not be for the sole making of any thing which is to be used for any purpose which is illegal, or 'contrary to law', such as implements for house-breaking, picking pockets, locks, etc. Such grants, however, it is clear would be void, not only on the ground of want of public utility, but also because they are contrary to the policy of the law; and indeed it would be absurd if, by one law, patents might be granted to reward persons for providing the means of violating any other law' (Hindmarch, 1846). It is interesting to reflect on this statement in the context of the present debate about the primacy of human rights law over intellectual property law. This will be discussed below.

Considerations of morality, equity and lawfulness were core parts of the jurisprudence concerning patents. In the American case, *Morton v. New York Eye Infirmary* (1962) Morton had discovered that a known agent (ether) had the effect of rendering a patient motionless and insensible during an operation. He obtained a patent for this discovery and brought proceedings against the Infirmary for infringement. The trial court declared the patent to be invalid. On appeal to the Second Circuit Court of Appeals, the decision was affirmed. The Circuit Court accepted that though the discovery 'rank[ed] among the great discoveries of modern times; ... its value was too great to be estimated in dollars and cents'. This ruling held firm in the USA until 1952 when a court allowed a claim for a medical procedure (*Becton-Dickinson v. Scherer*, 1952).

During the drafting discussion preceding the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights there was extensive debate as to whether intellectual property should be considered a right. The Eastern bloc objected to a provision on intellectual property being part of an article dealing with a right to benefit from scientific progress. Others asserted that the rights of authors and scientists should be protected. Chapman (2000) asserts that this history suggests that the rights of authors and creators were viewed as not simply good in

them but were understood as essential pre-conditions for cultural freedom and participation and scientific progress.

In the case of *Bristol-Myers Squibb Co. v. F H Faulding & Co. Ltd* (2000), the Honourable Justice J. J. Finkelstein began his judgement by saying '(t)he important question: is it ethical to patent a pharmaceutical substance or a method of medical treatment? admits of no satisfactory answer'. He noted that Dr E. R. Squibb himself is reported to have said 'I do not myself think that anything should be patented by either physician or pharmacist'. Finkelstein went on to refer to a case in 1983 in New Zealand (*Commissioner of Patents v. Wellcome Foundation*, 1983). In that case Judge McMullin held there was much to be said for developing the law to allow the grant of patents for methods of treatment of human illness. Human suffering may be alleviated. Research may be encouraged by the knowledge that what is discovered or invented will be protected from competition and assured of a reward. But the grant of a patent is the grant of a monopoly. In recognition of this, patents legislation aims to balance the desirability of encouraging technological advances against the restrictions or abuse which may result from monopolies. He said a shift in emphasis favouring one interest would be achieved only at the expense of the other.

The Parliament of the UK had considered this matter in the words of section 41 of the Patents Act 1949. It provided that the Comptroller of Patents should endeavour to secure the availability of medicines and surgical and curative devices to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. The 1977 Act provides for Crown use of patented inventions including the production or supply of specified drugs and medicines. The Crown may provide compensation to the patent holder but the Comptroller is not normally involved in such matters.

It is not only the content of patent law but also the mechanics that have been the cause of concern. Charles Dickens' short story *A Poor Man's Tale of a Patent* describes Old John's travails when trying to obtain a patent for his invention (Dickens, 1850). At the end Old John states, 'I went through thirty-five stages. I began with the Queen upon the Throne. I ended with the Deputy chaff-wax. Is it a man, or what is it?' Some reforms were made to the system, but not sufficient for Dickens who continued to satirize it in his novel *Little Dorrit* (Dickens, 1857). It was during this period that

calls to end the patent system were at their peak, but not just because of the cumbersome application process. It was understood that patents should not be granted too readily since this would create a proliferation of undeserved monopolies and work to the disadvantage of scientific innovation.

Unlike the arguments about corruption of royal patronage during the era of Elizabeth I, the opponents of patents in the nineteenth century saw them as anti-competitive, opposed to the operation of the free market. It was thought that industry no longer needed this sort of support. Switzerland and The Netherlands did indeed do away with their patent systems. However, by the time of the Great Depression, protectionism further ensconced patents as an important legal mechanism believed to support the development of local industry (Dutton, 1984). Those who have analysed the role played by patents in the market more recently, independent of the debate over access to essential drugs, have not been of one mind as to its benefits.

How might patents impact upon access to essential drugs in resource poor settings? The answer requires some basic familiarity with modern law and its administration.

Patents and world trade law

During the nineteenth century countries negotiated bilateral intellectual property treaties. The inefficiency of a country-by-country approach led to the Paris Convention of 1883 resulting in a union for the protection of industrial property including patents. Subsequently, in 1883, the World Intellectual Property Organization (WIPO) formed, becoming a UN agency in 1948. Despite the existence of WIPO treaties, countries maintained independent patent regimes. In addition, treaties entered into by State member did not require agreement to the dispute resolution processes so there was no effective means of enforcement of patent law between countries. By the 1980s the USA, the nation with the most to gain from enforcement of patent law, found this unsatisfactory and began to look for an alternative system (Braithwaite & Drahos, 2000).

In parallel, at the end of the Second World War (1939-45) as part of the Bretton Woods discussion (which resulted in the formation of the International Monetary Fund and the World Bank) a proposal was made for a conference to discuss reduction

of trade barriers. This resulted in the General Agreement on Tariffs and Trade (GATT). A number of 'rounds' of GATT negotiations took place. By the early 1960s, it was recognized that special policies were required for developing countries. A decision of the Tokyo Round (1973-79), made it possible to give tariff concessions to developing countries. But most developing countries were not able to take advantage of this because of their limited trading capacity.

By the time the Uruguay Round of discussions commenced (1986-94) the USA had begun to exert pressure on other member nations with respect to their patent regimes (Braithwaite & Drahos, 2000). Prior to the Uruguay Round, 50 States did not issue patents for pharmaceuticals including some developed countries such as Portugal and Spain. Between 1986 and 1989 developing countries refused to negotiate a trade agreement on intellectual property. However, industry complained stressing financial losses and the lack of dispute resolution processes. Industrialized countries argued, on what basis it is hard to know, that such an agreement would result in more foreign investment, technology transfer, and promotion of local research and development. This was despite the fact that at the time 4% of research and development took place in that the USA might limit the unilateral imposition of trade sanctions and rely on the international system. Eventually there was a political trade-off in which developing countries were to obtain access to markets for their textile and agricultural products, and intellectual property was incorporated into the world trade regime (Velasquez & Boulet, 1999).

The result of this process was The Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations signed on 15 April 1994 at Marrakesh, Morocco. The Act is a 'framework convention' and established the World Trade Organization (WTO). It consists of a number of Agreements including the Agreement on trade Related Aspects of Intellectual Property (TRIPS). Thus, world trade law was significantly expanded, now covering not only goods but also services and intellectual property and it had a permanent institutional base enabling resolution of disputes, the WTO. The overall results of the linkage of intellectual property law to trade law is the expansion of intellectual property law into countries in which its benefits are the subject of great controversy and the extension of the reach of pharmaceutical companies to enforce rights that were previously non-existent.

TRIPS and essential drugs

TRIPS law is new. It creates minimum standards to be observed in drafting national law. The next few years will be crucial in determining the balance between competing public interests, at its most basic – access to drugs and compensation to industry. At present few drugs on the Essential Drugs List (EDL) are under patent. Patents themselves are not part of the criteria used in determining whether drugs will be added to the list. However, the criteria for addition to the list state 'The cost-benefit ratio is a major consideration in the choice of some drugs for the list'. Therefore whether or not a drug is under or off patent will be a factor, if only indirectly. As new and important drugs are developed the issue of access to them must be addressed and patents are clearly part of the package of issues that must be considered.

Article 8 sets out the principles of the TRIPS Agreement. It states that members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. However, this Article, and the reference to public health has been given the most limited interpretation.

A Ministerial Declaration produced in Doha in November 2001 attempted to provide some guidance on the interpretation of TRIPS (WTO, 2001). The Declaration was made in an environment influenced by the events of 11 September 2001. At that time both the USA and Canadian governments had threatened to introduce compulsory licences for the supply of ciprofloxacin to treat anthrax, and the back down by 39 pharmaceutical companies in their action against the South African government. Under TRIPS it is permissible for countries, according to strict conditions, to issue licences to domestic third-party manufacturers for the production of pharmaceuticals still under patent.

The Doha Declaration stated that TRIPS does not prevent countries from taking measures to protect public health and that members of the WTO are entitled to use TRIPS provisions, which provide flexibility for this purpose. The Declaration also stated that countries have the right to grant compulsory licences for the production of needed drugs and determine the grounds upon which such licences are granted. It

confirmed that countries have the right to grant compulsory licences for the production of needed drugs and determine the grounds upon which such licences are granted. It confirmed that countries have the right to determine what constitutes circumstances of extreme urgency, including public health crises such as those relating to HIV/AIDS, tuberculosis, malaria and other epidemics (WTO, 2001).

It recognized the difficulty countries with insufficient manufacturing capacity face in making effective use of compulsory licensing provisions. Thus, the Council for TRIPS was instructed to find an expeditious solution to this problem before the end of 2002. This deadline has passed. The USA has retreated from the agreement and any resolution seems somewhat distant (Anonymous, 2002).

During April 2002, the WHO Expert Committee on the Selection and Use of Essential Medicines, recommended that the following antiretroviral medicines be placed on the EDL: nucleoside reverse transcriptase inhibitors (abacavir, didanosine, lamivudine, stavudine and zidovudine); non-nucleoside reverse transcriptase inhibitors (efavirenz and nevirapine); and protease inhibitors (indinavir, lopinavir/low-dose ritonavir, nelfinavir, ritonavir and saquinavir) (WHO, 2002). The Committee added 'Selection of two or three protease inhibitors from the Model List will need to be determined by each country after consideration of local treatment guidelines and experience, as well as the comparative costs of available products' (WHO, 2002). It is important that, for those essential drugs that are subject to a patent and for new drugs to be included, that TRIPS as interpreted by the Doha Declaration be relied upon in the drafting of effective national laws. It may, however, be predicted that such laws will be subject to local and international challenge.

TRIPS and the right to health

Although TRIPS forms part of international law it must be enforced so as to minimize conflict with other areas of international law. Here Article 12, the right to the highest attainable standard of health contained in the International Covenant on Economic Social and Cultural Rights will be examined. This right may be found in numerous conventions, declarations and charters and references to it are often made.

During 2000 the UN Committee on Economic Social and Cultural Rights (UNESCO, 2000) produced a General Comment providing guidance as to what is expected from States when demonstrating their fulfilment of this right. The obligations of States are said to include the provision of a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health. This includes making available essential drugs as defined by the WHO Action Programme on Essential drugs to all without discrimination. By placing the antiretroviral drugs described above on the EDL, the Expert Committee has clearly identified that, despite their patent status and expense, their availability should be thought of as a right. How this is to be achieved is less clear.

Article 12.2(d) obliges States to create conditions that would assure to all medical service and medical attention in the event of sickness. The General Comment includes the provision of essential drugs as part of this obligation. The Committee drew attention to the obligation of all states parties to take steps both individually and through international assistance and cooperation, especially economic and technical, toward the rights in the Covenant generally and the right to health in particular. States are required to facilitate access to essential facilities, goods and services in other countries, wherever possible and give aid where required. These words appear in the General Comment: 'States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact on the right to health. Similarly, States parties have an obligation to ensure that their actions as members of international organisations take due account of the right to health'. Later on it states 'States parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions of such goods should never be used as an instrument of political or economic pressure'.

The regulation of the global economy ought not to be divorced from global social concerns, including potential conflict with international human rights law. A consciousness of not only the rhetoric rights but of the system of law that is human

rights should be encouraged within the WTO. As noted, a strong argument may be put, on the basis of the General Comment, that lack of access to essential drugs is a breach of the right to health. This is not a loose use of the language of rights, but a highly tenable interpretation of the meaning of this particular right that should be introduced as often as possible into dispute resolution both in the WTO and national courts.

A human rights approach to intellectual property would no doubt subordinate this time limited corporate interest to alienable and permanent rights such as the right to health. This view has been acknowledged with approval by bodies within and outside the UN (United Nations High Commissioner for Human rights, 2001).

Price control mechanisms

If the present intellectual property regime is to continue, it is important that there by some mechanism for analysis of cost-effectiveness of a product and price control. Schemes for regulating the price of pharmaceuticals, such as those operating or being considered in Australia, the UK, Canada, The Netherlands, Italy, Portugal, Sweden, Norway and Finland, are options. However, some sections of the pharmaceutical industry have aggressively defended their positions with tactics that have been widely criticised. These have included legal challenges and threats to governments, advisory bodies and individuals in Canada, USA, UK and Australia.

With respect to the imposition of price controls, the International Federation of Pharmaceutical Manufacturers' Associations have recommended that local innovation be encouraged by avoiding price control, either directly or indirectly. They argue 'Price controls tend to reduce supply and damage incentives for the research and development based industry, as well as negatively affecting the development of GMP-based local genetics industry...' (Bale, 2000). However if existing drugs are unavailable the industry argument is of less force.

Conclusions

Essential drugs have a special status amongst the multitude of the world's drugs. The fact that they have been termed 'essential' dictates a degree of urgency in their provision. Access to essential drugs has been deemed a human right.

Governments are clearly entitled to build public interest considerations into their patent law and must make full use of the legal flexibility contained in TRIPS. Countries must take the time to formulate carefully balanced patent law to facilitate access to essential drugs. Board members hearing of disputes at the WTO should be encouraged to develop broadly based jurisprudence that takes into account the special nature of access to essential drugs. The impact of patent law on health is significant and must be balanced by other critical considerations.

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World Trade Organization wrestles with access to cheap drugs solution

(News) **THE LANCET** • Vol 360 • November 23, 2002 • 1670

The World Trade Organization (WTO) held a “mini-ministerial” meeting in Sydney, Australia, last week, to resolve by the end of the year how poor nations can get access to cheap drugs. The meeting focused on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), which governs the content of domestic patent law and how it influences access to pharmaceuticals.

Last year in Doha, Qatar, the WTO softened the impact of TRIPs with the “Doha Declaration”, which states that during a national emergency—such as “HIV/AIDS, tuberculosis, malaria and other epidemics”—it is permissible for a country to grant a compulsory license to a local “third party” manufacturer to supply a drug for domestic use despite the drug being under patent. However at Doha it was recognised that countries without manufacturing capacity would face difficulties in making any use of compulsory licensing provisions. The WTO has set itself the task of cracking this problem by the end of the year.

Oxfam and MSF have called for a further Declaration that would expand TRIPs’s article 30, which allows countries to provide limited exceptions to the rights conferred by a patent. This would permit generic drug manufacturers to produce drugs solely for export to countries that had issued a compulsory license. Production for export conditions would be defined under national law as an exception to the rights of patent holders. This plan is supported by India and Brazil.

The European Parliament has similarly recently amended a directive issued in 2001 to state that manufacturing should be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.

However, the USA has instead pro-posed that there simply be a long-term waiver against bringing disputes to the WTO for breach of TRIPs in these circumstances.

However, waivers are inherently unreliable and on this basis drug firms are unlikely to produce drugs in large supplies.

A third option is a short-term waiver and an amendment to one of the numerous conditions of a compulsory license prescribed under article 31 of TRIPs. Article 31(f) requires that any compulsory license authorise the supply of drugs mainly for the domestic market of the country issuing the license. The amendment would allow the export of drugs to countries without a manufacturing base. Critics say that this would continue to make countries in need of drugs reliant upon the exporting country. Also case-by-case approval would be necessary, as would the satisfaction of the other bureaucratic and complex requirements of article 31.

Inside US Trade, a trade newsletter, has reported that the USA had favoured the exclusion of advanced developing countries from qualifying as importing countries and had originally advocated that developing countries alone be eligible as producers.

Whatever option is settled upon, the TRIPs Council must reach a solution during their meeting in Geneva on Nov 25-27.

Bebe Loff.

No agreement reached in talks on access to cheap drugs

(News) **THE LANCET** • Vol 360 • December 14, 2002 • 1951

At a meeting on Nov 25–27 in Geneva, Switzerland, the Council for the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) was expected to finalise a plan that would enable generic drug manufacturers in countries such as Brazil, India, and China to export drugs still under patent, under certain circumstances, to countries with little or no manufacturing industry. Instead the TRIPs Council meeting, which followed a “mini-ministerial” meeting held earlier in November (see *Lancet* 2002; **360**: 1670), ended without any prospect of reaching agreement.

During the meeting the USA, Japan, and Canada argued in favour of the introduction of a temporary waiver against bringing disputes to the WTO if the case concerns generics that are to be imported to the least developed countries. Other countries, particularly developing countries, supported by groups such as Oxfam and Médecins Sans Frontières, preferred a permanent amendment of TRIPs. This, they suggested, would offer certainty to all parties and an encouragement to manufacturers of generics to gear up for larger-scale production.

At present, a WTO agreement interpreting TRIPs, known as the “Doha Declaration”, allows countries to issue compulsory licences during national emergencies such as HIV/AIDS, malaria, tuberculosis, and other epidemics. In these circumstances, a local third-party manufacturer may produce the necessary drugs for domestic use and reasonable compensation must be paid to the patent holder.

At the meeting, the USA attempted to limit the diseases that might be covered by the new agreement to HIV/AIDS, tuberculosis, and malaria, and “other infectious epidemics of comparable gravity and scale that may arise in the future”. This restrictive language was not acceptable to other members, however. Disagreement also arose at the meeting as to what might constitute reasonable compensation and who might be liable to pay it.

The USA further endeavoured to limit the number of countries that might benefit from the importation of cheaper generic versions of patented drugs. The Council agreed that the 49 least developed countries should be automatically entitled to benefit, but no agreement was reached on the extension of this to other developing countries. Developing countries rejected this division.

The US position is undoubtedly in line with the desires of industry. A letter dated 25 Nov, 2002, from 20 pharmaceutical companies to the US Trade Representative, Robert Zoellick, states: "An open-ended or unclear exception to the standards for patent protection would seriously undermine our interest and set back the long-term public health objectives Doha was designed to achieve. We urge you to negotiate a solution that is specifically limited to the diseases that were the focus of the Doha Declaration, namely HIV/AIDS, TB and malaria and other epidemics of similar scale. In addition, it should be clear that only truly disadvantaged countries in sub-Saharan Africa, be the recipient of the changed rule."

Bebe Loff

Chapter Five: Ethical issues that arise when conduction research in vulnerable populations

This chapter contains new work and 3 papers published in the Medical Journal of Australia, Nature Medicine and The Lancet. The Nature Medicine paper though jointly written was based on an earlier lecture of mine. This is made clear at the end of the article.

Since writing these papers my views concerning the relationship between bioethics and human rights have developed. I have therefore added an introductory piece on the relationship between ethical evaluation of research and the potential contribution of a rights based approach. Professor Carel Ijsselmuiden, Director of the Council on Health Research for Development has made brief comments on this work that I have taken into account in drafting.

Monash University

Declaration for Thesis Chapter 5

In the case of chapter 5, contributions to the paper "The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations" Nature Medicine 2000; 6: 615, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	33.3%	Conception and execution
Deborah Zion	33.3%	Conception and execution
Lynn Gillam	33.3%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature 1		Date
LYNN GILLAM		20/5/04
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Declaration for Thesis Chapter 5


In the case of chapter 5, contributions to the paper "The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations" Nature Medicine 2000; 6: 615, involve the following:

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- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
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Declaration for Thesis Chapter 5


In the case of chapter 5, contributions to the paper "The Declaration of Helsinki and research on vulnerable populations" MJA 2000; 172: 292, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	80%	Conception and execution
Jim Black	20%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		13.05.2004
Signature 2		13/05/2004.

HUMAN RIGHTS AND RESEARCH ETHICS – A NEW APPROACH

INTRODUCTION

It is undoubtedly the case that research can have social and political effects that may, on occasion, be undesirable. The ethical concerns articulated in guidelines such as the Helsinki Declaration are not designed to deal with the broad social implications of research, but to provide an ethical framework within which to consider issues raised by a research protocol. It is thus naive and in some ways irresponsible to think that when ethical guidelines have been satisfied, the job of determining whether or not research should proceed has been completed. However international human rights standards and norms are able to take account of these matters. Indeed this is their purpose. There will be situations in which a potential violation of human rights associated with a study may not amount to a breach of ethical guidelines, or at least not an obvious one. From a rights perspective this will make the study impermissible or only permissible when rights issues have been addressed. It will be suggested here that a human rights framework might have much to offer the field of medical research just as, some years ago, Jonathan Mann proposed that a human rights framework might contribute to the field of public health.

There is in many ways, an overlap between the concerns of bioethics and of concerns of human rights, which should result in them becoming mutually reinforcing approaches. It is well worth recalling that contemporary ethical guidelines for research arose in response to gross human rights abuses. Not surprisingly a principal theme of ethical guidance is to ensure that the vulnerable are not harmed. However the way ethical guidelines endeavour to achieve this outcome is by adopting what might be characterized as a charitable or paternalistic model. What is meant by this claim is that other than in the area of "informed consent", there is little opportunity for participants to be self-determining. Decisions are made well in advance of their involvement and there is insufficient public accountability for subject welfare (other than that which might be provided by an ethics committee or a Data Safety and Monitoring Board) during or subsequent to a study.

The foci of human rights are also the protection of the vulnerable, while explicitly aiming to promote empowerment and participation, and improving the transparency and accountability of social institutions. The considered and consistent application of human rights principles to bioethics should complement and strengthen some existing approaches to safeguarding the interests of research participants and perhaps challenge others. It is also contended that the process of health research review is likely to be more effective, and protective of the vulnerable, if international human rights principles are taken into account in addition to ethical guidelines. Human rights do not provide a detailed roadmap for action. However a rights based approach to research review introduces additional and, it is suggested here, crucial considerations. This approach should allow for a more complete analysis of both the societal conditions relevant to a research proposal and the ways in which the research might affect prospective participants. This contention will now be tested.

In the discussion that follows the content of a rights based approach will be detailed. This will draw upon inter alia, recent work in the areas of human rights and development and of human rights and poverty reduction. A well known study, the Tuskegee Syphilis Study, will be analysed from the perspective of human rights. Next a more modern debate, that of "informed consent by community elders" as opposed to seeking individual consent will be addressed. Finally conclusions will be drawn.

It is emphasised at the outset that human rights norms are discussed here as rhetorical tools, as heuristics, able to provide an alternative analytical framework. This paper is not seeking to establish whether or not, if formally tested in a court or treaty committee, rights would be interpreted so as to result in governments being admonished. For example, this paper will not examine, from a legal perspective, whether or not a government has breached the right to life when it "allows unregulated and dangerous clinical trials to cause arbitrary deaths".³⁹ It is also well recognised that human rights are far from perfect in both their articulation and expression.

WHAT SORT OF HUMAN RIGHTS FRAMEWORK?

“Whether explicit or implicit, norms and values shape policies and institutions. A human rights approach is explicit about its normative framework: international human rights.”⁴⁰

In 1997 the Secretary General called “on all entities of the UN system to mainstream human rights into their various activities and programmes within the framework of their respective mandates”. As part of the response 10 United Nations agencies convened a (second) workshop in May 2003 in Stamford, in the United States⁴¹. The workshop objectives were:

To review the state of art of human rights mainstreaming in the context of development policy and programmes;

To review current practices and generate an understanding of the challenges faced in applying a human rights based approach to the development and operationalisation of Common Country Assessments (CCA) and United Nations Development Assistance Frameworks (UNDAF); and in cooperation over Poverty Reduction Strategy Plans and the Millennium Development Goals;

³⁹ See Fidler D. “Geographical Morality” Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries. Summer 2001 42 Harv. International LJ 299

⁴⁰ Human Rights and Poverty Reduction: A conceptual framework. United Nations. New York. 2004 p2

⁴¹ The Human Rights Based Approach to Development Cooperation Towards a Common Understanding Among UN Agencies

<http://www.undp.org/governance/docshurst/030616CommonUnderstanding.doc>

(Report of the Second Interagency Workshop on Implementing a Human Rights-based Approach in the Context of UN Reform. Stamford, USA, 5-7 May, 2003)

To further develop a common understanding of a human rights based approach to development, and to identify needs for strengthening the text of the CCA and UNDAF Guidelines;

To work towards harmonisation of the practice of UN agencies in their respective application of a human rights based approach.

To emerge from this meeting was a Statement of Common Understanding on a human rights based approach to development cooperation and programming by UN agencies. When it is recalled that every country has signed and ratified at least one human rights instrument and that these internationally agreed principles apply to all people at all times, it may be assumed that elements of the Statement may be applied beyond development policy and programming by UN agencies, having far-reaching applicability and implications.⁴² In one sense it is entirely unnecessary to consider these models and simply consider anew what a rights based approach to research ethics might be. However there is much to be gained by considering the content of these examples drawing out what might be useful in this context.

The Common Understanding may be summarized as follows:

1. All programmes (of development co-operation, policies and technical assistance) should further the realisation of human rights as laid down in the Universal Declaration of Human Rights and other international human rights instruments.
2. Human rights standards contained in, and principles derived from, the Universal Declaration of Human Rights and other international human rights

⁴² This thought was discussed with Mac Darrow, the Human Rights Officer responsible for the "HURIST" the Human Rights Strengthening programme of the Office of the High Commissioner for Human Rights in November 2003.

instruments guide (all development cooperation and) programming in all sectors and in all phases of the programming process.

3. Development cooperation contributes to the development of the capacities of 'duty-bearers' to meet their obligations and/or of 'rights-holders' to claim their rights.⁴³ (Parentheses added)

In essence the Common Understanding requires that specific be paid to the realization of human rights. Otherwise it cannot be said that one has adopted a rights based approach. It is insufficient to have fulfilled human rights incidentally - as a by-product of other activities.

Human rights principles are said to (and do) apply to "programming" in all sectors including: health, education, governance, nutrition, water and sanitation, HIV/AIDS, employment and labour relations and social and economic security.⁴⁴ This is an all-encompassing assertion able to embrace medical research regardless of whether research is contained within a development agenda, though arguably when research is conducted within a developing country the impact of that research upon development and rights are relevant moral considerations.

Further, "(h)uman rights principles are to guide all phases of the programming process, including assessment and analysis, programme planning and design (including setting of goals, objectives and strategies); implementation, monitoring and evaluation."⁴⁵ This approach may perhaps have greater applicability to a research agenda, rather than an individual study though this may depend upon the size, importance and impact of the study. For example large studies investigating a vaccine for HIV may have such dramatic implications that a human rights assessment might be required from the outset.

⁴³ Ibid footnote no 41

⁴⁴ Ibid footnote no 41

⁴⁵ Ibid footnote no 41

"Duty-bearers" in this analysis may be States, organizations or individuals. The obligation to protect human rights requires States to prevent third parties from interfering with rights. Third parties include individuals and corporate entities, be they public or private. The obligation to fulfil means that States must actively adopt legislative, administrative, budgetary, judicial, promotional and other measures directed towards the full realisation of human rights. The obligation to respect human rights requires States to refrain from interfering with the enjoyment of a right. However, the Preambles to the International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights emphasize that individuals have duties to other individuals and to the community to which they belong, and are under a responsibility to strive for the promotion and observance of the rights recognized in the Covenant. General Comment 14 on the right to health of the Committee of Economic, Social and Cultural Rights provides that States must respect, protect and fulfil rights.⁴⁶ In a normative sense corporate entities of any description and individuals may all potentially be duty bearers. At this point however, courts will be unlikely to attribute formal liability for a breach of public international law to non-State actors unless they have acted under the direction, instigation or control of the State.⁴⁷

The standards and principles referred to in paragraph 2 of the Common Understanding are defined as: universality and inalienability; indivisibility; inter-dependence and inter-relatedness; non-discrimination and equality; participation and inclusion; accountability and the rule of law. These principles are explained in the Common Understanding as follows.

⁴⁶ Committee on Economic, Social and Cultural Rights. General Comment 14. The right to the highest attainable standard of health : . 11/08/2000. E/C.12/2000/4.

⁴⁷ Crawford J. The International Law Commission's Articles on State Responsibility: Introduction Text and Commentaries. Cambridge University Press. Cambridge 2002 cited in Ford J, Tomossy G. Clinical Trials in Developing Countries: The Plaintiff's Challenge, 2004 (1) Law, Social Justice & Global Development Journal <http://elj.warwick.ac.uk/global/issue/2004-1/fordtomossy.html>

- *Universality and inalienability:* Human rights are universal and inalienable. All people everywhere in the world are entitled to them. The human person in whom they inhere cannot voluntarily give them up. Nor can others take them away from him or her. As stated in Article 1 of the UDHR, "All human beings are born free and equal in dignity and rights".
- *Indivisibility:* Human rights are indivisible. Whether of a civil, cultural, economic, political or social nature, they are all inherent to the dignity of every human person. Consequently, they all have equal status as rights, and cannot be ranked, a priori, in a hierarchical order.
- *Inter-dependence and Inter-relatedness.* The realization of one right often depends, wholly or in part, upon the realization of others. For instance, realization of the right to health may depend, in certain circumstances, on realization of the right to education or of the right to information.
- *Equality and Non-discrimination:* All individuals are equal as human beings and by virtue of the inherent dignity of each human person. All human beings are entitled to their human rights without discrimination of any kind, such as race, colour, sex, ethnicity, age, language, religion, political or other opinion, national or social origin, disability, property, birth or other status as explained by the human rights treaty bodies.
- *Participation and Inclusion:* Every person and all peoples are entitled to active, free and meaningful participation in, contribution to, and enjoyment of civil, economic, social, cultural and political development in which human rights and fundamental freedoms can be realized.
- *Accountability and Rule of Law:* States and other duty-bearers are answerable for the observance of human rights. In this regard, they have to comply with the legal norms and standards enshrined in human rights instruments. Where they fail to do so, aggrieved rights-holders are entitled to institute proceedings

for appropriate redress before a competent court or other adjudicator in accordance with the rules and procedures provided by law.

Implied in a human rights based approach to development are further necessary elements:

- a) Assessment and analysis in order to identify the human rights claims of rights-holders and the corresponding human rights obligations of duty-bearers as well as the immediate, underlying, and structural causes of the non-realization of rights.
- b) Programmes assess the capacity of rights-holders to claim their rights, and of duty-bearers to fulfil their obligations. They then develop strategies to build these capacities.
- c) Programmes monitor and evaluate both outcomes and processes guided by human rights standards and principles.
- d) Programming is informed by the recommendations of international human rights bodies and mechanisms.

The application of this approach may become clearer in the example detailed below. Nevertheless, this is a human rights "how to" that asks: what are the claims; what are the obligations; build capacities of rights holders and duty bearers; monitor process and outcome; and ensure each step is informed by human rights principles.

Further essential elements are described as being unique to a human rights approach:

- 1. People are recognized as key actors in their own development, rather than passive recipients of commodities and services.*
- 2. Participation is both a means and a goal.*
- 3. Strategies are empowering, not disempowering.*
- 4. Both outcomes and processes are monitored and evaluated.*
- 5. Analysis includes all stakeholders.*
- 6. Programmes focus on marginalized, disadvantaged, and excluded groups.*

7. *The development process is locally owned.*
8. *Programmes aim to reduce disparity.*
9. *Both top-down and bottom-up approaches are used in synergy.*
10. *Situation analysis is used to identify immediate, underlying, and basic causes of development problems.*
11. *Measurable goals and targets are important in programming.*
12. *Strategic partnerships are developed and sustained.*

The Common Understanding concludes by noting that ultimately human rights norms move actions from the realm of benevolence or guidelines to law. Policies or activities that violate recognized human rights law may be prohibited. Human rights standards should be applied as a criterion for policy and programme development. The beneficiaries of policies and programmes should be actively involved in their creation and implementation. A rights based approach should influence both processes and outcomes. The identification of duty bearers and rights holders is fundamental.

FURTHER ELUCIDATION OF BASIC HUMAN RIGHTS PRINCIPLES

Non-Discrimination and Equality

Non-discrimination and equality are amongst the most fundamental principles in human rights law. All people are entitled to have their rights respected without discrimination of any kind. It is most often the case that those who are participants in research are also those who experience some form of disadvantage. Indeed it is hard to visualise research participants drawn from amongst the dominant and wealthy in our societies. Disadvantage may arise from, amongst other things, lack of resources, information, opportunity, or power. From this perspective the consideration of human rights in the context of research should ensure that proper attention is given to ensuring that research does not harm the "vulnerable, marginal, disadvantaged and

socially excluded individuals and groups" and their welfare" ⁴⁸ both within the context of the research *and* how that research impacts upon the political and social status more generally. A rights based approach demands that policies and activities not only be non discriminatory in their intent, but also in their effect. Thus any research protocol would need to be carefully dissected in order to identify any aspects that might introduce, play a role in, enhance or discrimination on any of the grounds set out in human rights law.

Participation

In explanation of the concept of participation the Stamford Common Understanding indicated that

"Every person and all peoples are entitled to active free and meaningful participation in, contribution to, and enjoyment of civil, economic, social, cultural and political development in which human rights and fundamental freedoms can be realised."⁴⁹

It is difficult to give an exact definition to the right to participation. It is fundamentally about enabling and empowering individuals and (normally excluded) communities (insofar as they may be defined) to take part in public affairs and the activities of public institutions. It underpins the existence and maintenance of good governance and publicly accountable democracies. It cannot be achieved without the provision of information and the creation of quite different decision making processes to those with which we are most familiar and most comfortable. Participatory processes are also necessary for the building of sound ethical approaches at the national and local levels.

⁴⁸ Ibid Footnote No 40 at p 17

⁴⁹ Ibid footnote no 41

In the research context the basic human rights message is that decisions cannot be made unilaterally. At present the requirement for participation is regarded as having been met when, after the most crucial decisions have been made elsewhere, certain issues are isolated for discussion and a group or individuals are identified to provide their comments. But the requirement for participation is not satisfied when people likely to be affected are presented with limited choices. It is certainly not satisfied by "informed consent". How to promote participation is likely to require determination on a case-by-case basis, but the general direction, at the very least, is clear.

Accountability

UNDP Guidelines that explain how to implement the Common Understanding assert that accountability is a key element in the fulfilment of human rights. Accountability it is suggested

"... means beginning with the identification of (1) an explicit standard against which to measure performance, (2) a specific person/institution owing performance (3) a particular right-holder (or claim-holder) to whom performance is owed; (4) a mechanism of redress, delivery and accountability".⁵⁰

As has been noted research has the potential to affect human rights and in some instances to have a serious and widespread impact. While ethical guidelines in research ought to be observed, may be monitored to some extent by ethics committees and may have funding implications when unethical practice is confirmed, further forms of accountability are commonly absent. Human rights grant people entitlements that should give rise to legal obligations on the part of others. A ratified treaty is

⁵⁰ "Toward a Measure of Dignity: Indicators for Rights-Based Development", Craig G. Mokhiber, Montreux, 4 – 8 September 2000 quoted in "Human Rights-Based Reviews of UNDP Programmes_ Working Guidelines" June 2003

<http://www.undp.org/governance/docshurst/030617Guidelines.doc>

binding on all branches of government. All duty-bearers must therefore be held to account.

Article 2 of the International Covenant on Civil and Political Rights requires each nation "to respect and to ensure ...the rights recognized" in the Covenant and "to take the necessary steps to ... give effect to the rights." Countries must provide effective remedies for violation of rights, and provide that those alleging that their rights have been breached can have these claims heard and determined by judicial, administrative or legislative authorities. Any remedies granted must be enforced. Similar though slightly weaker requirements apply to economic, social and cultural rights. Under article 2 of the International Covenant on Economic Social and Cultural Rights states that countries should take steps to achieve these rights progressively by all appropriate means.

Paul Hunt, the Special Rapporteur of the Commission of Human Rights on the right to health, has recently canvassed thoughts regarding accountability in his most recent report to the General Assembly. Though the discussion deals with the right to health it is worth devoting some time to it.⁵¹ He notes that right to health indicators can help States State monitor the progressive realization of the right to health domestically and internationally. This process involves the State selecting appropriate right to health indicators in order to monitor different dimensions of the right to health. Each indicator must be disaggregated on the grounds of discrimination. The State should then set national targets, benchmarks, in relation to each disaggregated indicator. Indicators and benchmarks are used to monitor the State's progress over time, enabling it to make policy adjustments as required.

Hunt quotes the United Nations Development Programme "Human Development Report 2000: Human Rights and Human Development". This Report argues,

⁵¹ Interim report of the Special Rapporteur of the Commission on Human Rights on the right of everyone to enjoy the highest attainable standard of physical and mental health, Mr. Paul Hunt

<http://www.coreinitiative.org/pub/UN-RighttoHealth.pdf> A/58/427 10 October 2003

"Statistical indicators are a powerful tool in the struggle for human rights. They make it possible for people and organizations — from grass-roots activists and civil society to governments and the United Nations — to identify important actors and hold them accountable for their actions ... Indicators can be used as tools for:

- Making better policies and monitoring progress;
- Identifying unintended impacts of laws, policies and practices;
- Identifying which actors are having an impact on the realization of rights;
- Revealing whether the obligations of these actors are being met;
- Giving early warning of potential violations, prompting preventive action;
- Enhancing social consensus on difficult trade-offs to be made in the face of resource constraints;
- Exposing issues that had been neglected or silenced."⁵²

The Special Rapporteur reinforces the notion of the interdependence and indivisibility of human rights when he notes that the right to health cannot be viewed in isolation. He states, the right to health is closely related to the

"enjoyment of other human rights and fundamental freedoms, including non-discrimination and equality — two concepts that reflect the pre-occupation of human rights with vulnerable and disadvantaged groups."⁵³

Similarly right to health indicators should not only reflect specific right to health norms, but also related human rights norms, including non-discrimination and equality. He recommends that this analytical framework also apply to States' responsibilities for international assistance and cooperation as described in many

⁵² Human Development Report 2000: Human rights and human development, UNDP. p89

⁵³ Ibid footnote no 51

treaties and declarations. This extends to the development of equitable trading, investment and financial systems conducive to the elimination of poverty.

Accountability mechanisms may be judicial, quasi judicial, administrative or political. Accountability mechanisms must be accessible, transparent and effective.⁵⁴ There is substantial debate at this point in time as to the nature of effective accountability mechanisms in the context of research. This remains an important challenge for future deliberation.

AN EXAMPLE – THE TUSKEGEE SYPHILIS STUDY

An example may offer a means by which the potential application of such a framework may be clarified. This case has been chosen because it is well documented and demonstrates a number of grievous breaches of ethical guidelines and human rights principles. There is controversy over some elements of the Tuskegee study but they are not central to this discussion so will not be addressed. Let us assume, for the purposes of this exercise, that the facts as presented are correct. They are derived from "Tuskegee Truths: Rethinking the Tuskegee Syphilis Study" edited by Susan Reverby.⁵⁵

In 1929 the United States Public Health Service (USPHS) conducted a study that indicated mass treatment for syphilis could be successfully implemented amongst rural African Americans. The findings of that study were not implemented, due in part to the depression. In one county, the poorest and predominantly black county, an unusually high prevalence of syphilis was noted. It was thought that this group would be suitable for further investigation, but it was to be investigation of quite a different nature. In 1932 the Tuskegee Study commenced. It involved around 400 impoverished and mostly illiterate African American men as study subjects and 200 who were then free of the disease and who served as controls.

⁵⁴ Ibid footnote no 40 at p16

⁵⁵ Tuskegee Truths: Rethinking the Tuskegee Syphilis Study edited by Susan Reverby. University of North Carolina Press, Chapel Hill. 2000

Originally the experiment was to have lasted 6 months and consist of a thorough physical examination of black males between 25 and 60 with syphilis. Calling for men for medical examination between these ages was likely to result in no one turning up, as it would be suspected that the physicals were a prelude to conscription. The request for individuals to be tested had to be vague. To discourage women from coming, doctors went to saw mills, the public works employment centres and the fields. Furthermore, and crucially, only the offer of treatment for "bad blood" and other health problems was likely to encourage participation so treatment was offered. This was despite the belief amongst some in the health service that these men were not necessarily interested in being treated.

At the end of the 6 month period a further proposal was developed. It was thought that if the men were followed for 5 to 10 years some knowledge might be derived concerning the natural history of untreated syphilis, particularly among black men. Treatments at this time were based upon arsenic compounds and bismuth injections with associated problems of toxicity, though certainly less serious consequences than those of the disease. Because of the high prevalence of the disease amongst this population the chief the Venereal Diseases Division of the USPHS believed that there was an unusual opportunity for what was described as "a study in nature". The study might demonstrate that anti syphilitic treatment was unnecessary. But there was no formal study protocol. It subsequently agreed that only at autopsy would anything of value be found so it became necessary deceive the men and their families until death.

None of the men were aware that they were research subjects. They were led to believe that they were patients of a joint federal and local medical and nursing programme at the Tuskegee Institute and the Macon County Health Department. The men were never given a clear diagnosis, but were examined, the examinations including spinal taps (badly done and without anaesthetic), and given placebos, tonics, aspirins, free travel and hot lunches. At first they were given inadequate amounts of treatment but this was not regarded as having biased the sample as it had not affected the outcome of the Wasserman tests. The men were promised burial insurance as a further and, in this context, a significant inducement. Their families had to agree to allow post mortems on the men who died this being most unpopular. Controls who became infected were simply shifted to the study group.

Like many places the law in Alabama required treatment - infected persons were obliged to report for treatment until the disease was no longer communicable. This law did not appear to bother the researchers who presumably knew of its existence. The first publication concerning the study appeared in 1936. Further papers were published every four to six years subsequently.

The CDC reviewed the study in 1969 and it was agreed that the study should continue even though it was clear that the life expectancy of those involved was substantially adversely affected by the presence of syphilis. Although the effectiveness of penicillin as a treatment for syphilis was discovered during the 1940s, continuing efforts were made to ensure that the men did not receive treatment from any source. But a few fortunate men did somehow manage to obtain treatment including antibiotics.

The USPHS followed the men for 40 years until a journalist published the lamentable details. At this time perhaps 100 of the men had already died of advanced syphilitic lesions, though this number has been subject to debate.

The Nuremberg Code, at the very least, and subsequently the Helsinki Declaration could have formed the framework within which to consider the research. In 1972 a panel was appointed to consider the study. It commenced meeting in 1973. In 1997 President Clinton offered a formal apology. None of the researchers involved were ever prosecuted. The government was sued and ended up settling for a paltry amount.

WHAT WOULD AN ETHICAL ANALYSIS OFFER?

Quite clearly this study is deeply unethical on many counts. The subjects did not volunteer for the study. There was no consent. There were undue inducements. The study involved deception. Effective treatment was withheld. The confidentiality of the subjects was not respected. The study design was flawed.

Ethical guidelines, however, do not locate research in the larger social and political context. Ethical guidelines do not ask the questions: is the research discriminatory; has it been developed through a participatory and accountable process; is it generally respectful and protective of human rights; does the research contribute to the fulfilment of rights; is it necessary to do the research in the circumstances

would lead to the fulfilment of rights; is this a priority; or how does it support development and so on? Using a rights based approach would raise issues such as these and more.

WHAT WOULD A HUMAN RIGHTS ANALYSIS OFFER?

If the basic framework of the Common Understanding is applied to this setting what might it tell us? It would indicate that a research programme should be planned taking into account human rights norms and aim to further the realization of human rights. Human rights principles apply to all phases of an activity including its planning, implementation, monitoring and evaluation. Paragraph 8 of the Helsinki Declaration states "Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights..." What is intended by use of the word "rights" in paragraph 8 is not entirely clear.

In conducting an analysis of the Tuskegee study the first step would be to identify the claim holders and the duty bearers. The claim holders obviously include the subjects of the study. Others that would have rights based claims include their families and their communities, as all would have been affected in some way. The duty bearers may be said to be the researchers, those who may have had some role in supervising the research, the research sponsors, the governing bodies of relevant institutions, and the county, state and national health departments. This brings the state and federal governments clearly into the picture. Others that could be described as duty bearers include doctors who agreed not to treat subjects who sought medical attention, peers who may have reviewed papers and editors of journals. The consequences of being a duty bearer will be addressed shortly.

A rights based analysis would ask questions about the participatory processes in the institutions that sponsored the trial and their accountability. It would bring to the fore discrimination created by racism and social disparities. Social Darwinism was prevalent attitude in the racialized medicine of the time. It was thought that "negroes" were in throes of a degenerative evolutionary process. There was an assumption that black men had an excessive sexual appetite, were of low intelligence and were indifferent to treatment. It was thought that they lacked moral standards.

Consequently doctors believed that treatment for sexually transmitted infections among blacks was impossible.

A rights analysis would raise the right to health. This right has been described as being dependent on the realization of a number of other rights viz:

“The right to health is closely related to and dependent upon the realization of other human rights, as contained in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition against torture, privacy, access to information, and the freedoms of association, assembly and movement. These and other rights and freedoms address integral components of the right to health.”⁵⁶

The study failed to respect the right to health in the most blatant manner by interfering with access to health care. It failed to respect the right to access to information by failing to provide information of direct relevance to the subjects such as the fact that they were members of a study, their health status and the availability of effective treatment.

Article 17 of the International Covenant on Civil and Political Rights states that no one shall be subjected to arbitrary or unlawful interference with their privacy. The right to privacy was breached in many ways. The right to privacy includes respect for physical privacy, which includes testing for diseases without a person's consent. (If testing is done compulsorily it could also constitute deprivation of liberty and violation of the right to security of the person under article 9.) In the case of research this is reinforced by article 7, which states

“No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.”

⁵⁶ CESCR The right to the highest attainable standard of health 11.8.2000 E/C.12/2000/4. (General Comments) Article 3

This right is non derogable which means it must be observed even in times of public emergency including war.

Other aspects of privacy include the collection and maintenance of data without the consent of the subject and the disclosing of identifying details to other medical practitioners from whom the subjects may have sought treatment.

The study had an impact on the right to work. It barely needs saying, but those who are particularly unwell will be unable to work. This will have flow on effects to other aspects of life such as the rights to accommodation and to food.

The right to share in scientific advancement and its benefits as set out in Article 15 of the International Covenant on Economic Social and Cultural Rights was denied to these men by virtue of the lack of provision of penicillin.

Article 8 of the International Covenant on Civil and Political Rights states that

“Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”

100 subjects were said to have died as a result of their untreated syphilis. Not only were the researchers unethical. They should perhaps have been charged with murder or manslaughter. Some have described this study as genocide, though it probably does not meet the requirements for genocide under the Genocide Convention. It has had a long lasting impact on the willingness of African Americans to participate in medical research.

In brief, the rights of spouses and children must also enter into the equation. Spouses and children have a right to prevention from infection, to life to accommodation, to food and so on. Article 10 of the International Covenant on Economic Social and Cultural Rights states that the widest possible protection and assistance should be accorded to the family, which is the natural and fundamental group unit of society, particularly for its establishment and while it is responsible for the care and education of dependent children.

A rights based approach requires accountability for breaches of human rights that involves all those who have been described as duty holders and remedies for breaches

of those rights. Eventually, after a class action began, a settlement was reached for a paltry sum to survivors and their heirs, living controls and heirs of deceased controls. It was not until 1975 that the United States government agreed to provide treatment to the wives and children who had contracted syphilis.

In summary the human rights "how to" in this instance would have challenged the research from the outset. (As already noted that an ethical review using current standards should have stopped this research as well but on other grounds.) The initial discriminatory premises should have stopped the research taking place at the outset. Observance of the principles of participation and accountability would presumably have made it far less likely that the research would have proceeded. The subsequent and numerous breaches of rights should each in themselves have provided additional weight to arguments that the study protocol should not have proceeded. If these arguments did not persuade those planning to conduct the study further accountability mechanisms might. It has to be said that most studies are not quite as clear-cut. However the possibility of challenge utilizing a different framework certainly opens up new and valuable possibilities.

INFORMED CONSENT BY COMMUNITY ELDERS

There are some researchers (and ethicists) who argue that the "universal" ethical requirement for informed consent by all potential research participants is a western construct and is offensive to some communities. In those communities it may be the village elders or a senior male in a family or clan who should be approached for his consent. Approaches made to others for their consent, it is said, will be viewed with suspicion, distrust and annoyance.

Setting aside for the moment debates concerning the nature of communities, the universalist versus relativist debate is also present in the human rights discussion. There are, of course, strong and weak conceptions of universalism and cultural relativism. A strong relativist view would suggest that human rights principles only have value and ought be respected within the communities from which they have been derived. And even then, amongst communities who utilise rights language there are very different conceptions of what should and should not be regarded as rights. The

traditional debate has been between those who believe that rights ought only to protect people from interference by government (civil and political rights) and those who believe rights entitle people to claim things from governments (economic, social and cultural rights). Most commentators no longer regard this as a meaningful debate but it continues to have resonance in countries like the United States.

But surely the significant question is when should cultural differences be respected and when not. Indeed it cannot be wrong to question members of a community, in a meaningful fashion, about whether they are content with their status. For example, some members of an indigenous group may feel quite justified in claiming that they wish to preserve their culture against external onslaught. On the other hand women within the same communities, while also wishing to respect aspects of their culture are not quite as enthusiastic about embracing those parts oppressive to them. Culture as preserved by community in this instance is not operating to benefit all members of that community.

The case of *Sandra Lovelace v Canada*, considered by the Human Rights Committee established under the International Covenant on Civil and Political Rights, is a well-known instance of this phenomenon. In 1977 Lovelace, an Inuit woman, forwarded a communication to the Committee alleging discrimination on the basis of her sex. In Canada a woman who married a non-Indigenous person could no longer be considered to be Inuit. This was not the case with men. This had certain consequences including the loss of the right to continue living in an Inuit reserve. Ultimately the Human Rights Committee found in favour of Lovelace and Canada amended its Indian Act to remove this discriminatory provision.⁵⁷ However, importantly for these purposes, it is an example of change promoted from within and recognition that preservation of culture does not always provide a sufficient answer perceived breaches of human rights.

⁵⁷ *Sandra Lovelace v. Canada*, Communication No. 24/1977, U.N. Doc. Supp. No. 40 (A/38/40) at 249 (1983) (information from Canada on measures taken).

<http://www1.umn.edu/humanrts/undocs/session38/24-1977.htm>

To say something is, is not the same as an argument that it should be. It has been suggested that

"Whatever the cause, according to radical critique, relativism has played directly into the hands of the oppressors throughout the world by its tacit support of the status quo. The relativists have not recognized that the exotic cultures to which they grant equal validity are poverty-stricken, powerless and oppressed"⁵⁸

On the other hand, even those who argue accept that human rights are universal agree that the application of human rights will always be subject to interpretation and this will take place within countries and cultures. The application of rights may be abused and may play into the hands of the governing authority. It is often the case that a government will claim that a right has been respected and this claim will be subject to administrative or judicial challenge. The interpretation of rights and the rights themselves have altered over time, particularly with the advent of the women's and indigenous rights movements. Rights too, must be continually re-examined to ensure that they do not entrench problematic practice.

Claims about the centrality of practices that violate human rights, to the survival of cultures, should be examined. Questions must be asked about whose interests are served by the continuation of these practices and the reasons a researcher might seek to reinforce these practices. Rights are clearly breached when consent is given on behalf of a competent person and their consent is not sought. These include the rights to information, privacy, liberty and security of the person, not to mention the right to provide or refuse consent to medical experimentation. Fundamental principles are undermined. These include: equality, participation and accountability. Even if it is possible to assume that once a protocol has ethical approval the research is benign and benefits outweigh risks, it is hard to imagine, on any account, how this and consent of

⁵⁸ Steiner HJ, Alston P. International Human Rights in Context: Law, Politics, Morals. Clarendon Press. Oxford 1996 p197 citing Hatch E. Cultures and Morality: The relativity of values in Anthropology. Columbia University Press New York 1983

elders could justify the breach of so many fundamental rights – rights agreed to by most countries.

CONCLUSION

This discussion has endeavoured to demonstrate what a human rights based approach might offer to the consideration of issues relevant to medical research. A rights based analysis looks at a research programmes and studies from the perspective of the rights holders. A raft of human rights standards and norms are identified as being relevant, and adding substantially not just in the protection of individuals participating in research (the 'classical' rationale for bio-ethics), but also in locating and justifying where, how and on whom research is being done. Such an analysis, it is suggested may ultimately make research more relevant to all rather than simply to researchers, industry and those who are the traditional beneficiaries.

Duty bearers must be identified and challenged to respond adequately to rights so as to ensure that they are respected. Although governments have the ultimate responsibility for ensuring that rights are "respected, protected and fulfilled" other individuals and groups must assist in this process. Human rights can provide a framework – international human rights standards and norms - from which to examine a study that asks larger questions than those to be found in traditional guidelines for research. Perhaps it is time to begin to consider these questions.

Violence in research

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VIOLENCE

"In international research collaborations, are genuinely non-exploitative relations possible between the research community of the 'north' and participants of the 'south'?"

Article 7 of the International Covenant on Civil and Political Rights states: "No-one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." Human history makes it understandable that torture and medical research should be joined conceptually in this internationally accepted Covenant, which entered into force on March 23, 1976. However, the phrasing might not have occurred to us today. Indeed, one can imagine the objections that might be raised if such a proposal were to be put forward anew: research is not torture; to combine these thoughts is to inappropriately impute evil intentions to well-meaning researchers; or, the purpose of research is to benefit humanity—occasionally something may go wrong but this does not justify a *prima facie* presumption that experimentation and cruel or inhuman treatment are associated.

It is, of course, the findings of the Nuremberg doctors' trials and subsequent Code that made the statement seem so acceptable to its signatories, if not the medical profession. Medical research is placed within the realm of torture and punishment, and only the "free" agreement of the participant can defend what is otherwise a breach of a fundamental right. So despite its utilitarian value, the goal of research cannot be placed ahead of the exercise of free will. It is the complexity and subtlety of what it means to truly respect human rights and treat research participants with dignity, beyond consent, that will be explored here. Human-rights documents, broadly including, for the purpose of this discussion, codes prescribing ethical standards for research such as the Helsinki Declaration, operate within a liberal discourse of universality. Their espoused universality may, in reality, have little to do with

protecting the human dignity of some populations. The egalitarian statements contained within these documents may result in a failure to take account of subcultures and their priorities even within nations. By way of comparison, human-rights instruments have long been criticised for their "gendered" and "European" expression and content. The impact of this bias must surely be exacerbated when privileged groups interact with others.

By focusing on statements of rights we find ourselves in polarised debates in which we can either agree or disagree with a standard—as is amply demonstrated by the current bitter dispute about the proposed revision of the Helsinki Declaration. In some instances this may be valuable, in others greater capacity for dialogue and contextualised analysis will be more revealing of the significant ethical issues.

Even within the conservative discipline of the law, judicial statements interpreting universally agreed rights may be lengthy and encapsulate a number of shades of opinion. Why do we imagine that codes governing research should be amenable to only one construction when the conditions of individuals are so varied? In international research collaborations, are genuinely non-exploitative relations possible between the research community of the "north" and participants of the "south"? Can we put in place protections that are not naïve, yet promote exchange of views, recognise diversity of approach, and avoid injustice? How can we honour the valuable intent of the Nuremberg and Helsinki documents without falling prey to shortcomings induced by a positivist or "single-minded" outlook? This is not an appeal to ethical relativism, rather a quest to identify and implement what might have been intended by the drafters and for procedural inclusivity. UNAIDS has published a guidance document entitled *Ethical Considerations in HIV Preventive Vaccine Research*. In it, UNAIDS attempts to deal with some of the issues that have discredited the research community. Let us leave to one side the requirement that researchers provide to participants the highest attainable standard of care in the host country, which is certain to be controversial. The guidelines demand that an exhaustive dialogue should take place. The fifth guidance point states: "To ensure the ethical and scientific quality of the proposed research, its relevance to the affected community, and its acceptance by the affected community, community representatives should be involved in an early and sustained manner in the design, development, implementation, and distribution of

results of HIV vaccine research." One would want to be sure that this process involved the most ostracised groups and not only the empowered. Of course the value of such a dialogue is limited in communities where deprivation is great. Research should not take place in such instances. With this proviso, surely the guidance point is well made.

The guidelines further demand a collaborative process involving strategies to capacitate host communities so that they can practise meaningful self-determination. Is this asking too much? Probably some of the current generation of researchers would say that it is, or, at least, that they do not have the right skills. Yet to object to these proposals is tantamount to saying that it is permissible to do research in a community whose diverse voices cannot be heard and responses transparently provided. Without wishing to rely upon extreme language, this seems like a form of violation and gives a contemporary resonance to the wording of Article 7.

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The Declaration of Helsinki and research in vulnerable populations

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Mooted changes to the Declaration on the agenda of the World Medical Association have sparked a vigorous debate on international research issues. The medical, research and ethics communities in Australia need to participate more broadly in this debate.

Introduction

The Nuremberg Code, which was formulated to prevent a recurrence of the horrific medical experiments carried out on humans during World War II, is unwavering in its commitment to the primacy of the human subject. It states that any person who is a research participant

"should be so situated as to be able to exercise free power of choice" and that "(t)he experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."¹

The Declaration of Helsinki² was the World Medical Association's (WMA's) response to the Nuremberg Code and its goal was to safeguard research subjects. However, in declaring the need to weigh the importance of the research objective against the risk to the subject (Article I.4), the Declaration was seen as a subtle retreat from the Code.³ Some fear that changes to the Declaration currently under consideration by the WMA would substantially "water down" the basic principles of ethical human research.

The Declaration does not specifically deal with international collaborations. In 1993, the Council for International Organizations of Medical Sciences (CIOMS) developed

the International ethical guidelines for biomedical research involving human subjects,⁴ which address issues pertinent to the conduct of research in developing countries.

Despite the existence of the Declaration and other documents, it is apparent that the application of safeguards to protect research subjects is far from uniform, especially among impoverished or marginalised people.^{5, 6}

Proposed revisions to the Declaration of Helsinki

A number of revisions are currently proposed to the Declaration to make it more relevant to researchers (some of whom, it has been suggested, commonly breach its provisions).⁷ Those who oppose the amendments fear that research participants will be made more vulnerable to harm in order to make research more efficient and perhaps expedient (see Box).⁸

Two proposals have generated a great deal of discussion and controversy. One concerns the abolition of the distinction between "therapeutic" and "non-therapeutic" research. The other (the main focus of this article) relates to provision of the best proven treatment and to use of placebo-controlled trials.

"Therapeutic" v "non-therapeutic" research

The introduction to the Declaration requires that

"a fundamental distinction . . . be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research".

Article II.6 states that in "therapeutic" research

"The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent

that medical research is justified by its potential diagnostic or therapeutic value for the patient."

Article III.2 states that in "non-therapeutic" research

"The subjects should be volunteers -- either healthy persons, or patients for whom the experimental design is not related to the patient's illness."

Robert Levine, Professor of Internal Medicine at Yale University School of Medicine, argues that these Articles together rule out "all rational research on the causes of diseases or on their pathogenesis or pathophysiology".⁷ He notes that clinical trials may include both therapeutic and non-therapeutic agents.⁷ Others believe the division between therapeutic and non-therapeutic research to be firmly entrenched in research guidelines developed since and influenced by the Declaration and to be well understood in practice.⁹

"Best proven treatment" v "highest attainable treatment"

The changes proposed to Article II.3 (see Box) have generated extensive debate. Opinions are polarised between those in favour of the "best proven treatment or method" and those for the "highest attainable and sustainable treatment or method". The problem with the "best proven treatment" approach is that it may prevent valuable research being done, as treatments and services will not be readily available in resource-poor settings and may not be provided by researchers and their sponsors. The problem with the "highest attainable treatment" goal is that it may lead to a marked decline in care -- there are no clear criteria for establishing what level of treatment is acceptable or firm safeguards for applying it.

The problem in resource-poor countries

Perhaps the real issues to be debated are how best to enable people to make meaningful choices and how to ensure that they are not treated poorly and without respect because of their circumstances. What should be examined are the problems

created in some societies by a lack of fundamental civil and economic rights, and whether this advantages proposed research projects.

To assume that all would like to be treated as people in affluent countries would, and to rely on this judgement as a basis for formulating an encompassing ethical ideal, is, to some extent, misguided. Classic egalitarian premises, upon which comparable rights documents, such as the Universal Declaration of Human Rights,¹⁰ are based fail to take account of subcultures and their priorities. Indeed, issues like gender and race are still inadequately addressed in these documents, in which the tacitly assumed "universal person" is the European white heterosexual male.¹¹ This difficulty is accentuated when privileged cultures interact with others. Is it true to say that standards appropriate for industrialised countries are equally relevant to others? If not, what are we left with?

Ruth Macklin, Professor of Bioethics at the Albert Einstein College of Medicine in New York, has analysed ethical concerns in international research according to the concept of justice.¹² She states that a prominent feature of justice is that no one group should "receive disproportionate benefits or bear disproportionate burdens",¹² a corollary being that like cases should be treated alike. One side argues that if the study is unethical in one place it is unethical in both. The other argues that risk-benefit ratios are different in resource-poor countries and therefore require a different response and, further, that if the benefit is actually to accrue and only to accrue to the developing country, this is ethically significant.¹² Her conclusion in this debate is that both sides can claim that their arguments observe the ethical requirement of justice.

Advocates of placebo-controlled trials in resource-poor countries cite local support and participation in defence of their views. Thus, in the case of trials of less expensive regimens to prevent vertical transmission of HIV, Edward Mbidde, a Ugandan physician, said in a now oft-cited statement, "(t)hese are Ugandan studies, conducted by Ugandan investigators, on Ugandans ... for the good of their people".¹³ It would be too simple a response to discount this comment entirely as being no answer to a breach of ethical standards.¹⁴

Yet, even when a host country agrees to allow drug trials, substantial ethical difficulties remain. One of us (JB), after working for 10 years as a clinician in

Mozambique (where the local provincial health service budget was about \$US3 per capita per year), believes that the basic rights of potential trial participants in some parts of Africa may be so compromised that refusal to participate is not an option:

"This is the sort of health service where every clinician finds him or herself from time to time looking at the pharmacy cupboard and wondering how to divide the remaining three vials of penicillin between the five patients in the ward who need it. (Whether to give starting doses to everyone in the hope that the promised new supplies will arrive, or just give it to one seriously ill child, for whom at least it represents a curative course.) From that perspective, enrolling patients in a clinical trial will always look attractive, no matter how unethical that research may turn out to be."¹⁵

Almost any reward, even bars of soap or transistor radio batteries, is likely to ensure trial participation.

Perhaps international collaborations, particularly those involving complex drug trials, should not be conducted where there is this degree of poverty. Speaking at the same symposium,¹⁵ Pascale Allotey, Lecturer in International Programs at the Key Centre for Women's Health, Melbourne University, made the point that the possibility of enhanced services or cash flow to a community will mean that community leaders will very likely agree to trials taking place, as, ostensibly, will community members. However, they may resent doing so. Fears of a diminished standard of care as a result of withdrawal from a trial are quite real in these circumstances.

Where to from here?

Are genuinely consensual relations possible between the research community and participants who otherwise have little or no access to healthcare or other basic rights and liberties? Can structures and criteria be implemented that promote dialogue and recognise diversity of approach, but discourage abuse of trial participants?

The following suggestions were offered to the participants in the aforementioned symposium¹⁵ for consideration, and most agreed that more discussion was required to

flesh out what these ideas might mean in practice (the suggestions are not entirely new and are broadly consistent with the CIOMS guidelines and draft UNAIDS guidelines¹⁶):

(a) Where a population does not possess basic economic or social rights it should be regarded, *prima facie*, as one whose members' capacity to freely consent is gravely impaired. Research studies in such populations, especially those involving randomised trials, require special justification. An exception might be where the research goal is to work out how to apply a proven technology: for example, an assessment of whether open or covered buckets are more suitable water containers in a refugee camp (Associate Professor Michael Toole, Macfarlane Burnet Centre for Medical Research, personal communication).

UNAIDS guidelines¹⁶ state that, in international collaborative programs, strategies should aim to balance inequalities by involving members of affected communities from very early on in the design and development stage, and by imposing a number of safeguards around the process of informed consent.

(b) A research protocol should describe the conditions that might make a research population vulnerable to exploitation and the steps that will be taken to overcome them.¹⁶ The UNAIDS guidelines impose this requirement on research protocols. We further propose that these steps should be described in publications derived from the research, in order to give the issues greater prominence and to further this discussion.

(c) In planning research in populations severely deprived of civil and political rights, agreements with governments and ethics committees are insufficient. This is especially the case when governments have demonstrated grossly repressive or corrupt behaviour, or where ethical review systems cannot be regarded as independent. Research should not take place in these circumstances. This recommendation should be distinguished from ethical guidelines applying to research in emergency or refugee settings.

(d) Thorough community-based consultation is required to determine local views, needs and priorities. Researchers need to establish what local research priorities exist (although, in many deprived populations, any problem area could be seen as a priority). This includes, in particular, consultation with people who have little power

or are ostracised for whatever reason. Ethnographic studies could be conducted in advance of a proposed project to determine actual rather than supposed local attitudes, and debriefing could be required after completion of a trial (Deborah Zion, Centre for Human Bioethics, Monash University, personal communication). Including nationals on committees, or agreement by host governments and ethics committees, are not substitutes for community consultation.

(e) An analysis should be made, in advance of a project, of the long-term consequences of the intervention. Long-term considerations should certainly include, but not be limited to, sustained access to a trial drug. One of the possible adverse consequences to consider would be the diversion of local researchers and healthcare providers into projects that are not local initiatives. Consistent with current ethical standards, if there is no prospect of benefit to the community in its terms the research should not be undertaken. At the very least, a memorandum of understanding should be prepared before the commencement of any international collaboration, indicating what each party -- community, government, research institution and sponsor -- expects prior to, during and as a consequence of the trial.

Conclusion

Angela Harris, Professor of Law at the University of California, Berkeley, has stated that modern human rights standards are at once indispensable and inadequate.¹⁷ The same may be said for ethical guidelines on medical research. The solutions are not clear cut. The WMA meeting in Tel Aviv, Israel, in October 1999, at which the Declaration of Helsinki was reconsidered, issued the following brief statement:

"The meeting heard of widespread support for retaining the existing structure of the declaration of Helsinki. It was agreed that the working group set up to consider amendments to the Declaration should report back with a proposed revision at next year's annual General Assembly meeting in Edinburgh, Scotland (3 October 2000)."

It is to be hoped that the Australian medical research community and other interested groups will debate the issues and arrive at a consensus.

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Some proposed revisions to the Declaration of Helsinki

Current statement: I.8: Reports of experimentation not in accordance with principles laid down in this Declaration should not be accepted for publication.

Proposed revision: Variances from these principles should be explained and justified in the report. Editors are obligated to consider carefully the justification for any variances from these principles in deciding whether to accept or reject the report for publication.

Current statement: I.10: ...the informed consent should be obtained by a physician who is not engaged in this investigation and who is completely independent of this official relationship.

Proposed revision: In some cases of this type, it may be preferable if the informed consent were to be obtained by a qualified person who is not engaged in the investigation, independent of the dependent relationship, or both.

Current statement: II.3: In every medical study, every patient, including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.

Proposed revision: In any biomedical research protocol every patient-subject, including those of a control group, if any, should be assured that he or she will not be denied access to the best proven diagnostic, prophylactic or therapeutic method that would otherwise be available to him or her.

Current statement: II.3: This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

Proposed revision: This principle does not exclude the use of placebo or no-treatment control groups if such are justified by a scientifically and ethically sound research protocol. When outcome measures are neither death nor disability, placebo

or other no-treatment controls may be justified on the basis of their efficiency.

Current statement: II.5: If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

Proposed revision: When permitted by applicable law, the requirement for informed consent may be waived by the independent research ethics committee. Such a waiver may be appropriate in research that presents little or no threat to the rights and welfare of research subjects as exemplified by use of anonymous tissue samples for research purposes and in certain other types of research in such fields as epidemiology and policy evaluation. It may be justified in research in emergency situations in which patient-subjects have temporary or enduring loss of decisional capacity and interventions or procedures must be initiated before informed consent can be obtained from patient-subjects or their legally authorised representatives. In the latter case the research ethics committee may require special procedures to protect the rights and welfare of subjects.

The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations

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COMMENTARY

In an attempt to broaden the current debate over proposed revisions to the Declaration of Helsinki, we define vulnerable subjects as those lacking basic rights, and examine the ethical risks inherent in research on such subjects. We then propose special ethical criteria for the conduct and publication of research on vulnerable subjects.

For the past 30 years, human subjects re-search has been directed by the principles set out in a central document, the Declaration of Helsinki. This statement on research ethics was put together in 1964 by the World Medical Association in an effort to ensure that medical research would follow ethical rules of practice and be of benefit to both researchers and research subjects. However, this document has recently come under considerable scrutiny. The goal of the declaration is presumably to protect the subjects of biomedical research from abuse and exploitation, but now it seems that the declaration may not be adequate to this task. It has not coped well with new challenges posed by clinical trials conducted by first world re-searchers in developing countries, particularly trials related to HIV/AIDS, a disease that has forced a reconsideration of many of our fundamental legal and bioethical tenets ¹. This is perhaps not so surprising, given that the Declaration of Helsinki was drafted over 30 years ago by a first-world elite, mainly in response to problems particular to that time.

Reviews of the declaration, including the review now underway, have occurred within the most narrow of formal frameworks. The debate so far has been far too polarized. It has been characterized by two opposing arguments about the standard of treatment that should be required for subjects in the control arm of a randomized trial (either the 'best-proven method of treatment' or the 'highest attainable and sustainable treatment

or method'), without any sustained attempt to consider the broader social and ethical issues. No real opportunity for the transformation of social relationships in the context of research has been offered.

It is time to reframe this debate, and explore other ways of thinking about the issues—ways that find some middle ground and relate more directly to the research subjects concerned. Here, we investigate some of the fundamental issues. We examine the ethical risks inherent in medical research conducted by people who are distant in economic, social and cultural terms from the participant communities from which the subject are recruited. We propose special ethical criteria that need to be met for research on these vulnerable populations. Then we suggest that, given the complexity and importance of the ethical issues in this sort of research, articles reporting results should include an 'ethical methodology' section as a standard requirement for publication.

Framing the ethical problem

Medical research takes place within a complex web of power relations, in which subjects—particularly subjects who are economically disadvantaged—are easily exploited. The sociopolitical environment in developing countries also compounds this possibility. Individual subjects are rendered passive because they rely on the presence of a research project for basic goods and services that would not otherwise have been available to them.

The Declaration of Helsinki does not address this type of exploitation. It is addressed to some extent in the commentary accompanying the Council for the International Organizations of Medical Science International Ethics Guidelines for Biomedical Research Involving Human Subjects, which states that "lack of alternative means of obtaining medical care or other expensive necessities" is one characteristic of those vulnerable to exploitation. But this recognition needs to be developed into a more comprehensive understanding of exploitation and vulnerability, which would then directly inform research practice. When working with such impoverished subjects, we must ask whether truly ethical research is even possible.

The following approach should be taken: Recognize that some subjects or populations require special ethical consideration and rigorous ethical accountability. These special groups are 'vulnerable populations' because they lack basic rights and liberties that make them particularly open to exploitation. They are often communities in the developing world, but this in itself is not a determining factor. Vulnerable populations can and do exist in developed countries as well. Our analysis of 'vulnerable populations' differs somewhat from other accounts, which often focus on particular groups like prisoners, children or incompetent adults-subjects who are frequently unable to make autonomous decisions. In fact, any population or group within a society must be considered vulnerable if they lack basic rights and freedoms that form an essential part of choosing the basic course of their life.

What are 'basic rights'?

The question of rights is always complicated in discussions of different cultures, and is further complicated by unequal power relations. Nonetheless, the political theorist Henry Shue has gone some way in distinguishing which rights should be universalized. He suggests that such rights are distinguishable from others, not because they are more important, but because they are foundational². Shue describes rights to goods like food and basic health care as primary, not because they are "more valuable or intrinsically more satisfying" than other rights, but because the enjoyment of such basic rights is necessary for other rights to exist. Similarly, certain kinds of political liberties such as the right to free speech, freedom of choice and freedom of movement can also be seen as fundamental. Thus Shue's 'basic rights' are a kind of foundation on which other rights are built.

Any population deprived of 'basic rights' should be regarded, for the purposes of medical research, as a vulnerable population, analogous to groups traditionally recognized as vulnerable in this setting, such as prisoners. Special justification should be required for medical research involving participants from these vulnerable populations in developing countries, just as it is for prisoners and other groups in developed countries.

The CIOMS guidelines—particularly guidelines 8 and 10—go some way to affording such protection. However, they do not go far enough. Moreover, these guidelines themselves are being reconsidered.

Specific issues for vulnerable populations

Vulnerable subjects must be treated with great care because they are prime candidates for exploitation. Desperate circumstances may lead these subjects to make decisions that are not in their own best interests, all things considered, even if researchers genuinely believe that the research is beneficial. The research may not address the most pressing needs of the local population, or may have detrimental long-term consequences, even if the re-searchers do not foresee or intend this. That is not to say that such subjects may not enjoy some benefits as the result of a first-world trial. But such trials may distract from important local issues, and the benefits gained are defined externally, rather than by the subjects themselves.

Informed consent

It is often believed that informed consent by the subjects makes trials ethically acceptable, even when they have some troubling features. However, when the subjects come from a vulnerable population, informed consent does not accomplish this.

It is already well recognized that cultural misunderstanding may abrogate the possibility of obtaining meaningful consent³. However, there is a more sinister dimension to the problem of in-formed consent. One African researcher recently asked, "In an environment where the majority can neither read nor write and is wallowing in poverty and sickness, hunger and homelessness, and where the educated, the powerful, the rich or the expatriate is a semi-god, how can you talk of informed consent?" (<http://hivinsite/ucsf/edu/topics/women/2098.33fo.html>).

Oyewale Tomoori's observation demonstrates the vital connection between exploitation and autonomy, the value on which the requirement for informed consent is based. In many accounts of informed consent, the rationality of the subject is enough to ensure his or her autonomy. However, this kind of account ignores the

important connection between autonomy and freedom. It seems farcical to suggest that subjects who are deprived of basic rights like food, or who live under regimes where the most fundamental liberties are denied to them, can be considered to be autonomous simply because they are rational. Thus, the conditions that make exploitation likely also inhibit the possibility of proper informed consent.

Conditions under which research might be ethically acceptable

Given all these difficulties, it may seem that medical research on vulnerable populations could never be ethically justifiable. However, to take this view would have substantial consequences. Although it would protect the most vulnerable individuals and their communities from the sort of exploitation described above, it would also prevent them from receiving the benefits of any re-search that really does address their particular needs. If some re-search projects could be beneficial from the perspective of the subjects themselves, is there a way of conducting them that is genuinely non exploitative, and thus is truly ethical? Is it possible to frame standards in such a way that truly ethical research is permitted, whereas research that is not ethical is prevented?

One way this might be achieved is through the use of a process of special justification when vulnerable subjects are involved. Some elements of an appropriate process are included in the CIOMS guidelines, but under these guidelines, there is still room for vulnerable populations to be exploited. Thus, the following conditions would need to be met for research on a vulnerable population to ethically acceptable. (See Box)

1. The research itself should directly address real health needs thought to be important by the subjects themselves (as indicated in CIOMS guideline 8). The CIOMS guidelines suggest that review by an ethics committee familiar with local customs would be an adequate safeguard. However, consultation with local ethics committees or national governments does not take into account the problems of corruption, and unequal power relations within and between different communities. Therefore, a sophisticated form of community consultation is required, which takes into account the complexity of such

power relations within communities, especially pertaining to gender, sexuality and ethnic minorities. This is particularly pertinent when researchers are external to the community from which the subjects are to be recruited.

2. Medical research should not proceed on vulnerable groups unless the research is specifically related to inherent characteristics of that group (and not related, for example, to the needs or preferences of the researchers), and these characteristics are crucial to the internal research design (that is, the research only makes sense when the participants have these characteristics). This would include, for example, research on a disease that only affects a particular population. This requirement is much stronger than the current CIOMS statement that "persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities." Our requirement focuses on the characteristics of the actual target re-search population and its needs, rather than on other possible research populations. This, we believe, is the correct focus, ethically speaking. These stringent justifications are particularly controversial at pre-sent because some commentators have suggested that trials in developing countries that could be done elsewhere also develop infrastructure and training for later trials. Such concerns are important, but in our view do not outweigh the problem of exploitation.
3. A process should be set in place to determine that subjects are not consenting from desperation, and genuinely understand the nature of the research and its potential risks and benefits. This is again a more stringent requirement than the CIOMS guidelines, which only require that informed consent is genuinely sought, rather than actually achieved. Clearly, developing an effective process would not be easy, but it is an ethical necessity, and we look forward to future discussion in the literature about means of achieving it.
4. The research should project contain an undertaking to analyze the long-term consequences of the project, through trial debriefing and follow-up studies. This kind of investigation should include any negative effect the original project has had, such as the distraction of local researchers from indigenous

health problems.

It is by no means obvious that these conditions could in fact be met. It is likely that many research projects now ongoing in developing countries would fail to meet them, despite the good intentions of researchers. The sorts of changes required would involve a substantial shift in philosophy and methodology, with financial consequences for those funding the research. A high degree of partnership and common purpose between researchers and participants would be required. But any medical research that does meet these conditions would offer real benefits in a manner genuinely respectful of the people asked to participate in it, and would be ethically acceptable. Medical research that does not meet these conditions, no matter how well-intentioned, would not be ethical, and should not proceed.

Accountability and publication

The Declaration of Helsinki at present requires that research not conducted according to its provisions should not be published. Research that does meet its provisions, however, is customarily published without comment. The intention here is commendable: to ensure that researchers do not gain any reward for conducting research that is unethical. However, this practice creates the impression (and is probably based on the assumption) that the issue is 'black-and-white': a research project is either ethical or not, and either way, there is no particular need for anyone to comment. But given the complexities of conducting research in developing countries, described at length here, this view is really somewhat inadequate.

The publication of research conducted in developing countries or on vulnerable populations should always be accompanied by a discussion of the relevant ethical issues. Questions of ethics will inevitably arise in such research, and it is appropriate to require evidence that researchers have given explicit and careful consideration to them, in just the same way that explicit description and justification of the scientific methodology of the research project is required. This can never be a matter of simply stating that the relevant guidelines have been followed. Whatever set of guidelines is ultimately adopted to govern medical research in this setting will necessarily be cast

in general terms, and will require interpretation and application to the local setting. The sorts of ethical tensions described above will always need to be worked through, and evaluation of the reasoning behind the chosen resolution ought to part of the part of the process of peer review and publication.

Journal editors, then, should routinely require that every paper reporting the results of medical research in this context contain a section on ethical methodology. This would give the issue much more prominence than the occasional refusal to publish, and in addition would help to build up a body of expertise in dealing with ethically complex research settings that is in the public domain and, thus, widely accessible. It would also avoid the problem, emphasized by the controversy over the vertical transmission trials, that post hoc justifications for ethically contentious research are often unconvincing and do little to allay concerns. Editors would naturally reserve the right to refuse to publish research that they believed to be egregiously unethical, but this would remain a rare event.

Acknowledgments

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Africans discuss ethics of biomedical research

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Cape Town, South Africa, provided the scenic backdrop for the Third Global Forum on Bioethics in Research held on Feb 21–23, which was followed by the Pan-African Bioethics Initiative (PABIN).

The forum provides a venue in which developing countries have significant input into the ethical debate on international collaborative research sponsored by industrialised countries and done in developing countries. Two thirds of the 110 delegates came from developing countries. Of the 40 countries represented, half were African. The forum is sponsored by the US National Institutes of Health and the Medical Research Councils of South Africa and the UK, WHO, and other international agencies. This year's forum was organised by the UK's Medical Research Council.

The meetings focused on some of the key issues in international collaborative research. These include whether current ethical guidelines constrain or promote post-trial access to drugs, devices, or vaccines; the difficulties in creating ethical guidelines and review processes in developing countries; the standard of care to be provided during trials; traditional medicines; genomics and global health; and culture and informed con-sent. Participants suggested that we need to move from the discussion on the content of ethical guidelines to their implementation.

Churchill Lukwiya Onen, from the Princess Marina hospital in Botswana, discussed concepts of justice in relation to post-trial access to drugs and devices. He noted that "differences in our interpretation and difficulties in translating research principles into realities must be urgently and amicably resolved".

A comprehensive picture of the difficulties of doing HIV vaccine trials involving women in South Africa was provided by Douglas Wassenaar of the University of Natal. Women in sub-Saharan Africa carry 82% of the global burden of HIV infection. Their vulnerability to infection is, not surprisingly, affected by their status. This in turn is affected by sexual practices including the decreasing age of sexual debut, dry-sex practices—where foreign material is placed in the vagina to lessen

lubrication and create more friction, male refusal to use condoms, a higher incidence of untreated STDs, female inability to behave assertively, transactional sex, and acceptance of multiple partners for males. There has also been an increase in child rape because of the belief that intercourse with a virgin will provide cure STDs. He noted that fostering voluntary consent is a new ethical agenda in some communities and "would be perceived as a subversive and politically destabilising action". Women's experiences of consent are likely to be severely compromised and it is these women who may be candidates for HIV trials. Like Onen, Wassenaar called for a transition from aspirational ethical codes to their practice relying on "emancipatory informed and sensitive social-scientific research and action . . . built on the voices of women".

Godfrey Tangwa of the University of Yaounde, Cameroon, talked about the second scramble for Africa and how the continent presents the biggest and most attractive laboratory for western researchers. Where ethical review committees exist they are inundated with applications. He highlighted the lack of regulation of research in some African countries, and called for the establishment of strong regional and national regulatory frameworks. This would also enable developing countries to make informed contributions to discussions about international guidelines.

With the greater involvement of genomics in drug development Peter Singer of the University of Toronto, Canada, posited that this science has the potential to increase the global pharmaceutical divide and increase health inequities. This effect, he said, was not unavoidable but much activity was required now. An opinion leader network should be created across different sectors: government, industry, NGO/patient organisations, scientists, and health-care leaders. Participants should familiarise themselves with the current state of genomics technology and frameworks for analysing ethical and legal issues. He called for a Commission on Global Genomics Governance to make recommendations for genome-related issues and activities. He asserted that there was an opportunity for pharmaceutical companies to become positive players.

The forum was treated to a visit to the South African Medical Research Council where the meeting heard from Motlalepula Gilbert Matsabisa. He discussed traditional medicines and a scheme being developed by the Council to try to ensure

that any benefit derived from knowledge acquired from local communities about traditional medicines would be shared by those communities.

PABIN is part of the Strategic Initiative for Developing Capacity in Ethical Review, a worldwide collaborative of institutions and people interested in promoting ethical review. It was established within the tropical disease research division in WHO. The intention behind PABIN is to "share understandings of good ethical practices between African experts and international organisations involved in research in Africa" and the meeting continued discussion of the issues raised during the forum.

Participants from African countries discussed the difficulties they face in creating rigorous ethical review processes. The lack of regulation of ethical review and unavoidable conflicts of interest arising amongst the small number of people with the skills to be members of ethics committees were consistent themes. Formal academic training in ethics is limited and, in many countries, non-existent.

Donna Knapp van Bogaert of South Africa talked about the challenges of corruption, which she said thrived in environments of poor governance, and were exacerbated by poverty. She described the politicisation of research, noting that in some states research could only proceed if it was authorised by a particular individual. People may be appointed to boards for factors unrelated to their knowledge or experience. It may be exceedingly difficult to act as a whistleblower, she said.

While the challenges of creating ethical guidelines and processes for research are significant in industrialised countries, fundamental issues arise for developing countries who may not have sufficient resources to create the infrastructure for ethical research. All participants agreed that it is crucial that support continues for initiatives such as PABIN.

Bebe Loff

Chapter Six: Health, law and human rights in Australia

This chapter examines issues pertinent to health law in Australia from a rights based perspective.

Monash University

Declaration for Thesis Chapter 6


In the case of chapter 6, contributions to the chapter "Health Law and Human Rights" in Human rights in Australian Law: Principles, Practice and Potential, editor David Kinley, The Federation Press, Sydney, 1998, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
Ian Freckelton	50%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		16.06.04
Signature 2		16.06.04

Monash University

Declaration for Thesis Chapter 6

In the case of chapter 6, contributions to the paper "Healthcare, rationing, patient rights and the law" Medical Journal of Australia 2001; 174: 472-473, involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	70%	Conception and execution
Jenny Majoor	30%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		23/6/04.
Signature 2		23.06.04

Health Law and Human Rights

Freckelton I, Loff Bebe. in Kinley D (ed), *Human Rights in Australian Law: Principles, Practice and Potential*, 1998, The Federation Press, New South Wales. pp 267-290

Introduction

Health rights postulate values that mediate the boundaries between patients and health care practitioners. The assertion of such rights necessarily embraces the contention that fundamental principles of human rights – entitlement to dignity, non-discrimination, confidentiality and equitable distribution of resources – are relevant to the provision of health care and to the allocation of priority in the distribution of limited health resources⁵⁹. It can legitimately be said that a collection of human rights, such as respect for autonomy, consent, truth-telling, confidentiality, personhood and persons, human dignity and justice permeates almost all scenarios that involve the intervention of health laws into the relationship between health professionals and their patients⁶⁰. However, it has been pointed out by a number of commentators, including Kennedy and Grubb, that legal obligations in relation to provision of health care services for a long time have not been sufficiently emphasised and recognised.⁶¹ The only partial exception to this proposition lies in the series of cases, in especially England and New Zealand, which have dealt with the circumstances in which life support for those in a permanent vegetative state or suffering from Guillain-Barré Syndrome should be able to be terminated. These decisions have tended to articulate relevant principles in a more organised and human rights-orientated manner than has

⁵⁹ Leary, V. "The Right to Health in International Human Rights Law" (1995) 1 *Health and Human Rights* 25 at 27.

⁶⁰ Kennedy, I and Grubb, A, *Medical Law: Text and Materials* (Butterworths, London, 2nd ed, 1994), p4; see also Kennedy, I, "Patients, Doctors and Human Rights" in Blackburn, R and Taylor, J (eds). *Human Rights for the 1990s: Legal, Political and Ethical Issues* (Mansell Publishing, London, 1991), p84.

⁶¹ *Ibid*, p52.

occurred elsewhere in the course of medico-legal judgments. They have stressed matters such as the dignity of the patient and the inutility of the provision of futile treatment. They have also taken account of the impact of continuing ineffective treatment upon patients' relatives.⁶²

Otto has usefully argued that:

Perhaps the most important outcome of conceiving health as a human right is that it makes human rights principles applicable to health standards and practices. A human rights framework provides new tools for challenging and reimagining the utilitarian and technical approaches to health that have been preferred by WHO and the conservative professional medical community.⁶³

While there is merit in principle for the analysis of health law in terms of human rights, such a vehicle for analysis historically has been subject to real limitations. In the context of medico-legal litigation initiated in Australia, it has been comparatively rare

⁶² See, in particular, the analysis of fundamental principles by the House of Lords in *Airedale NHS Trust v Bland* [1993] 2 WLR 316, in terms of sanctity of life and discussion of art 2 of the *European Convention for the Protection of Human Rights and Fundamental Freedoms* and art 6 of the *International Covenant of Civil and Political Rights* (ICCPR); the principle of self-determination; respect for the dignity of the patient; the operation of the doctrine of necessity; and the notion of the benefit able to be derived from the provision of medical treatment. See further Freckelton, I, "Withdrawal of Life Support: the Persistent Vegetative State Conundrum" (1993) 1 *Journal of Law and Medicine* 35; Kerridge, I, Mitchell, K and McPhee, J, "Defining Medical Futility in Ethics, Law and Clinical Practice: An exercise in Futility?" (1997) 4 *Journal of Law and Medicine* 235; Gillett, G, Goddard, L and Webb, M, "The Case of Mr L: A Legal and Ethical Response to the Court-Sanctioned Withdrawal of Life-Support" (1995) 3 *Journal of Law and Medicine* 49; Peart, N and Gillett, G, "Re G: A Life Worth Living?" (1998) 5 *Journal of Law and Medicine* 239; McLean, S, "Letting Die or Assisting Death: How Should the Law Respond to the Patient in a Persistent Vegetative State?" in Petersen, K (ed), *Intersections: Women on Law, Medicine and Technology* (Dartmouth, Aldershot, 1997).

⁶³ Otto, D, "Linking Health and Human Rights: A Critical Legal Perspective" (1995) 1(3) *Health and Human rights* 273 at 276

for principles of international law and even the instruments to which Australia is a signatory to impact upon the rulings of courts and tribunals. Moreover, the complex and competing principles which are relevant to health law decisions in the forensic arena for the most part have been ill-articulated and frequently not the subject of clear delineation in reported decisions. However, a number of charters of health rights and responsibilities on the part especially of government have started to enter Australian law. This has been part of the movement toward involvement of consumers in the formulation of health policy and of the creation of health complaints mechanisms. While the justiciability of such statements of rights remains to be finally determined by the courts, in principle, such charters may enable creative actions to enforce provision not only of services but services of the standard mandated within the charters.

Applying the broad approach of Kennedy and Grubb, whereby the notion of health rights is construed liberally, this chapter examines a range of areas of medical practice in which rights could be thought to arise for patients, and may be susceptible of enforcement via legal means. Given space limitations, it deals with a series of important issues that have come before the courts but does not address controversies relating to euthanasia and abortion in any detail. While these areas were highly controversial in Australia in 1997 and 1998, the law is clear in relation to the illegality of deliberately assisting another person to kill themselves and in relation to the unlawfulness of committing homicide, even if the victim consents.⁶⁴ In relation to abortion, important debates in Western Australia resulted in the Acts Amendment (Abortion) Act 1998 (WA), which provides that abortion is now available for adult women who consent to the procedure. However, elsewhere in Australia the common law remains as uncertain as it did in the 1960s.⁶⁵

⁶⁴ See, in particular, the discussion by Mendelson, D, "The Northern Territory's Euthanasia Legislation in Historical Perspective" (1995) 3 *Journal of Law and Medicine* 136.

⁶⁵ See, for example, Stuhmcke, A, "The Legal Regulation of Fetal Tissue Transplantation" (1996) 4 *Journal of Law and Medicine* 131; Eburn, M, "The Status of the Living Fetus" (1997) 4 *Journal of Law and Medicine* 373.

The chapter examines the role of public law in the context of the regulation and protection of people's rights, and the contribution made by international human rights instruments and local guidelines implementing obligations created by Australia's becoming signatory to such instruments to Australian citizens' rights to the provision of health care. It analyses an aspect of the Toonen decision⁶⁶ in which the Human Rights Committee accepted and applied arguments relating to Australian domestic law, including health law, framed in terms of international human rights law. Then it examines a range of important areas of Australian medical law, where individual patients have asserted their need for redress or assistance from courts, including consent to treatment, sterilisation, reproductive rights and the entitlement of patients to gain access to their medical records. The chapter concludes with an analysis of the significant "legal" steps forward in relation to the rights of the mentally ill to be accorded due process but highlights the fact that the clampdown on available resources and the emphasis on deinstitutionalisation have resulted in many patients who need treatment failing to receive what is required for them to return to reasonable health. However, it suggests means by which those with mental illnesses may be able to use legislative responses to Australia's international obligations to enforce their rights to particular kinds of health service provision. Wherever possible, the chapter examines rights issues in terms of patients' "rights" to "self-determination", information about risks, freedom to reproduce, rights to dignity and rights to information held about them.

PUBLIC HEALTH AND HUMAN RIGHTS

The discipline of public health focuses upon the health of populations rather than clinical treatment of individuals. It is a given to public health practitioners that a critical determinant of health status is socio-economic status.⁶⁷ However, because there seems to be no workable alternative, health policy and programmes continue to operate within a biomedical framework. This model tends to promote consideration of illness in individuals and a response to a series of individual problems, rather than

⁶⁶*Toonen v Australia*, Human Rights Committee, CCPR/C/50/D/488/1992; views of the Committee adopted on 31 March 1994, delivered on 4 April 1994.

⁶⁷ See, for instance, Reynolds, C, *Public Health Law in Australia* (Federation Press, Sydney, 1995).

focusing upon systemic factors of causation. Mann, who has been a leader in the development of thinking in the area of health and human rights, has argued that the difficulty for public health in

addressing the indisputably predominant social determinants of health status is exacerbated by the lack of a coherent conceptual framework for analysing societal factors that are relevant to health; the social class approach, while useful is clearly insufficient. Public health action based on social class is simply accusatory and it raises, but cannot answer, the question: "what must be done?"⁶⁸

In this sense, "poverty" as a root cause of ill health (though clearly not the only cause) is both evident and paralysing to further thought and action. Also, without a consistent approach or vocabulary, we cannot identify the societal factors common to different health problems (cancer, heart disease, injuries, infectious diseases) and to different countries. Finally since the way in which a problem is defined determines in part what is done about it, it is significant that the prevailing public health paradigm is unclear about the nature and direction of societal change that is needed to promote health.

This school of thought argues that health policies and programmes may be enhanced by placing them in a human rights framework. Instead of imagining the unwell person as the other, as commonly happens in the context of infectious disease, the aim is to maximise the individual's human rights in so far as this is consistent with good science. A good example of this approach is the Australian National Strategy on HIV.⁶⁹ The legal component of this Strategy promoted the protection of privacy, informed consent, graded coercive powers ranging from minor restrictions to detention and rights of review and appeal when restrictions are imposed. Harm minimisation approaches in the context of drug usage have also been informed by consideration of human rights. The creation of laws supporting needle exchange schemes is also, in part, a recognition of a right to health. Similar comments could be made about the supply of condoms in prisons.

⁶⁸ Mann, J, "Health and Human Rights" (1996) 312 *British Medical Journal* 924.

⁶⁹ See for example Watchirs, H "HIV/AIDS and the Law: The Need for Reform in Australia" (1993) 1 *Journal of Law and Medicine* 9.

Comparatively rarely under current Australian law have individual litigants been able to utilise international human rights instruments to enable them to assert their own rights. An exception is to be seen in *Toonen v Australia*⁷⁰ where health policy issues were the subject of attempts at lobby-induced change at the behest of two men who asserted health rights to practice their sexuality as they wished. In December 1991 the United Nations Human Rights Committee, received a petition from Nicholas Toonen, an activist for homosexual rights in Tasmania. He sought to challenge ss 122(a) and (c) and 123 of the Tasmania Criminal Code that criminalised sexual contact between gay men in private on the basis of their functioning in a discriminatory way. Ultimately the decision of the Human Rights Committee was based upon the right to privacy under art 17 of the ICCPR and what it characterised as an arbitrary infringement of this right.

However, in the course of argument before the Committee health issues were raised both in favour of and against the criminalisation of homosexual activity. Amongst the arguments proffered, Tasmania stated that, although laws criminalising homosexual activity might constitute an arbitrary interference with privacy, they should be retained in order to protect public health and prevent the spread of HIV/AIDS in that jurisdiction. This argument was opposed by the federal government which contended before the Committee that such laws impede public health programmes by driving people underground. Further, it pointed out that the position of the Tasmanian government ran counter to the National HIV/AIDS Strategy.

The Committee found that criminalisation of homosexual activity was not a "reasonable means or proportionate measure" to prevent or limit the spread of HIV.⁷¹ The Committee noted further that there was no evidence which demonstrated that criminalising homosexuality was effective in limiting the spread of HIV. The Committee did not accept the argument that this matter was a moral concern and thus a domestic matter. The Toonen decision highlights an opportunity, albeit a

⁷⁰ Above, n 8; see further, Joseph S "Gay Rights under the ICCPR – Commentary on *Toonen v Australia*" (1994) 13 *University of Tasmania Law Review* 393; and Ch 14 by Eastman and Ronalds in this volume.

⁷¹ Above, n 8, paras 8.4-5.

comparatively rare one, for health rights arguments to be invoked under the framework of the ICCPR to facilitate the achievement of health, in the broad sense of the concept, by individuals otherwise deleteriously affected by legislative impediments to their health.

Not surprisingly, though, individual case decisions on occasions have achieved the opposite result. The interpretation by the courts of important public health initiatives is not always consistent with the effective provision of needed services. For instance, in *Ateyo v Aboriginal Lands Trust*⁷² Templeman J found that the purpose of the legislation in preventing disease was not determinative and that the Crown, and therefore the Trust, was not bound by it. Thus, the purpose of the public health legislation was thwarted. The case was ultimately decided on the basis of the black letter issue of whether certain kinds of legislation should be taken to bind the Crown, but its resolution, and the manner of its resolution, in which health rights issues ended up becoming secondary considerations, have important, if depressing, ramifications.

In addition, some developments in the area of public health law are inconsistent with a rights based approach such as proposals for the criminalisation of the intentional spread of serious disease with a maximum penalty of life imprisonment. The risk thereby created is that fewer HIV positive persons will submit to testing and so more people will be put at risk of the transmission of the disease.⁷³ However, the health and human rights framework is gaining support amongst the international community.⁷⁴ It may be that the move toward the development of a "therapeutic jurisprudence", which explores ways in which, consistent with the principles of justice, the knowledge, theories and insights of the health and related disciplines can help shape the development of the

⁷² (1996) 93 LGERA 57.

⁷³ In relation to regulation of the passage of HIV to women see S Hardy, "Regulating the Conduct of HIV-positive Women" (1998) 6 *Journal of Law and Medicine* (forthcoming).

⁷⁴ See, for example, the *International Guidelines on HIV/AIDS and Human Rights* published by the United Nations (New York and Geneva, 1998) and the UNAIDS Guide to the United Nations Human Rights Machinery for AIDS Service Organisations, People Living with HIV/AIDS, and Others Working in the Area of HIV/AIDS and Human Rights (UNAIDS, 1997).

law,⁷⁵ has the potential to facilitate the evolution of health law in a direction which is consistent with an integrated rights framework. By its focus upon the development of law in a way which promotes health, such a jurisprudence carries the promise of influencing law-making by legislatures as well as the interpretation of laws in cases such as *Atyeo* to the advantage of those whose health such legislation is designed to enhance.

INTERNATIONAL LAW AND THE RIGHT TO HEALTH

In international law there are many references to the "right to health" but few to specific rights in relation to particular kinds of treatment, to what constitutes "adequate treatment", or to the remedies available for persons adversely affected by the treatment that they do receive. A right to health is not only located in the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic Social and Cultural Rights (ICESCR). References to a right to health may be found in the preamble to the Constitution of the World Health Organisation (WHO), art 24(1) of the Convention on the Rights to the Child (CROC), art 5(e)(iv) of the Convention on the elimination of All Forms of Racial Discrimination (CERD) and art 11(1)(f) of the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW).

The basic reference art 12 of the ICESCR, provides that:

The State Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The steps to be taken by the State Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:

⁷⁵ See, for example, Magner, ES. "Therapeutic Jurisprudence: A New American (?) School of Thought" (1998) 5(2) *Psychiatry, Psychology and Law* (forthcoming); Winick, B, "The Jurisprudence of Therapeutic Jurisprudence" in Wexler, DB and Winick, BJ (eds), *Law in a Therapeutic Key: Developments in Therapeutic Jurisprudence* (Carolina Academic Press, Durham, Nth Carolina, 1996).

The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

The improvement of all aspects of environmental and industrial hygiene;

The prevention, treatment and control of epidemic, endemic, occupational and other disease;

The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

This right is limited in the help which it extends for the framing of health legislation. For a start, the meaning of the article is not all that clear, although there has been an ongoing, albeit not very successful, international process aimed at its clarification. The Committee created to monitor the implementation of the covenant sought to issue a General Comment on Article 12 to provide a better standard against which to measure States' compliance. International health experts debating the possible content of such a General Comment struggled with the knowledge that health status is generally determined by social and economic factors. They concluded:

By over-emphasising the correlations between health and other factors, the impression may appear that any health specific effort is doomed to fail in the absence of general socio economic reforms. Next step would be that the State may feel justified to suspend its health promotion and health care programs until better times come. Given the fact that the "healthy and wealthy" hardly ever depend on State interventions in the field of health, the implications of such a State withdrawal would disproportionately affect the poor and vulnerable groups in society. The consequence of such a decision would be that the gap between rich and poor and between healthy and less fortunate would dramatically increase.⁷⁶

⁷⁶ See Henriks, A "The Right to Health" (1994) 1(2) *European Journal of Health Law* 187 at 195.

The right to health has been the subject of considerable controversy concerning whether it is a meaningful or enforceable right.⁷⁷ It has been suggested that if health is defined as "a state of complete physical, mental and social well-being" then it must be extremely difficult to implement and unlikely to be justiciable.⁷⁸ Defining human well-being is far from a straightforward exercise and it has been observed that public health and human rights have actually been used at times as powerful tools for maintaining the status quo and reinforcing hierarchies of power based on race, gender and class.⁷⁹

However, Gostin and Lazzarini have suggested that the right to health may be defined as "the duty of the state, within the limits of its available resources, to ensure the conditions necessary for the health of individuals and populations".⁸⁰ This definition only requires the state to act within its capabilities to achieve as good a standard of health as it can and recognises that while government may do a great deal to improve population health there are also many factors beyond the power of the state.⁸¹

Two important recent cases – in South Africa and New Zealand – have tested the right of patients to treatment.⁸² It is significant that both did so by using the mechanism of arguing that entrenched objectives of the provision of health care had not been met. It will be argued below that this is a mechanism likely to be more frequently availed of by litigants in the future, advocacy services and legal aid resources permitting.

⁷⁷ See, for instance, Bell, S, "Rationing the Right to Health" (1998) 6(1) *Journal of Law and Medicine* 83.

⁷⁸ Gostin, LO and Lazzarini, Z, "Human rights and Public Health in the AIDS Pandemic" (Oxford University Press, Oxford, 1997), pp28-29.

⁷⁹ See, for example, Freedman, L, "Reflections on Emerging Frameworks of Health and Human Rights" (1995) 1(4) *Health and Human Rights* 315.

⁸⁰ Gostin and Lazzarini, above, n 20, p 29.

⁸¹ However, note that the term employed in art 12 of the ICESCR is for the "highest attainable standard" of health to be striven for by the state.

⁸² For a useful discussion, see Bell, above, n 19.

In *Soobramoney v Minister of Health (Kwazulu-Natal)*,⁸³ a patient with renal failure sought to be reinstated on dialysis treatment by reliance on a provision in the South African Constitution which provided that all citizens had the right to health care services, subject to the availability of necessary resources, and that no-one could be refused emergency treatment. The court, while it conceded that the preservation of human life was of paramount importance, held that treatment for end-stage renal failure did not constitute emergency treatment and that acceptance of the patient's argument would have the effect of undermining the values which the provision in the constitution sought to protect by an unwarranted conflation of emergency and non-emergency treatment.

Similarly in New Zealand a number of decisions in the courts were generated by the refusal of access by the Northland Regional Health Authority to an end-stage renal failure programme for an elderly man with renal failure. The patient initially challenged the decision on the ground that the Authority was not fulfilling the duty it owed him under the Health and Disability Services Act 1993 (NZ), maintaining that the Authority was in breach of its obligation to provide the best health care and support to those needing health services and had failed its obligation to exhibit a sense of social responsibility and to provide its services in accordance with the ethical standards to be expected to providers of health and disability services. Thus the claim was one of treatment based upon application of the values statutorily mandated of health care providers. However, Salmon J of the New Zealand High Court applied the reasoning of Lord Donaldson MR in *Re J (A Minor)*,⁸⁴ holding that the obligations spelled out in the legislation were not absolute but subject to the exercise of clinical judgment. Balcombe J went even further, emphasising "the absolute undesirability of the court making an order which may have the effect of compelling a doctor or health authority to make available scarce resources...without knowing whether or not there are other patients to whom these resources might more advantageously be devoted. The court declined to interfere with the Authority's decision, holding that the clinicians had relied properly on the Authority's guidelines in relation to the allocation of resources in

⁸³ CCT 32/97, 27 November 1997.

⁸⁴ [1992] 3 WLR 507.

a principled manner and without any reviewable administrative deficiency. The Court of Appeal upheld the High Court's decision.⁸⁵

As already noted, of greater assistance in conceptualising health in terms of rights are the notions of rights to life, liberty and security of the person; the right to be free of arbitrary interference with one's privacy; the right to benefit from scientific advances; the right to seek, receive and impart information and ideas; and the right to found a family. Merely the enunciation of such a series of rights illustrates the indivisibility and interdependency of fundamental human entitlements. In this regard Leary has noted that a consequence of "embracing a human rights paradigm is the assumption that universal health standards, which are legally cognisable and enforceable, can be identified. That is, health is constructed as a legal entitlement rather than a privilege, commodity or result of altruism".⁸⁶

Nevertheless, it must be conceded that the statements of rights to health which emanate from international documents are frequently not immediately helpful in arguing cases locally. In areas where well-established precedent exists, such as in the area of medical malpractice, it is unlikely that submissions constructed in a rights framework will be accepted by an Australian court. Greater scope exists where the boundaries of current law are challenged and international human rights law may then become a useful resource. In addition, increasing scope exists for human rights, discourse and analysis to influence the development of new statutory regulation of health care processes.

AUSTRALIAN MEDICAL LAW

There is no specific right to "treatment" or to "good treatment" in Australia. However, the common law has entitled persons to sue if they have been harmed in the course of treatment. The law that has built up around medical malpractice, largely framed in terms of the law of tort (negligence, nuisance, and trespass to the person) goes some way toward enabling litigants to assert rights in respect of their bodies. The notion of a person's right to autonomy of decision-making and thus the right to make decisions

⁸⁵ *Shortland v Northland Health* (unreported, CA NZ, 10 November 1997, CA 230/97).

⁸⁶ *Ibid* at 276.

about accepting or refusing medical treatment on the basis of adequate information to make such decisions are central.

In the following discussion we concur with other writers in locating their deliberations concerning autonomy and consent in the right of the patient to security of the person.⁸⁷ Gostin and Lazzarini, for instance, suggest that to realise the right to personal security:

Individuals must remain free to voluntarily accept or refuse physical intrusions, even when the purpose is benign. The doctrine of voluntary consent to medical testing, treatment, or research, which much of the international community endorses, may be seen as arising from the right to security of the person.⁸⁸

Only when competent persons make uncoerced choices, based on full information, can they truly exercise their right to security of the person. Security of the person, then, requires "information, competency, and a voluntary assent to intervention absent undue influence, duress, or coercion".⁸⁹ Other options for classification of rights within the provision of healthcare are the right to self-determination or, remotely, the right to privacy, but in terms of Australian jurisprudence the right of a person not to be the subject of medical intervention, save in certain circumstances, can most usefully be termed not as a function of decision-making but as a right to bodily integrity, save when that is waived by the person's own decision.

⁸⁷ ICCPR art 17. Privacy is central in medical law and the right to privacy as understood in international law is relevant to this element. However, it is distinct from consent. Self-determination as a principle may apply both to populations and, especially in the medical law context, to individuals. For a useful discussion, see Jones, M and Marks, LA, "Female and Disabled: A Human Rights Perspective on Demand Medicine" in Petersen, above, n 4.

⁸⁸ Gostin and Lazzarini, above, n 20, pp14-15.

⁸⁹ Ibid, p 15.

Consent to treatment

The most significant Australian case in relation to patients' rights to sound treatment and to decide upon medical treatment is the High Court decision of *Rogers v Whitaker*.⁹⁰ The defendant ophthalmic surgeon, Rogers, conducted surgery on the injured and sightless right eye of the plaintiff, Mrs Whitaker. This resulted in a condition known as sympathetic ophthalmia and consequential loss of sight in the respondent's left eye, leaving her almost totally blind. Evidence was given that the chance of this occurring was one in approximately 14,000 cases and that the condition did not always result in loss of vision.

The ground upon which the case was argued was that the surgeon had been negligent in failing to warn his patient of the risk of sympathetic ophthalmia. The trial judge concluded that such a warning was necessary in light of the respondent's desire for this information, she having particularly expressed concern about the conduct of the operation and her capacity to continue to enjoy vision.

The traditional view applied by the English courts was that derived from the case of *Bolam v Friern Hospital Management Committee*.⁹¹ His was relied upon by the surgeon when he suggested that the standard of care required of him was no more than that of the ordinary skilled person exercising and professing to have a special skill. In this instance there was a body of reputable medical practitioners who would not have warned the patient of the risk of sympathetic ophthalmia, so it was said that the surgeon had behaved in accordance with the standard required.

This test had been applied by the English courts to diagnosis, treatment and the provision of information. Such a test is professionally-oriented, rather than orientated toward the wishes and needs of the patient. In *Sidaway v Bethlem Royal Hospital Governors*,⁹² Lord Scarman, in a dissenting judgment, stated that it was a matter of law whether or not a doctor has provided a patient with sufficient information. The

⁹⁰ (1992) 175 CLR 479.

⁹¹ [1957] WLR 582.

⁹² [1985] 1 All ER 643.

relevant standard, he held, was not a matter able to be determined solely by reference to current accepted practice. In arriving at this position, Lord Scarman referred to the Canadian decision of *Reibl v Hughes*⁹³ and, in doing so, recognised that the significant determining factor in the information to be imparted was individual autonomy, that is the patient's right to decide what will happen with respect to medical treatment.

In *Rogers v Whitaker*⁹⁴ the majority in the High Court held that:

[I]n the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and instead the Courts have adopted...the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the "paramount consideration that a person is entitled to make decisions about his own life".⁹⁵

They resisted characterising the obligations of the medical practitioner as a matter of "the patient's right of self-determination", seeing this as pertinent to cases where there may be doubt as to whether a person has agreed to a treatment or procedure generally. They suggested that concepts like self determination or informed consent were applicable to actions in trespass or battery, but not in negligence. However, the effect of the decision is to forge a connection between a patient's right to self-determination in terms of consent or refusal to treatment, a self-determination founded in the

⁹³ (1980) 114 DLR (3d) 1.

⁹⁴ See also the discussion in *Anasson v Koziol* (unreported, SC ACT, 20 December 1996) at 13, where Miles CJ commented that, "it might be observed that it seems that the *Bolam* principle is not as rigid as Australian lawyers have sought to express it in order to reject it. With respect to their Lordships, they might have been surprised to learn that they had delegated the duty of the courts to the medical profession (*F v R* (1983) 33 SASR at 193), let alone handed over their responsibilities to a section of the community with an interest in the outcome (*Reibl v Hughes* (1980) 114 DLR at 13). Some might regard *Bolam* as a case decided on its facts. It was not considered important enough to be published in the authorised reports".

⁹⁵ (1992) 175 CLR 479 at 487.

provision of information which enables the making of a considered decision about medical intervention.

While the court dealt with the case as one located within the framework of negligence law, the requirement imposed upon medical practitioners by the decision is broadly consistent with a rights framework and the right to security of the person in particular. The court held that:

The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.⁹⁶

The decision needs to be seen within context. It has not ushered into Australia the doctrine of the oft-used and somewhat amorphous phrase "informed consent". In fact, the court observed that there was nothing to be gained by reiterating expressions used in United States authorities such as "the patient's right of self-determination" or even "informed consent",⁹⁷ pointing out that the term "is apt to mislead as it suggests a test of the validity of the patient's consent and that, moreover, consent is relevant to actions framed in trespass, not in negligence".⁹⁸

The decision has been responsible for a major shift away from an environment of medical paternalism toward a recognition of patient autonomy in that the patient's views and desires are now preferred to what the doctor might paternalistically and without proper consultation consider to be in the patient's best interests.⁹⁹ However,

⁹⁶ Ibid at 490/

⁹⁷ Ibid at 490.

⁹⁸ *Breen v Williams* (1996) 138 ALR 259 at 298 per Gummow J.

⁹⁹ Note though the comment of Dawson and Toohey JJ in *Breen v Williams* at 278 that *Rogers v*

Whitaker had nothing to say about medical paternalism save, perhaps, to the extent that it decides that it

the High Court decision has left many questions unresolved in relation to doctor-patient interaction. Included among the uncertain factors in the aftermath of *Rogers v Whitaker* is the variable of the extent to which a doctor must take steps to acquaint him or herself with the personal circumstances of a patient so as to provide information responsive to idiosyncratic aspects of the patient's circumstances and wishes. Another fundamental question, that has troubled medical practitioners, is the extent to which remote risks, but of a kind which would prompt anxiety in patients, need to be drawn to their attention. If risks as remote as one in 14,000 need to be the subject of warning, where does the obligation cease? And how can it be discharged – for instance, by the provision of written information or video tapes descriptive of the procedure.

To what extent does communication through such media need to be supplemented by one-to-one doctor-patient interaction?

The difficulties inherent in the case of *Chappel v Hart*¹⁰⁰ are illustrative of the uncertainties that exist in relation to the entitlements of patients in the post-*Rogers v Whitaker* era. The plaintiff sued her ear, nose and throat surgeon for failing to warn her of the dangers of a procedure which he advised her undergo. She expressed concern about side-effects but was not advised of a significant complication of the operation that was ultimately undertaken. Notwithstanding the surgeon's exercise of due care and skill, her oesophagus was perforated and she developed an infection which damaged her laryngeal nerve, resulting in paralysis of her right vocal chord. The difficult aspect of the case was that she would have undertaken the operation even if properly advised of the risks. No negligence in the conduct of the procedure was asserted.

The New South Wales Court of Appeal found that had the patient been advised of the risks, she would have postponed the operation and had a more experienced surgeon

is for the court, not medical opinion, to determine whether the required standard of care has been observed.

¹⁰⁰ Unreported, CA NSW, 24 December 1996. See further Freckelton, I "Medical Malpractice Litigation" in Freckelton, I and Petersen, K (ed), *Controversies in Health Law* (Federation Press, Sydney, 1998) (forthcoming).

carry it out. However, the evidence was equivocal about whether this would have reduced in any way the risks of the complications which ultimately afflicted the patient.¹⁰¹ Mahoney JA, with whom Handley JA agreed, framed the duty to advise thus:

The doctor is responsible for the damage by reason of the failure to warn of the existence of the possibility of damage only when, in the circumstances, he has a duty to give a warning of it...[W]here, as here, it is accepted that there was a duty to warn, then the failure to warn may properly be held to be the cause of the damage when the risk eventuates.¹⁰²

Thus, the right to bodily integrity was very generously construed by the court and the burden placed squarely upon the medical practitioner's shoulders to ensure that adequate information was provided to the patient, the penalty for failure to do so being liability for any damage thereafter ensuing from the procedure undertaken by the patient in the absence of such information.

Sterilisation

If human rights are to have any role in medical law, it should be in the protection of the most vulnerable in our community. A case that demonstrates the influence of a human rights approach to a difficult health care issue is *Secretary, Department of Health and Community services v JWB and SMB (Marion's Case)*,¹⁰³ which involved an application for the sterilisation of a young intellectually disabled girl with severe deafness, epilepsy, behavioural problems" and an ataxic gait. Her parents sought and order authorising the performance of a hysterectomy and a bilateral oophorectomy.

¹⁰¹ For a discussion of the case, see Mendelson, D, "The Breach of the Medical Duty to Warn and Causation" (1998) 5(4) *Journal of Law and Medicine* 312.

¹⁰² At the time of writing, an appeal had been argued before the High Court and the decision was reversed.

¹⁰³ (1992) 175 CLR 218. For discussion of this case in the context of family law and human rights, see Ch 8 by Behrens and Tahmindjis in this volume.

The hysterectomy was sought to prevent pregnancy and menstruation and their psychological and behavioural consequences. The oophorectomy was proposed to stabilise the hormone fluxes, helping to eliminate consequential stress and behavioural responses. The term "sterilisation" was used as a shorthand reference to these procedures.

The issue before the High Court was whether such a sterilisation could be performed, and if so whether it could be done with the provision of parental consent or only in accordance with an order of the Family Court. Basic human rights, the concept of "best interests of the child" and the ability to distinguish therapeutic from non-therapeutic treatments or procedures were discussed in the course of the decision-making process by the Family Court and then, on appeal, by the High Court. The High Court addressed the power of parents to consent to medical treatment on behalf of a child, the capacity of a child to consent and the specific issue of sterilisation. The decision of the majority, comprising Mason CJ and Dawson, Toohey and Gaudron JJ, was that except where sterilisation is an incidental result of surgery performed to cure a disease or to correct a malfunction, the decision to sterilise a minor falls outside the ordinary scope of parental powers and thus the powers and duties of a guardian. They found that the task of the Family Court when approached in its *parens patriae* jurisdiction to authorise the sterilisation of a child is to determine what is in the child's "best interests". They remitted the task of formulating guidelines for determining what is in such a child's best interests to the Family Court.

The majority summarised the reasons given in previous cases for considering the authorisation of sterilisation to be beyond parental power: "first, the concept of a fundamental right to procreate; secondly, in some cases, a similarly fundamental right to bodily inviolability or its equivalent; thirdly, the gravity of the procedure and its ethical, social and personal consequences".¹⁰⁴ They found court authorisation to be necessary safeguard for sterilisation which is not the "by-product of surgery appropriately carried out to treat some malfunction or disease". Sterilisation was characterised as irreversible surgery carrying a significant risk of error which in turn could bring grave social and psychological consequences. Children with an intellectual

¹⁰⁴ Ibid at 249.

disability were recognised as falling into a particularly vulnerable category of the community.

The majority endorsed the well-known formulation of the principle of inviolability articulated by Cardozo J in *Schloendorff v Society of New York Hospital*:¹⁰⁵ "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault."

The majority judges in the High Court based their conclusion upon what they termed "a fundamental right to personal inviolability existing in the common law", a right which they said underscored the principles of assault, both criminal and civil, as well as upon the practical exigencies accompanying this kind of decision. They emphasised, though, that their conclusion did not "rely on a finding which underpins many of the judgments discussed; namely, that there exists in common law a fundamental right to reproduce which is independent of the right to personal inviolability".¹⁰⁶

The High Court's decision in *Marion's Case* is the most prominent example of a judicial decision in Australia which has canvassed in detail and with sophistication the conflicting human rights issues in a medical law context. However, the decision also included powerful dissents by Brennan, Deane and Wilson JJ.

The Human Rights and equal Opportunity Commission was permitted standing to appear before the High Court.¹⁰⁷ It argued that an invasive surgical procedure such as a sterilisation of a young woman who is unable to provide her own consent should only be undertaken with the authorisation of a court. It successfully contended that the welfare jurisdiction of the Family Court and "as such is sufficient the international

¹⁰⁵ 105 NE 92 (NY 1914), referred to at 234. *Schloendorff* was determined independently of the United States Bill of Rights considerations.

¹⁰⁶ *Ibid* at 253-54.

¹⁰⁷ See Ch 14 by Eastman and Ronalds in this volume.

Conventions and Declarations incorporated in schedules to the Human Rights and Equal Opportunity Commission Act".¹⁰⁸

Brennan J, in dissent, though, rejected the Commission's approach. He sought to identify the "basic principles of our legal system" since there were no cases of binding authority. He looked to what in the law governs physical integrity and noted that:

Blackstone declared the right to personal security to be an absolute, or individual, right vested in each person by "the immutable laws of nature".¹⁰⁹ Blackstone's reason for the rule which forbids any form of molestation, namely, that "every man's person [is] sacred", points to the value which underlines and informs the law: each person has a unique dignity which the law respects and which it will protect.¹¹⁰

He pointed out that human dignity"¹¹¹ is a value common to Australian municipal law and to international instruments relating to human rights:

The law will protect the hale and hearty and the dignity of the weak and lame; of the frail baby and the frail aged; of the intellectually able and the intellectually disabled... Human dignity requires that the whole personality be respected: the right to physical integrity is a condition of human dignity but the gravity of any invasion of physical integrity depends on its effect not only on the body but also upon the mind and self perception.¹¹²

In considering what is to be incorporated within the term, "physical integrity", he included the psychological impact of the physical interference and the impact upon that person's human dignity, a notion well known in human rights dialogue.

¹⁰⁸ (1992) 175 CLR 218 at 231.

¹⁰⁹ Ibid (*Blackstone's Commentaries on the Laws of England*, vol 1, pp124, 129; vol 3, p119).

¹¹⁰ Ibid at 266.

¹¹¹ Ibid, "[t]he inherent dignity of all members of the human family is commonly proclaimed in the preambles to international instruments relating to human rights": at 266.

¹¹² Ibid at 266.

Brennan J noted the idea of third party authorisation, or substituted consent, but dismissed it as a "semantic legerdemain" and the antithesis of consent, thus unreliable. However, he found utility in the distinction between "therapeutic" and "non-therapeutic", a distinction by contrast that the majority found to be imprecise. He defined treatment as being therapeutic when administered "for the chief purpose of preventing, removing or ameliorating a cosmetic deformity, a pathological condition or a psychiatric disorder, provided the treatment is appropriate for and proportionate to the purpose for which it is administered".¹¹³ His Honour accepted that the intellectually disabled should have the same rights as others "to the maximum degree of feasibility", as proposed under the Declaration of the Rights of Mentally Retarded Persons. He held that to accord in full measure the human dignity "that is the due of every intellectually disabled girl", her right to

Retain her capacity to bear a child cannot be made contingent on her imposing no further burdens, causing no more anxiety or creating no further demands. If the law were to adopt a policy of permitting sterilisation in order to avoid the imposition of burdens, the causing of anxiety and then the creating of demands, the human rights which foster and protect human dignity in the powerless would lie in the gift of those who are empowered and the law would fail in its function of protecting the weak.¹¹⁴

He expressed himself loathe to endorse a "best interests" approach on the basis of its failure to offer a hierarchy of values,

Which might guide the exercise of a discretionary power to authorise sterilisation, much less any general legal principle which might direct the difficult decisions to be made in this area by parents, guardians, the medical profession and courts...the best interest approach depends upon the value system of the decision maker. Absent any rule or guideline, that approach simply creates an unexaminable discretion in the repository of the power.¹¹⁵

¹¹³ Ibid at 269.

¹¹⁴ Ibid at 276.

¹¹⁵ Ibid at 270-01. Brennan J accepted the need for guidelines lest the law fail the person in respect of whom the order for sterilisation is sought. He held that a non-therapeutic sterilisation could only be

Because of the majority decision of the High Court, the matter was remitted to the Family Court for articulation of criteria on the basis of which a decision could be made as to whether Marion should or should not be sterilised.¹¹⁶ On remittal Nicholson CJ constructed the series of guidelines called for in the High Court¹¹⁷ and approved her sterilisation as a step of last resort in order to minimise the potential to her of further neurological damage and in particular to stem the effects of seizures to which she was subject.

justifiable if its purpose was of greater value than physical integrity. He added that financial security, for example, was not "to be preferred over the equal protection of the law of the human rights of every member of the community": at 275.

¹¹⁶ *Re Marion (No 2)* (1994) FLC 92-448.

¹¹⁷ The relevant factors which went to determining whether sterilisation was an intellectually disabled girl's best interests were held to be:

- (i) the condition which required the procedure or treatment;
- (ii) the nature of the procedure or treatment proposed;
- (iii) the reasons for which it was proposed that the procedure or treatment be carried out;
- (iv) the alternative courses of treatment that are available in relation to the condition;
- (v) the desirability and effect of authorising the procedure or treatment proposed rather than the available alternatives;
- (vi) the physical effects upon the person and the psychological and social implications for the person of authorising or not authorising the proposed procedure or treatment;
- (vii) the nature and degree of risk to the person of authorising or not authorising the proposed procedure or treatment; and
- (viii) the views, if any, expressed by the person's guardians; anybody entitled to custody of the person; anybody responsible for the person's daily care and control; and of the person themselves.

See also *In the Matter of P and P* (1995) FLC 92-615; *Re Jane* (1989) FLC 92-007

The decisions in the cases relating to Marion represent a high point in the analysis of basic and complex principles of health law in terms of rights asserted in international instruments and articulated in human rights discourse. The powerful dissent of Brennan J highlights the difficult balancing exercise when the rights of the intellectually disabled to autonomy and bodily integrity have to be placed in the scales against what objectively speaking is in the best health interests of a person unable to make their own decisions.

Reproductive rights

Article 10(2) of the ICESCR requires that "[s]pecial attention be accorded to mothers during a reasonable period before and after childbirth". Article 12, the right to health, requires reduction of the stillbirth rate and of infant mortality. Gender equity is a significant part of achieving reproductive rights and this, of course has its reflection in the CEDAW. In particular art 12 of that Convention states:

States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.

Notwithstanding the provisions of paragraph 1 of this article States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.

Reproductive rights are a recent concept:

One of the cornerstones of the concept of reproductive rights is the right of access to family planning. This idea has been fundamental to definitions of reproductive rights from the beginning, appearing repeatedly in population and human rights documents as the right to have the "information and means" to decide freely and responsibly the

number and spacing of children. Without such access, reproductive rights have, practically speaking, no real meaning.¹¹⁸

The International Conference on Population and Development held in Cairo in 1994 defined reproductive rights as embracing:

certain human rights recognised in national and international legal and human rights documents: the right of couples and individuals to decide freely and responsibly the number and spacing of their children, and to have the information and means to do so; the right to attain the highest standard of sexual and reproductive health; the right to make decisions free of discrimination, coercion or violence.¹¹⁹

Expressed in this manner, reproductive rights relate to much more than the entitlement to personal inviolability. They encompass positive rights articulated more fully at the fourth World Conference on Women in Beijing 1995.¹²⁰ Reproductive rights might include the freedom to have a safe and satisfying sexual life, the ability to have a safe pregnancy and childbirth, the ability to control one's own fertility, access to gender-sensitive initiatives to deal with sexually transmitted diseases and to information about reproductive health and access to safe abortions. They might also be said to include the right to be free from unwanted sexual interference which is an aspect of the right to bodily integrity.

The right to reproduce was not accepted as a right independent of personal inviolability by the majority in *Marion's Case* which held that:

If the so-called right to reproduce comprises a right not to be prevented from being biologically capable of reproducing, that is a right to bodily integrity. The same applies, though in different way, to a woman's "right to reproduce". Again, if the right

¹¹⁸ "Reproductive Rights and Reproductive Health: A concise Report" United Nations, New York, 1996).

¹¹⁹ "Action for the 21st Century: Reproductive Health and Rights for All" (Family Care International, New York, 1994), p 10.

¹²⁰ *Report of the 4th World Conference on Women, United Nations* (Beijing, September 1995), pp 4-15.

See also Ch IV of the Report, Part C, paras 89-111.

is, in fact, a right to do with one's person what one chooses, it is saying no more than there is a right to bodily integrity. Furthermore, it is impossible to spell out all the implications which may flow from saying that there is a right to reproduce, expressed in absolute terms and independent from a right to personal inviolability. We think it is important, in terms of the judgement, to make it quite clear that it is inviolability that is protected, not more.¹²¹

The majority classified the right to reproduce as a limited and indistinct right. It is apparent, therefore, that the approach of the majority of the High Court in Marion's Case is one that significantly circumscribes the extent of women's reproductive rights within Australian medical law. What this means in practice is that the range of issues regarded as coming into play in assessing whether or not there is an interference with a woman's reproductive capacity is far more limited than has been proposed by recent international forums on the subject.

Patient access to medical records

The matter of the rights of patients to medical records generated on their behalf has been a troubled and controversial one in Australia and internationally during the 1990s. It is an aspect of the privacy of the doctor-patient relationship, arguably comprehending the entitlement of the patient to know what it is that has been generated by her or his medical advisers in the course of consultations and tests conducted in order to provide advice or to facilitate decisions related to intervention or non-intervention. At an international level, it is significant that art 10 of the European Draft Convention on Human rights and Medicine prescribes that "everyone is entitled to know any information collected about his or her health". This is stated to be subject to the qualification that "in exceptional cases" restrictions may be placed on the exercise of such rights to information, where restriction would be in the interest of the patient.¹²²

¹²¹ (1992) 175 CLR 218 at 254.

¹²² See Ch III of the council of Europe's Draft Convention on Human Rights and Medicine, reproduced in (1997) 1(1) *International Journal of Human Rights* 115.

However, to a significant degree the issue is a limited one in Australia in light of the applicability of freedom of information legislation to records generated by public health facilities and the availability of records under prelitigation discovery, discovery and subpoena. In addition, 1997 legislation in the Australian Capital Territory has given patients significant rights to their records. However, the reasoning engaged in by the High Court in determining that patients have no common law right to their health records is of real moment for the construction of Australian health law and for understanding the nature of the doctor-patient relationship in this country.¹²³

In 1996 the High Court determined the issue authoritatively. Holding in *Breen v Williams*¹²⁴ that patients hold no proprietary right or interest in the information contained in a doctor's medical records. Such records were determined to be the property of the doctor, enabling medical practitioners to refuse patients access to such records. As a matter of contract and fiduciary law, the High Court repudiated the contention that patients are entitled to inspect their records on demand.¹²⁵

However, Brennan CJ held that in certain circumstances information with respect to a patient's history, condition or treatment which is obtained by a doctor in the course of giving advice or treatment must be disclosed to a patient on request. He found such circumstances to arise where refusal to make the disclosure might prejudice the general health of the patient, whether the request is reasonable, having regard to all the circumstances, and where reasonable recompense for the service of disclosure is tendered or assured by the patient.¹²⁶

¹²³ *Health Records (Privacy and Access) Act 1997 (ACT)*. See also the position in England (s 3 of the *Access to Health Records Act 1900*) and New Zealand (*Health Information Privacy Code 1994 (NZ)*; *Health Act 1956 (NZ)*; *Privacy Act 1993 (NZ)*); see McSherry, B, "Access to Medical Records: What Legislation Must Take into Account" (1997) 4 *Journal of Law and Medicine* 211; Blomberg, C, "Medical Records" in Freckelton and Peterson, above n 42.

¹²⁴ (1996) 138 ALR 259.

¹²⁵ For a provocative analysis of the case, see Olbourne, N "Patients' Access to Doctors' Records" (1998) 6(2) *Journal of Law and Medicine* (forthcoming).

¹²⁶ *Ibid*, at 263.

Dawson and Toohey JJ held that the contractual obligation of the doctor was to use reasonable care and skill in treating and advising the patient. They rejected the assertion that an incident of such duties was the provision of access to the patient's medical records. Gaudron and McHugh JJ held that a doctor does not impliedly promise to act in the best interests of the patient and found that the primary duty owed by the medical practitioner was to exercise reasonable care and skill. While they accepted that there is a tortious duty on the part of doctors to exercise reasonable care toward patients, they repudiated the implication of a general contractual duty of care and held that the uncertainty of "best interests" as an obligation further militated against the general implication of such a term.

The court had been pressed by the applicant for access to the records to follow Canadian case law¹²⁷ and to find a general relationship of fiduciary and beneficiary to exist between doctor and patient. However, the court did not accept such a characterisation, preferring to maintain the traditional English and Australian approach to fiduciary law and to find that aspects of the relationship are fiduciary and will be protected by equity where a doctor, for instance, exercises undue influence over a patient to their financial detriment.

The High Court's decision in *Breen v Williams* confirms the obligations of medical practitioners to take reasonable care in the provision for treatment and advice to patients where the failure to do so could result in a foreseeable risk of harm to their patients. However, it circumscribes significantly the extent of doctors' contractual duties to their patients. Most significantly, it has declined to characterise the relationship between medical practitioners and their patients as fundamentally fiduciary in the sense of this being a relation of unequals and "trust-like". The privacy interest of patients to know what has been generated about them in terms of notes and medical records is for the most part unenforceable save where statute intervenes to provide such a right.

¹²⁷ See, in particular, *McInernery v MacDonald* (1992) 93 DLR (4th) 415.

Rights of the mentally ill

The area of law probably most archetypally associated with the emergence of the legal protection of human rights in respect of health is that of mental health law. The past 30 years in Australia, as in other parts of the western world, have seen the emergence of substantial regulation of the circumstances in which the mentally ill can be involuntarily detained. The focus of the human rights lobby, which has been highly influential, has been to limit the autonomy of doctors to make decisions about the best interests of their psychiatric patients without being accountable and adhering to prescribed due processes, drafted to prevent the abuse or deprivation of liberty without just therapeutic cause. The past 30 years have seen the prescription of the processes of commitment by psychiatrists and the establishment of monitoring bodies, both review boards and tribunals, whose task it is to evaluate whether criteria for detention of those identified as mentally ill have been met. In addition, there has been increasing regulation of techniques of restraint and seclusion of those with mental illnesses who are housed within psychiatric institutions. Legislation has also stipulated in many jurisdictions when and how certain kinds of particularly intrusive treatment such as psychosurgery and electro-convulsive therapy can be administered.¹²⁸ To this extent, it can accurately be said that under mental health law, patients have been accorded statutory human rights to a degree unparalleled in other areas of medicine.¹²⁹

The more prescriptive medical environment that exists in relation to mental health law has generated a more sophisticated debate in some respects about consumers' health rights. In 1992 the Commonwealth Government in its National mental Health Policy endorsed the United Nations Principles for the Protection of Persons with Mental Illness. Such a step seemed to promise much for the rights of those with mental illness

¹²⁸ See Wilson, B and Freckelton, I, "Electroconvulsive Therapy: Ethical and Legal Issues" (1999) 6 *Journal of Law and Medicine* (forthcoming); Brookbanks, W, "Electro-convulsive Therapy and the Mental Health (Compulsory Assessment and Treatment) Act 1992 (NZ)" (1994) 1 *Journal of Law and Medicine* 184.

¹²⁹ See Appelbaum, PS, *Almost a Revolution: Mental Health Law and the Limits of Change* (Oxford University Press, New York, 1994).

to better treatment and facilities. Shortly afterwards, though, the Burdekin Report¹³⁰ in 1993 exposed an often-forgotten aspect of health rights – the fact that if adequate facilities for the provision of treatment are not available, this itself constitutes a serious impediment to a patient's potential to become well. Amongst many criticisms, the Burdekin Report made adverse findings in relation to the legislation in a number of Australian jurisdictions for having failed to ensure that the rights and freedoms of people with mental illness had been adequately protected.

Changes to legislation have taken place in most jurisdictions to implement the National Policy and to meet some of the criticisms levelled in the Burdekin Report.¹³¹ However, while greater specificity now exists in a number of jurisdictions in relation to the definition of mental illness, uncertainty remains about the difficult overlap between personality disorders and mental illness. Moreover, a number of commentators have accurately observed that the mentally ill have relatively few rights in relation to treatment which will meaningfully address their health when they are discharged from compulsory detention and returned to the community. Zifcak, for instance, has conceded that civil libertarian approaches to mental health law reform, while they have improved a number of the procedures for commitment of the mentally ill and ensconced due process in procedures for challenge to commitment decisions, have achieved relatively little in improving community care facilities, staffing levels, conditions, standards of conduct and treatment regimes.¹³² He has argued that mental health law now occupies a new space, influenced by the phenomena of deinstitutionalisation, mainstreaming of acute mental health services, the major provision of psychiatric services now being in the community, the decrease in funding of health services generally by governments, the role of managerialism in the delivery

¹³⁰ Human Rights and Equal Opportunity Commission, *Report of the National Inquiry into the Human Rights of People with Mental Illness* (AGPS, Canberra, 1993).

¹³¹ See, for instance, *Mental Health (Amendment) Act 1995* (Vic).

¹³² Zifcak, S, "The United Nations Principles for the Protection of People with mental Illness: Applications and Limitations" (1996) 3(1) *Psychiatry, Psychology and Law* 1 at 5; compare Delaney, S, "The United Nations Principles for the Protection of People With Mental Illness and Victorian Law" (1992) 18 *Melbourne University Law Review* 565.

of health services and the requirement for efficiency as a primary factor in health service delivery.¹³³

The Burdekin Report lambasted State and Territory governments for the quality of the follow-up available to persons discharged from psychiatric hospitals and pointed out the levels of homelessness among those recently involuntarily detained for mental illness. It also castigated the quality of boarding houses frequently resorted to by those with mental illness, the lack of support for families living with the mentally ill and the degree of poverty and discrimination against those with mental illnesses.

Little since the Burdekin report has changed save that the process of deinstitutionalisation has hastened. While patients who are involuntarily detained now possess a number of enshrined rights that regulate the circumstances of their detention, increasing numbers of still psychotic patients are discharged under pressure for hospital beds. Problems continue to exist with the coverage of disability discrimination legislation.¹³⁴ No appreciable increase in resources has been allocated for the escalating numbers of significantly symptomatic patients cared for within the community. In such circumstances, there is a real limit upon the extent to which it can be said that those with mental illness have rights to treatment and, in particular, to adequate treatment. A real issue within mental health law, as increasingly it is within the wider area of health law, is how patients can insist, with the assistance of the law, upon being provided with the treatment that they need for the alleviation of their pain and suffering.

Few cases in relation to the rights of the mentally ill reach the courts other than those in the criminal area in relation to insanity or unfitness to stand trial. A rare exception

¹³³ Zifcak, S, "Towards 2000: Rights, Responsibilities and Process in the Reform of Mental health Law" (1997) 4 *Australian Journal of Human Rights* 51 at 56-57.

¹³⁴ See Australian Law Reform Commission, *Making Rights Count: Services for People with a Disability*, Report No 79 (AGPS, Canberra, 1996).

was In the Matter of XY¹³⁵ where the Victorian Court of Appeal was required to determine whether an involuntary patient should be regarded as having been properly detained in a psychiatric hospital against his will and thus whether the Victorian Mental Health Review Board had jurisdiction to review his detention. The decision analysed what constituted due process for a person to be involuntarily detained and then found that if a person was in fact admitted and detained as an involuntary patient, even if technically wrongly so detained, they should not be disadvantaged by a technical illegality if they are in need of care and treatment. The court found that even if the person had not been properly detained, they should still enjoy the advantage of their status being reviewed by the mental Health Review Board. No recourse was overtly had by the Supreme Court to human rights principles or to international human rights instruments but the decision takes its place as a precedent supporting the right of persons detained to be accorded the right to have the propriety of their continued detention reviewed by an administrative review body, notwithstanding the possibility that their initial decision may have been wrongly determined.

However, legislation in a number of jurisdictions has latterly enunciated principles of treatment and care to which psychiatric patients are said to be entitled and objectives have been legislatively enshrined for the government health departments that have the responsibility for providing such treatment and care. For instance, s 6 of the Mental Health Act 1990 (NSW) states that the objectives of the New South Wales Health Department are to establish develop, promote, assist and encourage mental health services which:

develop, as far as practicable, standards and conditions of care and treatment for persons who are mentally ill or mentally disordered which are in all possible respects at least as beneficial as those provided for persons suffering from other forms of illness, and

¹³⁵ (1992) 2 MHRBD 501 (decided 6 March 1992 by the Victorian Court of Appeal). See also *Murray v Director-General, health and Community Services Victoria* (unreported, SC Vic, 23 June 1995) per Eames J.

take into account the various religious, cultural and language needs of those persons, and

are comprehensive and accessible, and

permit appropriate intervention at an early stage of mental illness, and

support the patient in the community and liaise with other providers of community services.¹³⁶

Similarly, s 4(1) sets out the objects of the Act in relation to the care, control and treatment of persons who are mentally ill and mentally disordered and s 4(2) stipulates that it is the intention of the New South Wales Parliament that every function, discretion and jurisdiction imposed by the Mental Health Act be performed or exercised so that:

persons who are mentally ill or mentally disordered receive the best possible care and treatment in the least restrictive environment enabling the care and treatment to be effectively given, and

in providing for the care and treatment of persons who are mentally ill or mentally disordered any restriction on the liberty of patients and other persons who are mentally disordered and any interference with their rights, dignity and self-respect are kept to a minimum in the circumstances.

In Victoria, the Mental Health (Amendment) Act 1995 introduced an even more extensive enshrinement of principles for the provision of services to those with mental illnesses. It listed a series of objectives for Victoria's mental health legislation, included amongst which are objects such as "to provide for the care, treatment and protection of mentally ill people who do not and cannot consent to that care, treatment and protection",¹³⁷ "to protect the rights of people with a mental disorder"¹³⁸ and to ensure that "people with a mental disorder are informed of and make use of the

¹³⁶ See also *Mental Health Act* 1996 (WA) s 5.

¹³⁷ *Mental Health Act* 1986 (Vic) s 4(1)(a).

¹³⁸ *Ibid* s4(1)(c).

provisions of this Act".¹³⁹ In addition, guidelines are listed for the interpretation of the legislation. These articulate values against which the legislation itself, the actions of the Department of Human Services and the behaviour of services providers and those reviewing their decisions can be measured. Important examples are that "people with a mental disorder are given the best possible care and treatment appropriate to their needs in the least possible restrictive environment and least possible intrusive manner consistent with the effective giving of that care and treatment",¹⁴⁰ and that "in providing for the care and treatment of people with a mental disorder and the protection of members of the public any restriction upon the liberty of patients and other people with a mental disorder and any interference with their rights, privacy, dignity and self-respect are kept to the minimum necessary in the circumstances".¹⁴¹

The legislation also states that it is the intention of the Victorian Parliament that a series of principles be given effect to with respect to the provision of treatment and care to people with a mental disorder. Included amongst these are that:

people with a mental disorder should be provided with timely and high quality treatment and care in accordance with professionally accepted standards;¹⁴²

wherever possible, people with a mental disorder should be treated in the community;¹⁴³

the provision of treatment and care should be "designed to assist people with a mental disorder to, wherever possible, live, work and participate in the community";¹⁴⁴

the provision of treatment and care for people with a mental disorder should promote and assist self-reliance;¹⁴⁵

¹³⁹ Ibid s4(1)(e).

¹⁴⁰ Ibid s4(1)(a).

¹⁴¹ Ibid s4(1)(b).

¹⁴² Ibid s 6A(a).

¹⁴³ Ibid s 6A(b).

¹⁴⁴ Ibid s 6A(c).

people with a mental disorder should be provided with appropriate and comprehensive information about their mental disorder, proposed and alternative treatments, including medication, and services available to meet their needs;¹⁴⁶

when receiving treatment and care the age-related, gender-related, religious, cultural, language and other special needs of people with a mental disorder should be taken into consideration;¹⁴⁷

treatment and care should be provided by appropriately qualified people and within a multi-disciplinary framework;¹⁴⁸ and

every effort that is reasonably practicable should be made to involve a person with a mental disorder in the development of an ongoing treatment plan.¹⁴⁹

The significant issue from a legal point of view that arises from the existence of these provisions has not as yet been tested in the courts. What the enunciation of these principles makes possible is challenge to decisions and the provision of care on the basis that they are not in accordance with the principles set out in the legislation. For instance, where the provision of care has failed to take into account the right of a person to care that is in accordance with professionally accepted standards because of fiscal restraints, an avenue for litigation is available. Where the provision of treatment has not been fashioned so as to assist a person with a mental disorder to work or return to work, this again may open up a means of redress. Similarly, if persons are treated at a place that is convenient to the treaters but against the patient's wishes, or is significantly geographically removed from the residence of their relatives, this may afford a means of challenge where previously none existed. While these provisions are new and as yet untested, they have the potential to enable a substantial number of court challenges in respect of the compliance by service providers with the intentions of

¹⁴⁵ Ibid s 6A(d).

¹⁴⁶ Ibid s 6A(e).

¹⁴⁷ Ibid s 6A(g).

¹⁴⁸ Ibid s 6A(i).

¹⁴⁹ Ibid s 6A(j).

Parliament as articulated in the codified principles for the treatment and care of those with mental disorders.

CONCLUSIONS

Relatively few rights exist under contemporary Australian law to assist those disadvantaged by illness. For those who are mentally ill or intellectually disabled, support and advocacy services are so inadequate, and the availability of legal aid is now so limited, that those few rights which they might loosely be said to possess cannot any longer be said to be meaningfully accessible.

Australia is a signatory to a number of relevant international human rights instruments, but the utility of these in directly affording protection to patients or in providing to them a means of enforcing a civil remedy against those who have impoverished their health is minimal. Those rights that do exist in respect of health have been little and narrowly articulated by Australian jurisprudence. By and large, there has been acknowledgment that patients are entitled not to be subject to treatment that affects their bodily integrity without their having provided their consent and having been advised of the risks and options in respect of the treatment. However, even with respect to so fundamental an entitlement, enforceable principally under the civil law, it has not been the subject of coherent and principled analysis within a rights discourse. Interpretation of the right has been limited to argument for the most part about whether provision of information in the context of a particular case has been adequate and whether an individual plaintiff can be said to have provided consent to treatment. This is not particularly surprising as rights for those adversely affected by medical procedures by and large exist under the civil law and only to the extent that economically quantifiable damages are available as a result of negligence, break of implied terms of the therapeutic contract, by reason of nuisance, breach of fiduciary duty or assault to the person.

However, means for patients to assert rights not only to treatment but to treatment that accords with the principles underlying the international human rights instruments to which Australia is signatory have been created by the enactment of guidelines and objects clauses within legislation binding those supplying health care services,

especially in the public sector.¹⁵⁰ The advent of such provisions at least in principle is creating a way in which individual grievances about the practices and priorities within the public health care system in Australia may become actionable using human rights principles. Such legislation has for the first time provided a bridge between human rights discourse and the forensically enforceable provision of health care.

¹⁵⁰ See Laufer, S, "A Code of Health Rights and Responsibilities: the Adequacy of Existing Recognition and Protection" (1994) 1 *Journal of Law and Medicine* 168 who instanced a range of statutory examples of the enunciation of such principles in Queensland: see, for example, *Health Services Act 1991* (Qld) s3.18(2)(a); *Disability Services Act 1992* (Qld); *Medicare Agreements Act 1992* (Cth); *Health Rights Commission Act 1991* (Qld) ss 37ff; *Health Act 1958* (Vic) s 119. However, it needs to be acknowledged that the attempt in *Shortland v Northland Health* (unreported, CA NZ, 10 November 1997, CA 230/7) to utilise guidelines for the provision of health care by way of an administrative law challenge was unsuccessful: see above.

Healthcare rationing, patient rights and the law.

Loff B, Majoor JW.

MJA. 2001. 174: 473-4.

We need frank discussion of healthcare rationing in Australia

Everyday in Australia, healthcare services and providers make resource allocation decisions on grounds that are not necessarily transparent or public. These implicit resource allocation decisions include, for instance, a hospital going on ambulance bypass or condoning long elective surgical waiting lists. Explicit healthcare resource allocation decisions in Australia are made by the legislature; the more widely recognised instruments of this resource allocation are the Medicare Benefits Schedule and the Pharmaceutical Benefits Schedule. Further rationing decisions, although not commonly perceived as such, are contained in the Australian Health Care Agreements, which establish the Commonwealth's contribution to the maintenance of State and Territory public hospital services.

In Australia, courts play only a minor role in resource allocation, and usually intervene only when healthcare negligence or discrimination is alleged. The impact of negligence litigation has been much debated and need not be discussed here.¹ Victoria's IVF legislation was challenged last year in *McBain v State of Victoria* on the grounds of discrimination.² The law in Victoria did not allow access to IVF services for single women; women had to be married or living in genuine de facto circumstances. The Federal Court found this aspect of Victoria's legislation to be invalid. The few examples of court interference in Australia that do not fall within negligence or discrimination relate to overservicing^{3,4} or challenges to decisions of the Pharmaceutical Benefits Advisory Committee (PBAC).⁵ For example, in the Federal Court last year, in the case of *Pfizer v Birkett*, Pfizer challenged the decision of the PBAC to deny a subsidy for Viagra (sildenafil). In her judgment, Matthews J noted:

I should commence by emphasizing the limited role of this Court in reviewing the decisions of administrative decision-makers. It is not the function of the Court to

review the merits of these decisions. Its role is to ensure that administrative decisions are reached according to law, that proper procedures are followed and that appropriate considerations are taken into account. Unless a decision is so manifestly unreasonable that no reasonable decision-maker could have made it, the Court will not intervene in the fact-finding process or otherwise explore the merits of the case.⁵

Pfizer is currently appealing the court's decision to uphold the PBAC's ruling.

Should a particular individual or group not have access to new drugs or services, there may be an opportunity for redress through the courts, on a range of grounds such as we have described.

The situation differs in the United States. On 13 July 2000, the US Supreme Court handed down its decision in the case of *Pegram v Herdrich* (Box).⁶ Although this case arises out of the context of managed care, it is of interest to us because the US Supreme Court gave its imprimatur to rationing within healthcare.

Two main issues are embodied in this case. The first is primarily a legal one that pertains to the interface between state and federal law in the United States and is not relevant to our discussion. The second issue is a complex ethical and medicolegal one and relates to the trade-off between clinical risk and cost-containment strategies. In June 2000, the American Medical Association stated in a press release that the case "provides a compelling argument for a strong patients' bill of rights".⁸ In effect, the organization was suggesting that an independent mechanism is necessary to protect patient health and minimum entitlements because HMOs can not be trusted to do so. Of course, not all would agree with this view.

Are there implications of *Pegram v Herdrich* for Australia? On the legal front, as noted in *Pfizer v Birkett*,⁵ Australian courts are loath to interfere in resourcing decisions of government bodies unless a decision is "so manifestly unreasonable that no reasonable decision maker could have made it"; an example of such a decision would be failing to provide medical services to prisoners. The avenue for consumer redress in matters of healthcare rationing, regardless of recommendations resulting from coronial inquiries or other expert sources, would tend to be political rather than legal. For instance, long elective surgery waiting lists attract media attention rather than litigation based upon delays in treatment and resultant harm. Legislating for the rights of healthcare

consumers might alter this position, as courts might then be empowered to measure provision of services against statutory criteria.

We suggest that individual medical practitioners have both a fiduciary duty to the patient and a responsibility to use resources efficiently and effectively. These two duties are often felt to be mutually exclusive, and doctors often resent the reality of limited resources in healthcare. In general practice, constraints are imposed by both the pressure of the waiting room and the Medicare system. In hospitals, resource constraints may be forced by limiting staff or supplies. There are more complex issues that arise in rural, remote and Aboriginal healthcare. Rationing is a fact of life for Australian medical practitioners but, unlike doctors in US managed care or the UK fundholding system, Australian doctors have been protected from having to acknowledge openly their role in it.

Our medical practitioners fear that US-style managed care and health maintenance organizations (HMOs) will be imported into Australia. Successful campaigns have already been waged defeating the possibility of private insurance companies extending their influence over clinical medical decision-making.⁹⁻¹¹ The recent amendment to the National Health Act 1953 (Cwlth) relating to medical purchaser provider agreements provides that such agreements must "maintain the medical practitioner's medical freedom within the scope of accepted clinical practice to identify appropriate treatments in the rendering of professional services to which the agreement applies".¹² *Pegram v Herdrich* will undoubtedly be cited in future discussion as an example of the ills of HMOs and their mandate to reduce expenditure. However, although HMO-style managed care has been avoided in Australia, the healthcare system is still subject to cost-containment strategies to accommodate increasingly scarce resources. Although rationing within the Australian healthcare system is not discussed openly, it is implicitly understood that rationing occurs. We need more frank public debate on how we manage our resources rather than sporadic and superficial media attention.

Pegram v Herdrich highlights that cost-containment can have a price and, if that price is quality of care, the system is in trouble. There is no doubt that there is a need to transparently and scientifically measure and monitor the effects of managerial financial decision-making and its impact on clinical outcomes. This should be done against clearly defined and agreed criteria. This applies to both the public and private sectors,

whether managed care exists or not. The scientific evaluation of clinical outcomes and quality of care is a continuing challenge that we should not shy away from on the basis of difficulty, medical dominance, or the mistaken view that this is a wasteful effort by the "bean counters".

Pegram v Herdrich⁶ (Supreme Court of the United States)

Lori Pegram, a doctor employed by a health maintenance organization (HMO), examined Cynthia Herdrich. Herdrich was experiencing abdominal pain. Six days later, Dr Pegram found a six by eight centimeter inflamed mass in Herdrich's right iliac fossa. However, rather than ordering an ultrasound of the area at the local hospital, Dr Pegram decided that Herdrich should wait eight days so the procedure could be performed at a clinic operated by the HMO, more than 50 miles away. Before the day of her ultrasound appointment, Herdrich's appendix ruptured.

Herdrich successfully sued Dr Pegram under state law for medical malpractice. She also brought an action against the HMO under the federal Employment Retirement Income Security Act of 1974,⁷ stating that the HMO was in breach of its fiduciary duty of care to plan members. The basis of this claim was that the HMO had deprived plan beneficiaries of proper medical care on financial grounds and retained the resulting savings in what could be thought to be a conflict of interest.

The US Supreme Court found unanimously that "since inducement to ration goes to the very point of any HMO scheme, and rationing necessarily raises some risks while reducing others (ruptured appendices are more likely; unnecessary appendectomies are less so), any legal principle purporting to draw a line between good and bad HMOs would embody, in effect, a judgment about socially acceptable medical risk". This the Court preferred to leave to the US Congress. Thus simply because the owners of the HMO provided an end-of-year distribution to themselves of profits derived from the difference between subscription income and expenses of care and administration, this was not a sufficient basis for the Court to find against them.

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Chapter Seven: Health And Human Rights Issues Pertinent Indigenous Australians and to Refugees

This chapter contains two articles dealing with the health of Indigenous Australians that were peer reviewed and other published items dealing with Aboriginal health and human rights. The chapter also contains two pieces dealing with detention of refugees. Of the two papers dealing with detention only one paper was peer reviewed, the paper entitled "Detention of Asylum Seekers in Australia" and authored by myself.

Monash University

Declaration for Thesis Chapter 7

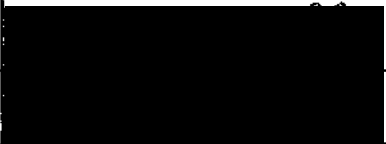
In the case of chapter 7, contributions to the paper "Aboriginal reconciliation still a long way to go" Lancet 2000; 355: 2070", involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
Ian Anderson	50%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		24.06.04
Signature 2		21/6/04

Voices lost: Indigenous health and human rights in Australia

Ian Anderson, Bebe Loff

THE LANCET • Vol 364 • 2004 ??-??

Australians will soon be spending another Saturday morning at the polling booth, voting to decide who will lead their country for the next 3 years. Although health funding and policy have been key issues leading up to the polls, a specific Indigenous health policy remains far down the list of priorities for both parties. The health status of Indigenous Australians remains a national disgrace. Life expectancy and disease prevalence in this group is worse than that in many developing countries. And unless the social context in which Indigenous Australians find themselves is more appropriately addressed, current health development strategies will continue to fail.

For 1999-2001, life expectancy at birth for Indigenous Australians was 56 years for men and 63 years for women; for all Australians, the figures were 77 years 82 years, respectively.² The greatest differences in death rates occur in people aged between 35-44 years and 45-54 years, where mortality for Indigenous men and women is up to five times greater than that in the general population.² Indigenous Australians also encounter a significant burden of morbidity, as a consequence of chronic disease (such as diabetes, circulatory system disease, end-stage renal disease), infectious diseases (such as pneumococcal disease, hepatitis B, or sexually transmissible infections) and mental health.³

In a national study of expenditure in the 1989-99 financial year, 2.6% of all health expenditure was on services for Indigenous Australians.⁴ The study captured spending on Indigenous-specific and general programmes, and in both government and private sectors. For each dollar spent on health services for non-Indigenous Australians, \$1.22 was spent on health services for Indigenous people.⁴ In view of the extent of Aboriginal disadvantage in health, this amount is surprisingly small and highlights significant problems in the allocation of health care resources relative to

need. Although there is much debate about what methods might be applied to enable needs-based allocation of resources, there are no protagonists in the debate who suggest that current levels of health funding for Indigenous Australians are adequate.

There has also been much discussion about models of health care that would provide greatest benefit. Current patterns of health spending show that Indigenous Australians use tertiary care at a higher rate than do non-Indigenous Australians. Expenditure on Indigenous people in public hospitals is twice as much per person. On the other hand, outlay through the Medical and Pharmaceutical Benefits Schemes (mainstream primary-care subsidy schemes) is much lower for Aboriginal people-per person spending through these two programmes was 37% of that for non-Indigenous people. Aboriginal per person expenditure on private sector services was only 23% of that for non-Indigenous people.

Before 1996, when the current government gained power, some gains had been achieved in furthering the recognition of Indigenous rights. The politically conservative agenda that has now emerged has wound back these gains and forced a shift to narrowly focused programmes. Emblematic of the growth of the conservative agenda in Aboriginal affairs, was the decision in April 2004, to abolish the Aboriginal and Torres Strait Islander Commission (ATSIC). ATSIC, established in 1989, brought together a range of existing federal programmes, to form a structure in which regional councils (with elected Indigenous regional councillors) were responsible for regional allocation of resources.

The board of Commissioners, elected by ATSIC regional councils, was responsible for national policy development and the oversight of national programmes. In merging democratic processes with programme administration, ATSIC represented an important development in Indigenous self-determination.

From the beginning, the relationship between the conservative Government and ATSIC was problematic. On one side, the Government continually raised concerns about corruption in ATSIC, and to a lesser extent, there was unease emanating from the Indigenous community about the effectiveness of the Commission. On the other side, ATSIC leaders resolutely refused to sign-up to the Government's conservative agenda. Instead, they campaigned for Indigenous rights, and supported native title and

other symbolic issues, such as a more inclusive approach to the telling of Australian history. Between these two disparate positions were those advocating reforms in ATSIC, but championing some of the critical values, including Indigenous self-representation that ATSIC had come to symbolise.

A Government-commissioned review of ATSIC recommended that the Commission be retained as the primary vehicle for representing the aspirations of Aboriginal people to all levels of government and as an agent for positive change in the development of Indigenous policy and programmes. Despite this report, the government abolished ATSIC. More tellingly, the proposed new structures for the administration of Aboriginal programmes at a national level have no provision for any form of democratically elected Aboriginal representation.

Furthermore, in advancing an agenda that is antagonistic to the symbolic recognition of oppression (such as the acknowledgment of an Aboriginal history or the provision of apologies for past ill-treatment) and resistant to any form of political process that suggests that Indigenous Australians have a distinct political history and rights flowing from their status as a colonised population, the Howard coalition government has alienated Aboriginal people. Such alienation has, then, compromised their cooperation with the more practical 'bricks and mortar' agenda in areas such as health.

The current government has actually had quite a good record of increasing resources to Indigenous primary health care programmes. Yet, increasing the capacity of primary health care services is unlikely to yield substantial improvement in Indigenous health. If Aboriginal people have no voice, if there is no capacity for self-government, if there is no means for coming together to identify and address problems, there cannot be any hope of progress in addressing the appalling disparities between the health of Indigenous and non-Indigenous Australians. A "practical" agenda will come to nought. It is remarkable that this simple fact continues to be ignored.

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Aboriginal reconciliation still a long way to go

THE LANCET • Vol 355 • June 10, 2000 • 2070

The Australian Council for Aboriginal Reconciliation was set up a decade ago with a 10-year mission to deal with unresolved issues between Aboriginal and non-Aboriginal Australians. On May 27, 2000 a national document of reconciliation was launched. Instead of a celebration, the event may only signal further deterioration in the relationship between Aboriginal people and the Australian government.

In the Northern Territory recent mandatory sentencing provisions state that for a third offence, no matter how trivial, the penalty is 1 year in prison. These laws apply to juveniles aged 15–17 years and adults. Aborigines constitute only 28·5% of the Territory's population comprise, but 70% of the prison population.

For his second offence—stealing oil and paints worth Aus\$40—Johnno Warramarra was sentenced to 28 days in detention. His first offence had been the theft of a pen and felt-tip pens worth Aus\$50. His parents were dead and his Aunt had died shortly before of kidney failure, an endemic problem in the Aboriginal community. The magistrate was unable to exercise discretion. Johnno Warramarra committed suicide in the detention centre. An Aboriginal woman, Margaret Nalyirri Wynbyne was convicted of stealing a can of beer. She was sentenced to 14 days in prison, which meant that she was separated from her breastfeeding child.

Australian diplomats were instructed to negotiate a watering down of impending UN condemnation on this issue. A critical report was to have been issued finding that Australian law breached a number of conventions. After meetings with UN agencies, a document was released without the concluding findings.

The Committee on the Elimination of Racial Discrimination subsequently issued a damning report, commenting both on sentencing laws and the government's watering down of native title laws. This caused the government to institute a review of its participation in the UN treaty system.

The Commonwealth government also recently chose to argue at a Senate Committee hearing that there had never been a "stolen generation". This term, long in use in Aboriginal English to refer to past child-removal practices, was adopted by the 1997 National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families. As an explanation, Senator John Herron said that according to the best estimates from the Australian Bureau of Statistics only 10% of a generation, not a whole generation of Aboriginal children, had been removed from their parents as part of a government programme of forced assimilation. This argument also reflects a broader position being promoted that these child-removal policies were benign in intent, which has been gaining currency in one of Australia's more influential right-wing journals. Despite this, the anguish of many Aboriginal families who witnessed or suffered the devastating effect of child removal was palpable in the Australian media in the days after the release of the Senate Committee submission. Not even an outpouring of Aboriginal grief moved the Prime Minister, who eventually apologised for upsetting people through the presentation of the argument (but not for its content). He continues to refuse to apologise on behalf of the Australian government for the removal of Aboriginal children arguing that his government and the Australian people cannot be held accountable for mistakes of previous generations.

The Prime Minister initially refused to intervene in the mandatory sentencing debacle. This reluctance was surprising in light of the recommendations from the 1991 Royal Commission into Aboriginal Deaths in Custody to develop strategies to divert Aboriginal offenders from the prison system. With mounting party pressure from government moderates, and rumoured unfavourable public polling, negotiations eventually took place with the Chief Minister of the Territory. The Federal government finally offered to provide the Territory with funds for a diversionary programme to be implemented by police so juveniles are not sent to court after a first offence.

The Prime Minister's first public act when elected was to launch, alongside his Minister for Aboriginal Affairs, a stinging attack on the "Aboriginal industry". Since that time relationships with indigenous Australians have deteriorated. It is difficult to foresee any reconciliation.

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Aboriginal people trade land claim for dialysis.

Bebe Loff, Stephen Cordner.

Dispatches **THE LANCET** • Vol 352 • Oct 31, 1998 • 1451

A representative of Michael Reed, the member of government for Katherine, Northern Territory, Australia, has denied that it was his intention to do a deal in which a land claim by the Jawoyn aboriginal community was traded for an alcohol-rehabilitation centre and two renal-dialysis machines. Aboriginal people in this part of Australia have renal disease at a rate that is about fifty times the Australian national average; the average Aboriginal life expectancy from time of diagnosis is 233 days.

It transpires that the land claim would have limited a local horticultural development and the Jawoyn community had been approached to lift the claim. It has also been alleged that the government had illegally issued licences to parties to use the land. In any event, the government had not advised the Jawoyn of the horticulture project, which they are obliged to do under native title and land rights legislation.

The Jawoyn traditional owners had originally decided to trade their land claim for the much-needed health services but the government had refused to negotiate for 2 months. The reason for this initial refusal is unclear, but is not surprising since no other person or group in Australia is required to make a direct payment for renal dialysis equipment.

The Northern Lands Council, an aboriginal agency with responsibility for land claims, is the legal representative of the Jawoyn and has the obligation to ensure that aboriginal owners are fully consulted in any matter that relates to their land. The council had encouraged the community to seek some recompense in exchange for agreeing to lift the claim.

Nevertheless, the council have subsequently said that "trading away your land for services that the government should be providing anyway is very serious business and creates a dangerous precedent". The governing body of the council has instructed it to

go back to the Jawoyn to discuss the issue and to encourage the government to deliver adequate health services to aboriginal people free of the requirement that aboriginal people trade their land rights.

The Jawoyn have said "some may be critical of land being exchanged for community services, but the old people said there are no sacred sites here; there are no ceremony places; it is not a hunting area. We worry about countrymen with kidney disease and our people on the grog . . . Renal disease is affecting many, many people in the Katherine region--especially aboriginal people. Until now people with end-stage renal disease have been forced to move to Darwin for dialysis. This has been destructive of family life and has forced people to leave the traditional land that they love".

Officers of the Northern Territory Department of Health seemed to be surprised to hear that the deal had taken place because a budget allocation for the dialysis equipment had already been approved for the current financial year. This information was available to Reed. The Jawoyn have also agreed to contribute A\$20 000 of their funds for the dialysis equipment, stating that although the allocation had been made they were not hopeful of seeing this commitment fulfilled for several years.

The vice president of the Australian Medical Association, Sandra Hacker, was quoted as saying "it is clearly not proper to barter for health care . . . These are health provisions that non-indigenous Australians consider ought to be provided at their major city hospitals . . . I think it's an extraordinarily sad thing that aboriginal people feel this is the only option that they've got".

A representative of the Jawoyn has said that if this deal were to form a precedent it would be a tragedy.

Aborigines raise money for dialysis treatment.

(News) Bebe Loff; Stephen Cordner

THE LANCET • Vol 356 • 25 Nov, 2000 • 1830

In 1998 the Jawoyn Aboriginal community in the Northern Territory of Australia agreed to trade their land claim for much needed renal dialysis services and an alcohol rehabilitation centre (see *Lancet* 1998; 352: 1451). The community was concerned that its members could only receive treatment in Darwin and would probably die there, miles away from family. The Jawoyn had hoped that this would not create a precedent. Unfortunately, in a country where there is supposed to be universal access to publicly funded health services, it seems that another Aboriginal community has made a similar choice.

A high proportion of Aborigines have renal problems. Members of the Kintore community, often the respected elders, must travel 500 km for dialysis services. When treatment is required several times a week there is no choice but to move to Alice Springs. Many of these patients do not speak English and are not familiar with non-indigenous culture. Some aborigines have refused to go.

To compound the Kintore community's problem, the government of the Northern Territory decided not to provide funding for a renal unit in the Kintore area. However, several well-known artists lived in the community and an auction of their art held by Sotheby's in London, UK raised Aus\$1 million, and a dialysis unit will be built in Kintore next year.

Critics have argued that the provision of dialysis services does not attack the root cause of the problem faced in Aboriginal communities or that there are other areas where money might be better spent. But in the face of the need for this service in a country like Australia, these arguments have a hollow ring. Some have suggested that such criticisms would not even be considered in non-indigenous Australia.

Australian Aboriginal leaders tackle welfare of indigenous population.

(News) Bebe Loff, Stephen Cordner.

THE LANCET • Vol 358 • 22 Dec, 2001 • 2138

Australian Aboriginal community leaders finalised plans to address family violence on Dec 6, in the wake of the publication of allegations concerning physical and sexual assault in indigenous communities earlier in the year.

The first national Indigenous Women, Men and Youth Roundtable on Family Violence has called for more solid commitment by federal and state governments to tackle family violence in indigenous communities. The Roundtable endorsed the formation of a working group to deal with the problem, which it described as being of "plague proportions". The group will first do an audit of programmes dealing with family violence, examine their effectiveness and identify whether the money set aside for the programmes actually reaches the target communities.

The Aboriginal and Torres Strait Islander Commission, Australia's national policy making and service delivery agency for indigenous people, comprised of elected indigenous representatives, has been concerned about this issue for some years. The Commission's Social Justice Commissioner Brian Butler said that "I have been impressed by the level of commitment shown by delegates to tackling problems of violence in indigenous communities.

The new plans follow the publication in November of The Cape York Justice study, which was established by the government of Queensland and investigated violence in indigenous communities in the Cape York Peninsula of Queensland. Queensland Premier, Peter Beattie, noted that there was widespread agreement with the recommendations of the landmark study that attitudinal and behavioural changes, which are essential to the survival of communities, is best brought about by the people themselves.

Tony Fitzgerald, the lead investigator on the study, identified the reduction of alcohol and substance abuse as key issues. The study notes that while the current circumstances of these communities are "linked to their history of invasion, dispossession, dislocation, institutionalisation and the destruction of traditional economies" indicators of current dysfunction are rooted in welfare dependency.

There is a clear connection between paydays, alcohol abuse, violence, and crime demonstrated by hospital admission data--admissions are significantly higher on Thursdays and Fridays. "All we want is for the violence to stop . . . we as a community have to try to address to issues of alcohol, drugs, and violence", said Fitzgerald in the Cape York study.

Death rate of aborigines in prison is increasing.

(News) Bebe Loff, Stephen Cordner.

THE LANCET • Vol 357 • 28 April, 2001 • 1348

Almost three times as many Aboriginal people are dying in prison than in the past decade, according to a new report by the Australian Institute of Criminology.

In 1991, the report of the Royal Commission into Aboriginal Deaths In Custody (RCIADIC) made 339 recommendations to Australian governments, which aimed to reduce the rate of Aboriginal deaths in police custody. The new report, *Deaths in Custody: 10 Years on from the Royal Commission*, compares the number and circumstances of deaths in custody for the decade examined by the Commission with those which have occurred in the decade since.

According to the report the average annual rate of death in custody for indigenous people decreased from 4.4 deaths per 100 000 people between 1980 and 1989, to 3.8 deaths per 100 000 people between 1990 and 1999. The Institute reported that as a proportion of all deaths in custody or police operations, deaths of indigenous people decreased from 21% to 18 %. Deaths of Aborigines in police custody decreased from 32% between 1980 and 1989 to 15% between 1990 and 1999. On the other hand, deaths in prisons increased from 67% to 84%, in real terms almost three times as many people as in the previous decade.

The RCIADIC found that the high number of Aboriginal deaths in custody reflected a "glaring over-representation of Aborigines in custody" (see *Lancet* 1998; 352: 1800) and this continues to be the case. That report and others since have called for a response to the systematic discrimination against Aboriginal people in the Australian community. Nevertheless with the introduction of mandatory sentencing policies for minor offences in Australian jurisdictions with large Aboriginal populations (see *Lancet* 200; 355: 2070) the situation could deteriorate. Not so long ago Johnno Warramarra, sentenced under this regime to 28 days detention for his second offence,

that of stealing paints worth Aus\$40, committed suicide in custody. Others have since followed.

UN condemns Australia over Aborigines.

Bebe Loff, Stephen Cordner

THE LANCET • Vol 356 • Sept 16, 2000 • 1011

(News) (Statistical Data Included) (Brief Article).

On Sept 3, the United Nations Committee for Economic Social and Cultural Rights roundly condemned Australia for its continuing failure to improve the status of Aboriginal Australians. The committee of 18 experts met between Aug 14 and Sept 1 and chose to express its "deep concern" about the position of indigenous Australians and discrimination in the area of health and other economic, social, and cultural rights.

Aboriginal Australians continue to have poorer health, substantially lower life expectancy, high maternal infant and mortality rates, and higher rates of infectious diseases. The Committee had previously noted that, despite commitments by the Australian government to improve housing for Aborigines, there have been forced evictions from the Sydney Aborigine suburb, Redfern, because of its proximity to the Olympic City centre. Aboriginal groups have said that they intend to conduct peaceful protests during the period of the Olympic games.

In response to this and earlier criticisms of the status of Aboriginal Australians by other United Nations committees, the Federal government of Australia has decided, among much domestic controversy, to limit its participation with United Nations committees. The government has also decided not to sign the Optional Protocol to the Convention on the Elimination of All Forms of Discrimination Against Women. This, when in force, will allow women to bring complaints of discrimination, including discrimination in the area of health care, to the United Nations. Before this recent announcement Australia had been actively lobbying for the introduction of the Optional Protocol.

Detention of asylum seekers in Australia

THE LANCET • Vol 359 • March 2, 2002 • 792

Detention is the most draconian punishment known to most liberal democratic societies. To incarcerate a person for an indefinite period when they have committed no crime is difficult to justify under any circumstances. Australia places many asylum seekers, most of whom have suffered past trauma, including torture, in open-ended terms of detention. Terms of 4 years or more are not uncommon. Children are not exempt from such treatment, whether or not accompanied by a family member. The health effects of detention have been previously documented (see Lancet 2001; 357: 1436–37). In addition, recent reports¹ indicate that compromises are being made in the provision of ethical health care offered by the private company Australasian Correctional Management (ACM), which is responsible for the running of the detention centres in Australia on behalf of the federal government. There have been continuing acts of self-injury, hunger strikes, and attempted suicide in Australia's six detention centres and similar tales in the newly established Australian-funded centres in Pacific countries of Papua New Guinea and Nauru. On more than one occasion in recent years, asylum seekers have sewn their lips together to draw attention to the hopelessness of their situation. In August, 2000, ACM used tear gas, and for the first time in Australian history, water cannons to quell a riot in one of the centres.¹

A recent edition of the Medical Journal of Australia featured discussion on the health of asylum seekers. Of note was the impact of detention itself, compounding the psychological effects of earlier experience under inhumane regimes.² Detainees may be called by number not name, and are subject to line-ups, head counts, and room searches, often at night. Asylum seekers may be placed in solitary confinement. Detainees commonly lack meaningful activities. These conditions, characteristic of imprisonment, are hard to justify. Of particular concern are the effects on children. As A Sultan and K O'Sullivan note² "A wide range of psychological disturbances are commonly observed among children . . . At the most severe end of the spectrum, a number of children have displayed profound symptoms of psychological distress, including mutism, stereotypic behaviours, and refusal to eat or drink."

ACM is responsible for the provision of health care to detainees. Nurses work in the centres and general practitioners, who do not necessarily have relevant experience (see Lancet 2001; 359: 683) are commonly contracted and seen by appointment. Consultations sometimes occur in the presence of guards. Access to medical care at times other than the contracted periods must be negotiated through staff. If official escorts are unavailable, appointments may be cancelled. Should a detainee require treatment outside a centre or admission to hospital, they may be handcuffed or otherwise restrained and accompanied by one or more guards. The Australian Medical Association has asserted that detainees are often deprived of basic medical care, particularly emergency care. It has argued that the government should provide temporary access to Australia's universal subsidised system of health care.

The Royal Australian and New Zealand College of Psychiatrists has been outspoken in raising the ethical concerns for medical practitioners working in the centres. Without calling for a ban on medical practitioners working for ACM, the college has stated that medical professionals need to seriously consider the ethical implications of accepting such positions given the inadequacy of health services available in the centres. Louise Newman, the Chair of the Faculty of Child and Adolescent Psychiatry told The Lancet "Medical practitioners face the dilemma of an intrinsic conflict between the desire to provide appropriate care, and the compromising of this by supporting a pathological system. This is similar to the issues that confronted doctors in Soviet Russia or Nazi Germany."

An incomplete version of the contract between ACM and the federal government for the running of immigration detention centres is publicly available (www.immi.gov.au/illegals/acs.htm). Medical officers are to monitor solitary confinement, and chemical restraints may be used only under medical or nursing supervision. In at least one instance, however, a general practitioner gave authority to an accompanying nurse to apply chemical restraint with haloperidol to avoid difficult behaviour by a family being forcibly deported.

The ACM contract for health-care professionals working at the centres states that the care needs of detainees are to be regularly monitored and they are to be provided with necessary care and reasonable dental treatment. Expectant mothers are to have access to antenatal and postnatal services. There is now substantial evidence to suggest that

these contractual obligations have not been met. Yet it is difficult to ascertain what action is being taken by the government on these issues.

Australia must remain true to its traditions of welcoming people who have fled there fearing persecution in their original homeland. Despite mounting criticism, the Australian government continues to assert that it is not in breach of its international obligations to asylum seekers. But what of health-care personnel in their provision of care? In 1982 the UN General Assembly came to the decision that "Health personnel, particularly physicians, charged with the medical care of prisoners and detainees have a duty to provide them with protection of their physical and mental health and treatment of disease of the same quality and standard as is afforded to those who are not imprisoned or detained". This standard is not being uniformly upheld.

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“Inside” Australia’s Woomera detention centre

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On Feb 6, the Australian Human Rights and Equal Opportunity Commission announced that the Woomera Immigration Reception and Processing Centre is in breach of several articles of the Convention on the Rights of the Child, to which Australia is a signatory. Woomera, in South Australia, is the newest of three national processing centres, which are mainly used to hold unauthorised asylum seekers who arrive by boat. Another three detention centres house people in breach of visa conditions, and a further four centres are planned. In January this year, the number of people incarcerated at the Woomera centre fell to around 650 asylum seekers from a peak of around 1400 late last year. Conditions are now less crowded, but detainees still face harsh conditions. Woomera is located in Australia’s isolated desert heart, where temperatures reach up to 50°C. Independent observers have great difficulty getting inside Woomera. However, information we have gathered during inter-views with ex-detainees and centre staff paints a picture of a grim and punitive environment.

Staff and ex-detainees we have interviewed describe the compound as U-shaped. Detainees are assigned to sections according to the stage of processing of their immigration application. People from different sections cannot easily communicate with each other except by shouting. A grassed administration complex sits in the centre of the compound, separated from the asylum seekers’ quarters by a double razor-wire fence and outside the perimeter fence, two water cannons are ready for use.

Many families live in portable units. Air conditioning is often broken and sometimes these units house two families separated by only a curtain. Others live in very small rooms or dormitories. Personal belongings, including photographs, are taken from detainees when they arrive. Children don’t have enough room to crawl or play inside, and the climate is too extreme for outside play.

According to the staff and ex-detainees we have spoken to, four musters are held every 24 h, some-times at night—staff shine torches into peoples’ faces to identify

them. Detainees are identified by number and have reported feeling dehumanised by this process.

Housing units have no running water, and the toilet block can be up to 500 m away. Because of the distance, children have been known to wait until they are incontinent. Visiting specialist professionals with limited access have noticed mat-tresses left drying in the sun. When the camp was set up in November, 1999, water for washing and drinking was available only in the toilet blocks. Water ran hot because the pipes were exposed to the sun. People tried to run the water long enough for it to become cool, but were reprimanded for being wasteful. Eventually, detainees were given small tanks for storing drinking water.

Meals in the centre are provided in an area some distance from the accommodation. Food consists largely of rice, vegetables, and meat thought unpalatable by detainees because it is badly cooked. Furthermore, despite official assurances, the Muslim asylum seekers are not convinced that the meat is halal. Some of the women help with cleaning the kitchen and chopping food. Detainees volunteer but are not allowed to help with the cooking. Because many children do not like the food, parents supplement their diets with crisps and sweets if they can afford them, and some children are reported to have lost weight.

Education is available only for children aged 12 years and younger, several older children receive almost no schooling. Teaching was provided in one portable unit, 4 days per week for 2 h, by detainees with teaching experience or some English language. In the past week, there has been some improvement, with some children being bussed to local church buildings for 3 h schooling per day.

There are few recreational facilities for children. Only one swing was observed for about 50 children, and fights erupt. Families face difficulties getting their children appropriate clothes that fit—they are given what is available or can place orders that can take from 6 to 9 months to be delivered.

Mothers do not get routine maternal and child health support for breastfeeding or weaning. Nor are weaning foods provided that are appropriate for the age of the children. Each week, families are given 2 L of cow's milk, which some mothers feed to infants younger than 12 months.

To obtain disposable nappies, detainees have to submit a form to designated staff at certain, set times. Because of this difficulty, many mothers make nappies from old sheets or other material. Changing nappies is hindered by the lack of running water. Women also have to complete a form including the date and personal details when they need sanitary towels. They are supplied with ten pads and face possible questioning by a staff member, who is not always a woman, if more are needed. Health care is provided in an area separated from accommodation by a wire fence. Detainees are discouraged from seeking health care outside working hours, often have to wait in strong sun, and are introduced by number. Medical staff at the centre are not trained in the treatment of disorders that are common in the home countries of detainees, and have no cross-cultural training. Dental care is not provided routinely to the asylum seekers and consists mainly of extractions—restorative care is almost non-existent.

These conditions have had an enormous effect on the emotional and physical wellbeing of detained families. Parents, frustrated and fed up with trying to care for their families in cramped, oppressive conditions, as well as bearing the uncertainty of their immigration status, find it very difficult to remain positive. Many children are unhappy, some cry a lot, and others, craving attention, are aggressive, irrational, and disobedient. One asylum seeker who had experienced both detention and imprisonment in Australia was quite clear—he preferred prison.

Bebe Loff, Beverley Snell, Mick Creati, Mary Mohan

Chapter Eight: The Relationship Between Human Rights and International Humanitarian Law

This chapter has a slightly different emphasis to the previous chapters in that it examines two bodies of law and their impact in times of conflict and humanitarian emergencies.

Monash University

Declaration for Thesis Chapter 8

In the case of chapter 8, contributions to the paper "International Humanitarian Law and International Human Rights Law – a brief overview", involve the following:

Name	% Contribution	Nature of contribution
Bebe Loff	50%	Conception and execution
Helen McKelvie	50%	Conception and execution

Declaration by co-author/s

The undersigned hereby certify that:

- (1) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least part of the publication in their field of expertise;
- (2) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (3) there are no other authors of the publication according to these criteria; and
- (4) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

		Date
Signature 1		25.06.04
Signature 2		27/06/04

International Humanitarian Law and International Human Rights Law – a brief overview

Helen McKelvie and Bebe Loff

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Introduction

International human rights law and international humanitarian law are two different, but related areas of law with the common goal of safeguarding the fundamental rights of the individual. International human rights law focuses on the relationship between the State and the individual. All human rights are considered to be interdependent, indivisible and interrelated. The law applies to all people simply because they are human, and is therefore universal and inalienable. Humanitarian law focuses on issues arising in times of armed conflict, when many human rights may be restricted. It seeks to limit the effects of armed conflict on those who are not, or are no longer, participating in hostilities, and to restrict the means and methods of war to the attainment of the objectives of the conflict. These two branches of public international law are contained in international treaties and conventions and in what is known as "customary law" – a rule of conduct that as a result of long and consistent practice has come to be considered by States to be legally binding. The International Bill of Rights comprising the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Cultural and Social Rights forms the framework for human rights thinking and practice. The Geneva Conventions and their additional protocols are the primary documents underpinning international humanitarian law.

This paper will provide a brief overview of both these branches of international law, including their history and current status and the institutions involved in implementing and enforcing them. In providing this overview, the authors acknowledge the information provided by the International Committee of the Red

Cross, the British Red Cross and the UN Office of the High Commissioner for Human Rights.

International humanitarian law

What does international humanitarian law (IHL) cover?

There have been laws governing the conduct of war as long as there has been war. Today IHL is regarded in the main, as comprising of six major treaties (the four Geneva Conventions and their two protocols) that include over 600 'articles' or 'provisions' and a complex web of customary laws. The nuances of these laws are the province of diplomatic services and international legal experts, but can be summarised into a few basic rules:

Civilians and those who are no longer taking part in hostilities must be respected, protected and treated humanely. This includes the provision of care for the wounded, sick and shipwrecked.

Prisoners must be treated humanely and protected from acts of violence, particularly torture, and should be afforded the fundamental protections of judicial process.

The use of force in armed conflict must be limited to achieving the objectives of the conflict and no superfluous injury to people or damage to property should be inflicted.

There are other bodies generating international standards and norms that may be characterised as coming under the umbrella of IHL. Indeed the Charter of the UN states that one of the purposes of the UN is to maintain peace and security. The Security Council, as is well recognized, carries the primary responsibility for this task. The Convention on Prevention and Punishment of the Crime of Genocide (that entered into force in 1951) may be particularly pertinent during times of war. If the Security Council determines that genocide is taking place, the international community is bound, in theory at least, to intervene.

The Optional Protocol to the Convention on the Rights of the Child on the involvement of Children in armed conflict adopted by the General Assembly is

another example of law that focuses upon humanitarian concerns. The Security Council has, in addition, recently passed a resolution dealing with children in armed conflict. The ILO also has something to say about children and war. In its convention dealing with the prohibition of the worst forms of child labour deals with the recruitment of children for use in armed conflict.

There are multilateral treaties in force that encompass matters including the non-proliferation of nuclear weapons, chemical weapons, antipersonnel mines and excessively injurious conventional weapons. The International Criminal Court will, unlike the International Tribunals for the Former Yugoslavia and for Rwanda, provide a standing venue for dealing with war crimes and its future jurisprudence should enlarge the existing body of humanitarian law (see below).

When does IHL apply?

IHL applies in all armed conflicts whatever their origin or cause. The rules of IHL must be respected whether or not the persons in need of protection are victims of what is considered a "just war". However IHL does distinguish between different types of armed conflict. The four Geneva Conventions deal extensively with international armed conflicts, which are those between nation States. Wars of national liberation, where a people is fighting against a colonial power as an exercise of self-determination, are also recognised as international conflicts under Protocol I, which was added to the Geneva Conventions in 1977. Civil wars within a State (which constitute the majority of conflicts going on in the world at the present time) are considered conflicts of a 'non-international character'. They are subject to a 'simpler' version of the IHL rules (contained in Article 3 common to all four of the Geneva Conventions, and basically reflected in the summary above).

The history of IHL

Like human rights law, international humanitarian law has its origins in the principles of early religions, as well as the customs of warfare recognised by ancient civilizations. For example, the Catholic Saints Augustine and Thomas Aquinas, and in Islam, the Prophet Mohammed addressed the question of 'just means' to be

employed during warfare. Conventions for combat, the treatment of civilians and captured enemy soldiers were also subject to unwritten rules of humane conduct amongst ancient civilizations. In the seventeenth century the Dutch jurist and political thinker Hugo Grotius also made a lasting contribution to the development of international humanitarian law with his text *On Laws of War and Peace* which defined what should be regarded as justifiable and unjustifiable wars and which appealed to heads of state to restrain their conduct during wartime.

In the nineteenth century, at the instigation of a young Swiss man, Henri Dunant, IHL began to be codified. In June 1859, Dunant found himself, more or less by accident, amongst 40,000 Italians, French and Austrians wounded after the battle of Solferino in northern Italy. His efforts and those of a few other volunteers to ease the suffering of the wounded inspired him to write a booklet, (*'Un Souvenir de Solferino'*) published in 1862, which suggested that national societies should be formed to care for the victims of war, without discrimination on the basis of race, nationality or religion. He also made a further proposal that states should make a treaty recognising the work of these national organisations, in order to guarantee better treatment for those wounded in war.

With the aid of four colleagues Dunant then established the International Committee for Aid to the Wounded, (which was subsequently renamed the International Committee of the Red Cross (ICRC)). A diplomatic conference convened by the Swiss government in Geneva in 1864 saw the meeting of several newly formed national societies, based on Dunant's ideas, and the adoption by 16 European states of the Convention for the Amelioration of the Condition of the Wounded in Armies in the Field. This document was the first Geneva Convention, which formally laid the foundations of IHL. It enshrined the principles of universality and tolerance without distinction between race, nationality or religion. It also established the now almost universally recognised Red Cross emblem to distinguish military medical personnel. (The other well known emblem of the Red Crescent was adopted by the Ottoman Empire in 1876 during the war with Russia. It was recognized in the 1929 Geneva Convention – see below.)

The codification of IHL continued with a new draft in 1868 extending the principles contained in the convention to maritime conflicts. In the same year the St. Petersburg Declaration was made renouncing the use of explosive bullets. In 1899 and 1907 two International Peace Conferences were held at The Hague, which resulted in a series of conventions being adopted that defined the laws and customs of warfare, and forbade certain practices including: bombardment of undefended towns; the use of poisonous gases and soft-nosed bullets.

During the First World War adherence to the Geneva Convention and the operations of the ICRC were seen to have some effect in protecting lives and ameliorating suffering, but it was recognised that the Convention needed strengthening. In 1925 a Protocol was adopted prohibiting the use of asphyxiating and poisonous gases. In 1929 a further conference in Geneva adopted a convention with more robust provisions about treatment of the sick and wounded. A second Convention was adopted regarding the treatment of prisoners of war.

The four Geneva Conventions of 1949, which are still in force today, are the legacy of the Spanish Civil War and the Second World War. The atrocities perpetrated during those conflicts prompted the international community to renew its commitment to improving the protection of war victims. In particular, agreement was needed on rules to prevent a recurrence of the genocidal actions of the Nazis in interring and exterminating 6 million Jews, gypsies and others. The inadequacy of the original Geneva Conventions was highlighted by the lack of action taken to denounce the Nazi concentration camps or intervene on behalf of the Holocaust victims interred in them. The ICRC has acknowledged its moral failure in this context, and has expressed regret for its possible omissions and errors of the past, but has never formally apologised.

Each of the four conventions of 1949 deal with a different category of protected person:

First Convention: Care of the wounded and sick members of the armed forces in the field

Second Convention: Care of the wounded, sick and shipwrecked members of the armed forces at sea

Third Convention: Treatment of prisoners of war

Fourth Convention: Protection of civilians during war. It outlaws torture, collective punishment and the resettlement by an occupying power of its own civilians on territory under its military control (which specifically deals with the issue of the concentration camps).

These four Conventions did not attempt to incorporate the 'Hague law' – dealing with the customs of warfare developed at the Peace Conferences of 1899 and 1907. Since they were drawn up, new technologies and new weapons have been developed and the number of States has more than doubled with the process of decolonization, which brought with it new types of conflict – wars of national liberation. Also an increasing number of civil wars necessitated increased protections for victims of these non-international armed conflicts. These challenges were met at a Diplomatic Conference convened in Geneva in 1974. Over three years two new treaties were developed, which became the Protocols Additional to the Geneva Conventions. These two protocols deal with both protection of individuals in international armed conflicts and those between the armed forces of a government and dissidents or other organized groups in control of part of its territory.

IHL continues to develop with further conventions being agreed, for example:

The 1980 Conventional Weapons Convention and its four protocols

The 1993 Chemical Weapons Convention

The 1997 Ottawa Convention on anti-personnel mines

The 2000 Optional Protocol to the Convention on the Rights of the Child on the involvement of children in armed conflict.

Implementation and compliance

As with all international legal conventions and treaties it is up to individual States to become party to them by a process of signature and ratification or accession. [A treaty is open for signature for a certain time after the conference that has adopted it. Signature is not binding until it is also ratified, usually following a process in the domestic parliament. If the time for signature and ratification has passed, a state may still become a party to the treaty by the single act of accession.]. For example, there are 191 parties to the Geneva Conventions of 1949. 161 are party to the First Protocol and 156 to the second.

States that are party to a treaty or convention are legally obliged to comply with its provisions and all States must respect those provisions that are accepted as customary law (whether or not they are parties to a treaty that covers the same provisions). All states are expected to respect their international commitments and this includes taking necessary measures to effectively implement international laws. Under the Geneva Conventions and the Additional Protocols party States are required to undertake a number of specific measures to facilitate compliance. Some are peacetime measures and others are to be taken in times of armed conflict. Two examples of the many measures contained in the Conventions and Protocols are:

Instruction and training of the armed forces. It is imperative for effective implementation that the rules of the Geneva Conventions and the Additional Protocols are provided to members of the armed forces in a form that can be clearly understood and are relevant to their rank and function.

Translation to domestic legislation. States (Parties) must enact their own domestic legislation that gives effect to the provisions of the Conventions and Protocols, to guarantee they fulfil their international obligations. For example, grave breaches of IHL, (also known as "war crimes") must also be crimes under domestic law, and capable of being prosecuted in domestic courts.

The international community has in recent years taken further steps to encourage compliance. By establishing two international tribunals to prosecute war crimes perpetrated during conflicts in Rwanda and the former Yugoslavia, it is hoped that the

prospect of being held accountable for violation of IHL will be a real disincentive to those contemplating future violations. In 1998 an international treaty, known as the Rome Statute, created the International Criminal Court (ICC). (See below for further details about the operation of the international tribunals and the ICC.)

Violations of IHL

Unfortunately, being a party to a convention or treaty and undertaking implementation measures are not of themselves guarantee of compliance. And despite war no longer being an acceptable way to settle differences between states, (as clearly stated in the Charter of the United Nations in 1945), armed conflicts happen, and there are countless examples of IHL being violated. This is especially true in the context of the increasing number of wars waged within national and regional borders, noted earlier. Sadly, these conflicts often involve deliberate attacks on local citizens and displaced persons. These may take the form of physical and sexual violence, terror, starvation, and "disappearances", as well as destruction of infrastructure like homes, water sources or hospitals. These attacks aim to weaken enemy forces by targeting host or supportive communities, to gain territorial control or access to natural and other resources, or are simply random acts of violence.

In 2003 the UN Secretary-General Kofi Annan reported on the unacceptably high toll of injuries and deaths amongst innocent citizens caught up in violent conflicts around the world. He highlighted particular examples with the conflicts in:

The Sudan – where aid workers have collectively been dismayed by the pattern of attacks on civilians, humanitarian workers and facilities, including attacks on civilians at or near food distribution sites.

Afghanistan – where several different groups of non-state combatants control territory, creating major difficulties for provision of aid and humanitarian protection of civilian victims of the conflict.

The Democratic Republic of the Congo (DRC) – where war in the east of the country, motivated by the illegal exploitation of natural and mineral resources has had appalling humanitarian consequences, including the deaths of over 3 million people.

In a further example of IHL violation, international attention has also been drawn to the situation in Guantanamo Bay in Cuba where the United States is using its Camp X-Ray naval base as a holding facility for alleged Al Qaeda, Taliban and other detainees who have come under U.S. control during the "war on terrorism". Rather than classifying these detainees as prisoners of war, the U.S. has adopted the term "illegal combatants". This has been done in order to avoid the need to adhere to the requirements of the Geneva Conventions which include repatriation of prisoners at the end of a war. Some of these detainees have been held without charge for over two years, prompting calls for an end to their seemingly indefinite detention beyond the reach of the law.

Prosecuting IHL violations

As already noted the international community has taken steps to hold to account perpetrators of major humanitarian law breaches. Formal prosecution trials were first held by the international community in November 1945 in Nuremberg, Germany. The so-called International Military Tribunal (IMT) was set up by the victorious Allies (the U.S., France, Great Britain and the Soviet Union) at the end of World War II. Prosecutors from those four countries indicted a total of 22 Nazi German officials on three basic charges - conspiring and ultimately launching an "aggressive war," committing war crimes and committing "crimes against humanity." The trials lasted 11 months. Of the 21 defendants in custody, a total of 11 were sentenced to death, three were acquitted and the rest received prison terms. Ten men were hanged in November 1946; one of those sentenced to death, Hermann Göring, committed suicide hours before his scheduled execution.

More recently the UN Security Council passed resolutions to establish the International Criminal Tribunal for the former Yugoslavia (ICTY)(1993) and the International Criminal Tribunal for Rwanda (ICTR)(1994). The ICTY has a mandate to:

bring to justice persons allegedly responsible for serious violations of international humanitarian law during the conflict in the former Yugoslavia since 1991

justice to the victims deter further crimes contribute to the restoration of peace by promoting reconciliation in the former Yugoslavia.

To date, 91 accused have appeared in proceedings before the tribunal with a range of outcomes including: 20 convictions; 5 acquitted/found not guilty; 21 indictments withdrawn including 21 convictions; and 14 accused have died. There are several on going including that of former President Slobodan Milosovic.

The ICTY has not been without problems and has been criticised on a number of fronts including: it is insufficiently resourced and does not have powers of arrest, instead of relying on other agencies to apprehend and extradite indictees; its processes are overly legalistic which is in part the reason for the length of time taken to complete trials; a disproportionate number of the indictees are Serbs; and the tribunal was established by the UN Security Council instead of the UN General Assembly which makes it seem like a court established by the great powers to try citizens of smaller nations.

The ICTR was established for the prosecution of persons responsible for genocide and other serious violations of international humanitarian law committed in the territory of Rwanda between 1 January 1994 and 31 December 1994. More than 70 accused have been indicted, with 13 trials completed (12 convictions and one acquittal). Eight trials are currently in progress involving 20 defendants. Those convicted include Jean Kambanda, the Prime Minister of the Rwandan Government during the genocide, who was the first head of Government to be indicted and subsequently convicted for genocide. This conviction demonstrates that international humanitarian law can be applied to the highest authorities and has helped to create the conditions in which prosecutions could be undertaken against former Heads of State General Augusto Pinochet of Chile, President Hissein Habre of Chad and Slobodan Milosevic of Serbia.

As mentioned earlier, (although not without problems) the effectiveness of the ICTY and the ICTR have paved the way for a permanent court. The International Criminal Court (ICC) was established by the Rome Statute 17 July 1998, when it was adopted by 120 States. The Statute came into force on 1 July 2002, when the 60th State ratified it. The ICC is the first ever permanent, treaty-based, international criminal

court established to promote the rule of law and ensure that the gravest international crimes (genocide, crimes against humanity and war crimes) do not go unpunished. A number of legal and practical steps have yet to be taken before the ICC begins operating sometime after September 2004. The ICTY and the ICTR were set up more swiftly within the framework of the United Nations, whereas the ICC will be established as a new international organisation.

Role of the ICRC

The organization founded by Henri Dunant in 1863 has evolved into the primary voice for victims of war and international advocate for adherence to IHL. The mission of the ICRC states that it "is an impartial, neutral and independent organization whose exclusively humanitarian mission is to protect the lives and dignity of victims of war and internal violence and to provide them with assistance.... in situations of conflict. It also endeavours to prevent suffering by promoting and strengthening humanitarian law and universal humanitarian principles."

The Geneva Conventions confer special status on the ICRC to undertake these activities. This includes parties to an international conflict being obliged to allow ICRC delegates access to occupied territories, prisoner of war camps and areas where civilians may be detained. Its unique role has further international recognition in the form of its observer status at the United Nations General Assembly. Although it has a worldwide reach through its network of workers and volunteers in the Red Cross and Red Crescent movements, the ICRC has maintained its character as a private institution, governed by Swiss law and with Swiss citizens constituting its governing body. Its funding comes from voluntary contributions from States that are party to the Geneva Conventions, from national Red Cross and Red Crescent societies and private donors. It is therefore able to play an international role, independent of governments that are not in a position to influence its activities. It acts as a neutral intermediary between the two (or in some cases, several) sides to a conflict, utilising an approach of confidential diplomacy. Where this approach is ineffective, the ICRC can make public appeals to the combatants, although this approach is rarely employed. Over 125 years the ICRC has had some success in persuading states and other parties to respect humanitarian law in the midst of armed conflict.

Médecins Sans Frontières (Doctors Without Borders)

Not all of those working for the Red Cross were content with its neutral approach. During the Biafran war between 1968 and 1970, some doctors working for the Red Cross became frustrated with the obligation to maintain silence in the face of what they were confronted with. In 1971 Dr Bernard Kouchner founded Medecin Sans Frontieres (MSF) with the intention that it should both provide medical assistance and speak out about human rights abuses. In 1987 Dr Kouchner published "Le Devoir d'Ingerence" (The duty to intervene) which posited the view that liberal democracies were morally obligated to override the sovereignty of a State abusing human rights. He eventually became Minister for Health in France.

MSF is now a well recognised international humanitarian aid organisation with over 2500 volunteers providing emergency medical assistance to populations in danger in more than 80 countries. In carrying out its humanitarian assistance, MSF seeks also to raise awareness of crisis situations; MSF acts as a witness and will speak out, either in private or in public about the plight of populations in danger.

International human rights law

Origins of international human rights law

The classical doctrine of natural law can be seen as a starting point for the development and understanding of international human rights law. The doctrine dates from ancient Greece. During the 13th century Thomas Aquinas described four types of law: eternal law (laws that govern the nature of an eternal universe); natural law being that part of eternal law discoverable through processes of reasoning; divine law revealed in scripture (necessary to observe in order to achieve salvation); and human law consisting of rules supportable by reason articulated by human authorities for the common good. These laws derive their authority from natural law. This leap in thought is of course controversial. He also suggested that any human law in conflict with natural law was not binding but obedience to it may still be appropriate to avoid civil disturbance.

This concept evolved to become intermingled to different degrees with social contractarian philosophy. Thomas Hobbes in the 17th century described the life of man in a state of nature as 'solitary, poor, nasty, brutish and short'. By social contract citizens surrendered their natural liberty to the unlimited power of the State sovereign in order to ameliorate their nasty condition. John Locke, arguing at a slightly earlier date, suggested that some natural rights survived within the social contract and when not observed provided the basis upon which governments could be changed. In a complex amalgam of contract and nature, Jean-Jacques Rousseau insisted that there were some natural rights that no positivist law could take away. Legal positivists do not believe that law is discoverable through abstract reasoning, some seeing the law as no more than a series of rules. The utilitarian Jeremy Bentham is regarded as the founder of this school of thought. In any event the American and French revolutions give rise to the principles – all men(sic) have the natural rights to life, liberty and pursuit of happiness -- or -- life, property, security and resistance to oppression respectively.

During the 17th century Hugo Grotius and Samuel Pufendorf shifted ideas of natural law from the domestic domain to the laws made between princes, the laws of war, and these become the origins of public international law. This more modern amalgam of natural law, legal positivism and international law are the foundations of 20th century human rights law and these laws are, of course, heavily influenced by moral and political debates.

The 20th Century saw major strides in the formalisation of human rights. The horrors of the World Wars motivated the international community to develop structural frameworks for the administration of universally agreed standards. After World War I the Allied Powers established the League of Nations, approved as part of the Treaty of Versailles at the Paris Peace Conference in 1919. The mission, as stated in the League's Charter was "to promote international co-operation and to achieve international peace and security." The League was ineffective in stopping the military aggression that led to World War II and it ceased its work during the war, dissolving on April 18, 1946. The United Nations assumed its assets and carries on much of its work.

The concept of human rights underpins all UN operations. For example, the Preamble to the Charter of the United Nations contains the "reaffirm[ation] of faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small..", which sentiment is echoed throughout the Charter in various Articles. The importance of human rights as the driving force of United Nations actions has been consistently promoted by the current Secretary General, Kofi Anan.

Declarations and treaties

The UN Charter and the Universal Declaration of Human Rights, adopted by the UN General Assembly in 1948, form the basis of modern international human rights law. Since that time the scope of human rights law has gradually expanded as has the specificity of the articles contained within the various international instruments. There are different types of instruments and mechanisms by which they have effect. Declarations are made by the international community as an exposition of ideal standards. Generally speaking declarations are not legally binding. The exception to this is the Universal Declaration of Human Rights 1948 (UDHR). The UDHR is so widely accepted that is regarded as being "customary" international law. It was originally thought that the fairly broad statements contained in the UDHR would be expanded in a more detailed convention. However, with the coming of the Cold War, this was not to be the case. Thus two treaties were drafted: the International Covenant on Civil and Political Rights; and the International Covenant on Economic Social and Cultural Rights. Though approved by the General Assembly in 1966, they did not come into force until 1977 having taken this time to receive sufficient ratifications. Together these treaties are known as the International Bill of Rights.

Other significant human rights covenants are the:

Convention on the Prevention and Punishment of the Crime of Genocide (entered into force 1952)

International Convention of the Elimination of All Forms of Racial Discrimination (entered into force 1969)

Convention on the Elimination of All Forms of Discrimination against Women
(entered into force 1981)

Convention against Torture and Other Cruel Inhuman or Degrading Treatment or
Punishment (entered into force 1987)

Convention on Rights of the Child (entered into force 1990)

International Convention on the protection of the Rights of All Migrant Workers and
Members of their Families (adopted 1990, not yet in force).

Monitoring and compliance

As the main deliberative body of the UN, the General Assembly, made up of 191 member states, is closely concerned with reviewing and taking action on human rights issues that are referred to it by the Economic and Social Council and its "Third Committee". (The General Assembly has 6 main committees. The Third Committee is the Social, Humanitarian and Cultural Committee.) There are also various bodies that have been established under the umbrella of the UN to monitor compliance with human rights instruments and to investigate alleged breaches. There are both Charter-based human rights bodies and Treaty-based ones. The Charter-based bodies have been established on the basis of provisions contained in the Charter of the UN. They hold broad human rights mandates (in line with the UN Charter) and address an unlimited audience (the entire international community). The Commission on Human Rights and the Subcommission on the Promotion and Protection of Human Rights are both Charter-based UN bodies established under the authority of the Economic and Social Committee of the UN. They utilise special rapporteurs, representatives and expert working groups to investigate, discuss and report on specific human rights issues. (For example in 1990 a special rapporteur was commissioned to report on the situation of human rights in Haiti following the overthrow of the constitutionally elected President, Mr. Jean-Bertrand Aristide, and the use of violence and military coercion and the subsequent deterioration of the situation of human rights in that country. Similarly a special rapporteur was dispatched to Chechnya in 2002 in light of continued reports of widespread violence against civilians and alleged violations of human rights and humanitarian law, in particular forced disappearances, extrajudicial,

summary or arbitrary executions, torture, arbitrary detentions, ad hoc detention locations and continued abuses and harassment at checkpoints by Russian State agents.)

Treaty-based bodies derive their existence from specific treaties and hold more narrow mandates - based on the issues covered in the relevant treaty, with their audience limited to the countries that have ratified the treaty. Examples of treaty-based human rights bodies are:

Committee Against Torture, established pursuant to Article 17 of the Convention Against Torture and Other Cruel Inhuman or Degrading Treatment or Punishment.

Committee on Economic, Social and Cultural Rights, established to supervise the implementation of the International Covenant on Economic, Social and Cultural Rights. Unlike other treaty bodies, this Committee was not established by the Covenant. The Economic and Social Council created the Committee, following the unsatisfactory efforts of two previous bodies.

Committee on the Elimination of Discrimination against Women, established pursuant to Article 17 of the Convention on the Elimination of All Forms of Discrimination against Women, to supervise implementation of the Convention.

Human Rights Committee, established pursuant to Article 28 of the International Covenant on Civil and Political Rights.

Members of these committees are experts in their areas and are elected by the State Parties (except the Committee on Economic Social and Cultural Rights, whose membership is elected by the Economic and Social Council of the General Assembly). Implementation of treaty obligations is monitored at the national level, with the treaty bodies examining reports submitted by State Parties. This process may be followed up with dialogue with certain countries (up to 100 per year) about the local human rights situation and how it might be improved.

In addition to these formal UN bodies, other mechanisms are employed to monitor compliance with human rights standards. These include the Secretary-General appointing "Representatives", "working groups" or "special rapporteurs" on thematic

issues, for example: internally displaced persons; summary or arbitrary executions; torture; religious intolerance; racism; violence against women.

The Secretary-General can also use his "good offices" to confidentially intervene with a member state to raise human rights concerns. This includes such issues as release of political prisoners and commutation of the death sentence. Any such use of the Secretary-General's "good offices" is reported to the Security Council.

All these measures do go some way to preventing human rights abuses and ensuring that member states are aware of their obligations. There are some concrete results in the form of, for example, suspension of executions, release of detainees and changes to domestic legal systems to properly reflect international human rights treaty obligations.

Use of international human rights law by individuals

One notable development in the implementation of human rights law has been in its use by individuals. This is especially true in the context of the European Court of Human Rights, whose jurisdiction is based around the European Convention on Human Rights, to which all 45 member states of the Council of Europe are signatories. The Court provides a direct method of complaint by a person claiming to be a victim of a violation of the Convention, usually after they have exhausted avenues of legal redress in their own domestic courts. Where an infringement is proved, the European Court of Human Rights is able to make a ruling to provide redress against the relevant state. Since it was convened in 1998, (building on the work of the European Commission for Human Rights before it), the Court's judgments have provided guidance on how fundamental human rights are to be respected and protected, not only for member states of the Council of Europe, but also other countries, thus becoming a leading mechanism for human rights protection. Its significant role in acknowledging individuals as rights holders has catalyzed a trend that is gradually being followed elsewhere in the world, creating further levels of protection than might have been envisaged as the inter-state treaty system was developed.

Role of the Human Rights Commissioner

In acknowledgement of the increasing significance of human rights in the world arena, the post of High Commissioner for Human Rights was created in 1993 as the principal UN official responsible for these issues, accountable to the Secretary-General (this is in addition to the other UN bodies, described above). The Office of the High Commissioner for Human Rights (OHCHR) is based in Geneva in Switzerland, and also has an office at the UN Headquarters in New York. The High Commissioner has a leadership role in the international human rights movement, travelling widely making public presentations, providing a voice for victims and at the same time engaging in dialogue with governments to strengthen cooperation and adherence to human rights principles. The Office works with a range of players in the human rights arena -- non-government organisations involved in aid work, academic institutions and relevant private sector organisations to promote human rights as widely as possible and provide educational opportunities about human rights issues. It also offers administrative services, research and other expertise and advice to other UN bodies, and to the numerous experts appointed to investigate and report on human rights issues.

Conclusion

Both human rights law and international humanitarian law are crucial expressions of what the international community regards as the fundamental rights of the individual during peace time and during times of war. During armed conflict, when some human rights may be justifiably suspended (other than those set out in Article 4 of the International Covenant on Civil and Political Rights - this includes the right to life, the right not to be subjected to torture or to cruel, inhuman or degrading treatment or punishment, the right not to be held in slavery or servitude, the right not to be imprisoned for failure to perform a contractual obligation, the right not to be subject to retroactive penal measures, the right to recognition as a person before the law, and the right to freedom of thought, conscience and religion), humanitarian law should be employed to protect those civilians and prisoners caught up in the conflict. Of course, the aims of both human rights law and humanitarian law are achieved only in so far as they are recognised and acted upon by governments and individuals. This is an on-

going challenge for the UN and the other international agencies devoted to promoting and acting upon them. Providing support for these agencies to fulfil their mandates remains a challenge for us all.

Chapter Nine: Conclusions.

This collection of works has demonstrated that it is possible to approach health issues from human rights based perspective. It has been argued here that, far from being at odds, the promotion and protection of human health is consistent with respect for human rights. This has been the contention put forward in each chapter of this thesis. What has not yet been established is whether the rhetoric can be consciously implemented and be reflected in improvements in health status. A rigorous examination of this question must be the next step.

This thesis has dealt with matters pertinent to: public health generally; sexual health; access to pharmaceuticals; the conduct of medical research; and law governing health in Australia. In each case it makes sense to introduce a rights based discussion. In each case this discussion raises matters that might otherwise remain unasked if issues were approached solely from a health perspective.

The paper has not suggested that rights are to be promoted in every instance. It is undoubtedly true that there may be occasions when rights may be limited in favour of health, such as in the case of seat belts – or more controversially – the isolation and detention of a person with a serious infectious disease suspected of placing others at risk. However, when rights are to be limited there are a number of matters to consider. The first of these is the strength of the evidence that exists to support the health measure sought. The second is whether any less restrictive measure can be used to achieve the same aim. The measure should not be discriminatory in its application and where an action is to limit a fundamental right it must be supported by law.

Rights based questions are guided by the following principles: universality; interdependency and indivisibility; discrimination and equality; participation; and accountability. An understanding of these and of the specific content of rights instruments is required in order to obtain the more detailed guidance required for informed substantive decision-making in policy development and programme implementation.

If such an approach was to be adopted in a rigorous fashion, it is suggested that not only would the claims of the vulnerable gain greater prominence, they might also begin to be addressed in a more comprehensive fashion. However, further work of an interdisciplinary nature is required to test these assertions. How this might be done remains a matter for urgent discussion.

The work of Michael Marmot and others examining issues of social status and control are a small indication of the differences that might possibly be wrought if certain human rights standard norms were to be respected.¹⁵¹ But how are we to know? The tools of those including the clinician, epidemiologist, ethicist sociologist, and anthropologist must be brought together with those of the lawyer to begin to form questions that might be tested and tested with real rather than nominal involvement of the communities in question. The analyses made through the coming together of each group for a common purpose, that of improving human well being, must be far more compelling than each discipline working in isolation. Perhaps this is the key thought, the "take home message" that has underpinned each of the preceding works.

¹⁵¹ See for example Marmot M, Wilkinson RG, eds. *Social Determinants of Health*. Oxford: Oxford University Press; 1999.

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Health and human rights

Torture, ill-treatment, and sexual identity

On 18 September, a 16-year-old Egyptian boy was sentenced to 3 years' imprisonment for alleged homosexual behaviour.¹ Amnesty International's (AI) recent report on the torture and ill-treatment of lesbian, gay, bisexual, and transgender people highlights that such human-rights abuses, ranging from loss of dignity to assault and murder, are widespread.² Much of this abuse is sanctioned by governments and society through prejudices, religious traditions, and discriminatory laws such as those limiting rights to freedom of expression and association. The AI report implicates health professionals not only as passive bystanders, but also as active perpetrators of abuses citing, for example, the use in the military of apartheid South Africa of discredited therapies aimed at "repairing" homosexual orientation.

The concerns of lesbian, gay, bisexual, and transgender populations have long been neglected in human-rights agendas.³ Recognition is now growing that although constructions of sexuality and gender may vary, these people all over the world share experiences of stigma, discrimination, and ill-treatment. By identifying global patterns of abuse based on sexual orientation and gender identity, the AI report makes universal what have been perceived as local concerns and places these issues firmly within international human rights discourse. Attempts to rationalise discrimination through claims that diverse sexual

identities are foreign to cultural or religious beliefs are rightly rejected.

Discrimination affects the health of lesbian, gay, bisexual, and transgender people in many ways.⁴ First, a social environment characterised by homophobia (negative attitudes toward gay men and lesbians), heterosexism (negation of forms of sexuality or relationships that are not heterosexual), and social isolation can be stressful, leading to poor physical and mental health. Second, heterosexism has resulted in marginalisation of these people's health issues in public-health agendas. Third, health research can stigmatise people who are not heterosexual and contribute to discrimination and ill treatment. For example, the association of HIV/AIDS with gay men in the USA has been used to justify violations of gay people's rights, such as segregation of prisoners with HIV, as part of public-health efforts to curb disease. Fourth, homophobia and heterosexism within health-care institutions can increase barriers to health care for lesbian, gay, bisexual, and transgender people and lead to substandard care. Also, despite the declassification of homosexuality as a mental-health disorder, some forms of sexual identity are still treated as diseases. For example, gender-identity disorders, a category that describes atypical or non-conforming modes of gender expression, is still included in the *Diagnostic and Statistical Manual for Mental Disorders* (DSM IV). Medicine

can thus function as a form of social control, as shown by the forced admission to psychiatric hospitals of lesbian, gay, bisexual, and transgender people in Russia and the Ukraine.⁵ In these and other cases, health-care providers put the interests of the state before the interests of patients, thereby helping to uphold discriminatory social systems.

What, then, are the roles and responsibilities of health professionals and their institutions? Some organisations, such as the American Psychiatric Association and the British Medical Association, have affirmed their opposition to discrimination and medical education is being used to change professional attitudes towards lesbian, gay, bisexual, and transgender people.⁶ The increasing demands of these consumers for appropriate health services have resulted in innovative programmes that might provide models for services elsewhere.⁴ Furthermore, research in mainstream health journals on concerns such as the effects of discrimination and violence based on sexual identity is growing and contributing to debate.⁴

Nevertheless, much work is still needed to place the health and human rights of lesbian, gay, bisexual, and transgender people on health agendas. Governments must act against discrimination through interventions with civil society, such as human-rights education with medical academic and training insti-

Measures that governments should take to prevent torture and ill-treatment based on sexual identity

1. Repeal laws that could result in the discrimination, prosecution, and punishment of people solely for their sexual orientation or gender identity.
2. Condemn torture and ill-treatment, whoever the victim, and give clear indications that this will not be tolerated.
3. Provide safeguards to protect lesbian, gay, bisexual, and transgender people from torture or ill-treatment in custody.
4. Prohibit forced medical treatment, including non-consensual treatments aimed at changing sexual orientation or gender identity.
5. Ensure that all allegations of torture and ill-treatment are investigated and those responsible brought to justice.
6. Protect lesbian, gay, bisexual, and transgender people, including children, against violence in the broader community, including domestic violence.
7. Protect refugees fleeing torture based on sexual identity.
8. Protect and support human-rights defenders at risk because of their work on issues of gender and sexual identity.
9. Strengthen international protection for lesbian, gay, bisexual, and transgender people through ratifying international human-rights instruments and ensuring that the human-rights issues of these groups are advanced by UN and regional human-rights agencies.
10. Combat discrimination through legal protection against homophobic abuses, initiate antidiscrimination campaigns, and ensure that lesbian, gay, bisexual and transgender organisations and individuals have freedom of association and assembly.

Adapted from reference 2.

tutions, organisations of health professionals, the criminal-justice system, and individual health-care providers (panel).

Efforts by human-rights organisations and lesbian, gay, bisexual, and transgender people worldwide are leading to more powerful demands for access to rights within health care. Health-care providers and organisations of health professionals have a moral and professional responsibility to work in supporting measures to uphold rights and promote the health of this group. As the AI report notes, "If we tolerate the denial of rights to any group, we undermine the whole

protective framework of human rights by taking away its central plank—the equal rights and dignity of all human beings."

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Rising tensions: Sharia law in Nigeria

A recent increase in the number of Sharia punishments handed out by courts in the northern states of Nigeria has caused outrage and condemnation from both national and international human-rights groups. Although the number of documented human-rights abuses has lessened since Nigeria's return to civilian rule in 1999 after 16 years of repressive dictatorships, the recent extension of Islamic Sharia law for criminal offences may have set the country's human-rights record back many years.

And there is much to be concerned about. Only this month an Islamic court in Gwadabawa, Sokoto State, in northern Nigeria ruled that a pregnant woman be sentenced to death by stoning. The court had found Safiya Hussaini Tungal-Tudu guilty of having premarital sex, a punishable offence under Sharia law. Recent reports indicate that the sentence may now be delayed until after she delivers the baby. A teenage girl was given 100 lashes in January for a similar offence, even though her appeal was still pending at the time. Earlier this year, a 16-year-old boy from Kebbi State was found guilty of stealing money and sentenced to having his hand amputated. Human-rights groups say that all these cases flout international law.

Such religious issues, as with everything in Nigeria, are complex. Life for most people is a desperate and constant struggle, more so perhaps in the predominantly Muslim northern regions that are often seen as worse off than the Christian south. Resources are scarce, poverty is rife, and the area bears witness to some of Africa's worst health-care statistics. It

comes as little surprise, therefore, that support for Sharia law is widespread among Nigeria's Muslim communities. With an ineffectual secular government struggling with issues of corruption, poverty, and violence—so the argument goes—perhaps a code of justice based on God's law will be more up to the task. Nigeria is a secular state, but the government allows for application of Sharia law for consenting Muslims.

Although northern governments have offered assurances that the application of Sharia law will be restricted to Muslims, minority Christian groups living in the area remain unconvinced. Furthermore, says Bronwen Manby of Human Rights Watch, many Muslims are also expressing reservations about

the way Sharia is being implemented in Nigeria. "There are serious concerns with the use of vigilante squads who administer 'instant punishments'", Manby told *The Lancet*, "and with the appointment of new Sharia tribunals headed by very inadequately trained judges with poor respect for due process when they hear cases".

Such issues seek only to fuel pre-existing religious and ethnic tensions in the northern regions, an area that has long been the focus of widespread violence. It is estimated that more than 6000 people have been killed in predominantly Muslim-Christian clashes throughout the country since 1999. 2000 people died in clashes in Kaduna last year, and reports from Bauchi state tell of hundreds killed and thousands displaced when Christians rioted in protest against imposed Islamic law. Many of the displaced are yet to return home, and remain reliant on the Red Cross for food and shelter. Adding yet more fuel to the fire, Nigerian Islamic leaders have warned against possible repercussions within Nigeria as a result of America's so-called war against terrorism.

Yet according to Cathy Huser of Médecins Sans Frontières, a group that has been based in Nigeria since 1996, the international community must not ignore the fact that such violence is rooted in politics and economics. "Essentially these outbursts of violence in Nigeria are all to do with controlling land and resources, in the face of extreme poverty and human misery; although religious and ethnic sparks often fuel the conflict", says Huser. "In Nigeria, a cumulative effect of frustrations and



Mosque damaged in anti-Sharia riots, Kaduna

unmet promises, and threats to limited resources, mean that different categories of people have to fight hard for what they see as their rights."

How last month's massacre by the Nigerian army of 200 unarmed villagers in central Nigeria fits into these patterns of violence is currently the

cause of much speculation. Nigeria's turbulent history of successive and violent military coups suggests that if this latest incident is not properly dealt with, there could be far-reaching repercussions. However, one thing is clear. By addressing issues of poverty, death, and disease

in Nigeria, many of the problems may just go away. In a country with a wealth of oil reserves, this is surely an achievable goal.

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Are human rights good for your health?

Twenty years into the epidemic of HIV/AIDS and more than 3 years after Jonathan Mann's death, Mann's insight that human rights and health are inextricably connected has not been fully explored. To address this challenge, Temple University (Philadelphia, USA) and the American Society of Law, Medicine and Ethics held an international conference in Philadelphia from Sept 29 to Oct 1, 2001 on "Health, Law, and Human Rights: Exploring the Connection". The conference brought together epidemiologists, social scientists, lawyers, human-rights advocates, policy makers, and activists from around the world to address two key questions that Mann left unanswered: what empirical evidence supports or elucidates the relation between health, law, and human rights? And what do we know about using human-rights initiatives and law reform as tools for public-health interventions?

Until researchers and advocates begin to answer those questions, human rights can be dismissed too easily as "feel good" rhetoric and law as a sterile province visited only by lawyers. Health problems such as AIDS that often strike the most vulnerable in society remain intractable, because traditional public-health initiatives seem inadequate to address underlying conditions, such as social inequality, that put people at risk. It is not enough to rely on assertions of a special relation between health, human rights, and law. We must begin to examine and justify our reliance on that relation with empirical evidence.

Research on law should explore its links to fundamental determinants of disease such as racism, income inequality, lack of education, and poor social cohesion. Law and human-rights practices can affect health on many levels and in two broad ways. First, they can form pathways along which broader social determinants of health have an effect. For example, criminal law and law-enforcement practices might be means through which low social status is converted into disparities in social health. In many places, the way in which

criminal-justice systems are operated results in disproportionate imprisonment of low-status people and their exposure to diseases such as tuberculosis and HIV/AIDS in prison. Second, laws or legal practices could contribute to the development and stability of social determinants of health. For example, law is one of the means through which the subordinate status of women is established and maintained. Where it prohibits women from holding property, or does not prevent discrimination, law is one of the causes of women's subordination.

"While acknowledging the tragedy of the events of Sept 11, he reminded the meeting that every day 10 000 people die because AIDS drugs are too expensive"

Good law does not necessarily lead to good health. Research must also address whether human-rights initiatives and law reform are effective tools of public-health advocacy. Three health catastrophes were used in the conference to investigate this issue: the epidemics of tuberculosis and HIV in Russian prisons, the effect of structural-adjustment policies on health and health care in Zimbabwe, and racial disparities in access to health care that have persisted in the USA despite civil-rights laws forbidding such discrimination. These cases illustrate dilemmas often faced by those who use human-rights instruments and other law to promote health. What happens when human-rights laws exist, but are unenforceable? Or when countries adopt human-rights rhetoric but do not provide resources for realisation of those rights? What can health workers do when the legal system, or any government institution, cannot serve the population? Despite these challenges, the conference yielded many positive examples of the effects of human-rights laws, from the importance of rights claims in recent legal battles for affordable access to HIV

treatments to the development and application of measurement tools to measure the effect of such laws.

Ronald Bayer set the health and human-rights movement in historical context, reminding participants that an appreciation of the connection between public health and social justice was not new. Mann and colleagues, like reformers from Virchow and Engels to John Ryle and Richard Titmuss, sought to harness tools for social change to bring better health.

Eric Sawyer, a founding member of ACT UP (AIDS Coalition to Unleash Power), New York, described how, as a person living with AIDS for 20 years and as an international activist for treatment, he had retained the conviction that every life matters and deserves to be fought for. While acknowledging the tragedy of the events of Sept 11, he reminded the meeting that every day 10 000 people die because AIDS drugs are too expensive and 16 000 people contract HIV infections. Although the USA could mobilise US\$15 billion to rescue the airline industry in the wake of the terrorist attacks, the USA and other developed nations have yet to completely fund even 1 year of the United Nations Global Fund to Fight AIDS (need estimated at \$10 billion per year).¹ Sawyer asked how AIDS, other infectious diseases, and health issues overall could be reintroduced through human-rights activism into a public discourse that seems totally preoccupied with war, security, and retribution against terrorism?

The fundamental question to arise from the conference was how can we, as members of societies (both with and without long traditions of civil institutions), use laws, policies, and human-rights doctrines to improve the health and wellbeing of all people?

1 Roylance FD. UN is warned on anti-AIDS strategy; drugs alone might fail poor nations, panel says. *Baltimore Sun*, Nov 1, 2001: A3.

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Imatinib for chronic myeloid leukaemia: a NICE mess

Sir—Virginia Barbour, in her Nov 3 commentary,¹ suggests that the UK must sharpen its response to requests for drugs such as imatinib (formerly known as signal-transduction inhibitor 571 [STI571]). However, the issues are broader than timing alone.

Any organisation wishing to improve the health of the population it serves should take account of the Maxwellian principles of accessibility, relevance to the population need, effectiveness, equity, social acceptability, and efficiency or economy.² If the National Institutes for Clinical Excellence (NICE) or others are to pronounce upon the suitability of provision of new technology within the National Health Service, they must assess cost effectiveness and, in that context, take into account affordability. Moreover, the notion of opportunity cost must be acknowledged within the process. There seems to be no explicit ethical basis for the decision-making processes used by public-sector organisations. Some elements of the NICE process seem robust. However, how the outcomes from this process translate into recommendations is unclear.

The imatinib situation is pertinent. There are early pilot and phase I studies, but not with survival or quality of life as endpoints.^{3,4} We did a limited search of reports. No identified study set out evidence on quality of life or survival. There might be a clear case for continuing treatment, but we have not been able to establish one. We accept that, in view of the problem of so-called NICE blight, it is not beyond the scope of government to undertake a rapid appraisal process to formulate policy. However, in the context of continuing financial struggles to implement the recommendations already made by NICE, the justification, ethical or otherwise, for funding this group of patients in preference to others must be made clear.

It cannot be appropriate for the government to insist, apparently on a whim, that individuals or groups of patients are funded in this

way without a clear and public justification.

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Sir—Imatinib, discussed by Virginia Barbour,¹ is a remarkable but expensive drug that has generated great interest from patients with chronic myeloid leukaemia, haematologists, and, latterly, from those who fund health care, and government ministers. Several expensive new agents are available for treating cancer and leukaemia, and the concerns surrounding all of these agents are similar. I am delighted that the Department of Health has taken the unprecedented step of directing that funding should be made available for imatinib, but over the past few months two things have become very clear to me.

First, the mechanism for assessing the appropriate funding for new cancer drugs in the UK is hopelessly ineffective. Complexity can be dealt with if the mechanisms are clear. However, the difficulties surrounding the funding of imatinib have highlighted that the appropriate mechanisms are far from clear. Who should consider and approve these impressive but expensive new drugs? Trust drug and therapeutics committees? Regional or strategic health authorities? Primary-care trusts? Regional drug assessment units? NICE?

Furthermore, where should funding come from? Cancer networks generally have no money to spend on drugs and there is confusion about whether hospital trusts, health authorities, or primary-care trusts should fund. £255 million is allegedly pledged by the government for improvements in cancer care this financial year (£370 million next year), and yet we are constantly in debate about who should be responsible for funding, and are uncertain about how the funds are being spent. Such funds need to be earmarked directly for spending on cancer and leukaemia care and made available in a nationally coordinated way.

Second, we simply do not spend enough on cancer drugs in this country. The proportion of gross national product spent on health care, and especially cancer and leukaemia care, in the UK is among the lowest in Europe. This spending needs to be addressed urgently at a national level.

I suggest a simple model to improve leukaemia care in the UK. First, NICE should make appraisals available at the time of drug licensing. Second, I suggest that doctors should initially not be allowed to use expensive new agents outside of approved national or international clinical trials, and should be obliged to contribute data. Third, there should be a single price negotiating, purchasing, and distribution mechanism for these drugs, with central government funding; trial drugs could be purchased and distributed from one location. The model would achieve best possible prices for drugs because of bulk purchase; control drug distribution to ensure the highest standards of protocol adherence and allow data collection for clinical studies; precise monitoring of drug costs for the National Health Service and Department of Health, which is impossible with current local mechanisms; avoid innumerable local negotiations and postcode prescribing.

There are some remarkable developments in leukaemic agents. We can afford these new drugs, and radically improve the outcome for patients with leukaemia, if an effective

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Learning a culture of respect for human rights

"Explaining is not excusing, understanding is not forgiving"

See page 1852

The Report of the South African Truth and Reconciliation Commission (TRC)¹ notes repeatedly, in different ways, that the perpetrators of gross human-rights violations under apartheid were neither evil nor psychologically unwell (vol 5, ch 7). Circumstances common to the perpetration of atrocities are identified and dissected. At the risk of losing some of the many dimensions of the analysis, the report, in seeking to understand the actions of perpetrators, pointed to: the difference in perspective between perpetrator and victim; the historicopolitical environment (the cold war, anticolonialism, and racism); social identity and the influence of group membership in diminishing moral restraint through compliance with and internalisation of group norms; and the contribution of language in allowing the dehumanisation of others.

Clearly, the message of South Africa must be heeded by all. South African doctors, including those who participated in or supported immoral action, like doctors who cooperated in the Holocaust, merge seamlessly into the medical professions of other countries. Doctors must ask themselves whether, in similar circumstances, they would be capable of the same horrors.

Under apartheid, district surgeons (forensic physicians or police surgeons) had dual and incompatible responsibilities to provide medical care for prisoners and to protect national security. The isolation and ostracism of those doctors who worked within police and prison systems served to mould and entrench their attitudes and behaviour. The report details chilling examples of surgeons' participation in torture, the turning of blind eyes, and the failure to provide necessary care. Forensic pathologists also "omitted crucial information and falsified post mortems" (vol 4, ch 5, para 53) in collusion with police, lawyers, and courts. The report also noted that health professionals with dual loyalties are "at risk of becoming involved in overt or covert abuses of the human rights of their patients Appropriate measures are needed to prevent or pre-empt the moral and ethical dilemmas that may arise for health professionals faced with the (commonly conflicting) needs of their patients and their employers" (vol 4, ch 5, para 21).

The Report of the Royal Commission into Aboriginal Deaths in Custody (RCADIC) would seem the obvious report from which an Australian might draw some analogies with the TRC report. In the RCADIC report,

prison medical services attracted most criticism. Authorities fundamentally misunderstood their duty of care to prisoners, a misunderstanding compounded by poor communication between prison medical services and correctional institutions.

RCADIC identified the poor management of health conditions of Aborigines in custody. This deficiency was attributed partly to the stereotyping of Aboriginal people and others with chronic alcohol problems, and to the exaggerated impact of common infectious diseases in malnourished people (vol 4, p 237). Nevertheless, the high number of aboriginal deaths in custody (99 over 10 years) reflected primarily a glaring over-representation of Aborigines in custody. The rates of death for indigenous and non-indigenous communities in custody were basically the same. RCADIC called for the elimination of disadvantage and an end to the domination of Aboriginal people.

It is, however, the recognition of the genocidal practices in colonial Australia that is most relevant to comparisons between Australia and South Africa. *Bringing them Home*, the report of the National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families, makes the point that the removal of children from their families by law, ostensibly in their own interests, constitutes systematic racial discrimination amounting to a gross violation of human rights. *Bringing them Home* recognises this violation as genocide. Further, indirect racial discrimination continues today, despite repeal of obviously discriminatory laws. Discrimination is evident in both child-welfare and juvenile-justice systems that at worst treat cultural difference as abnormal or criminal.

Lessons must be learnt from the South African experience. There must be awareness of the incremental effect of tolerance of human-rights abuse. The TRC made recommendations for the prevention of future atrocities that are applicable to the medical profession and the teaching of medical ethics (vol 5, ch 7). Doctors must be alert to the dangers of unquestioning obedience to authority; resist compliance with group norms; and resist the compulsion to respond to the immediate situation without reflection.

From which report did the following quote come?

"The Commission recommends that government accelerate the closing of the intolerable gap between the advantaged and disadvantaged in our society by, inter alia, giving more urgent attention to the transformation of education, the provision of shelter, access to clean water and health services and the creation of job opportunities. The recognition and protection of socioeconomic rights are crucial to the development and sustaining of a culture of respect for human rights."

It is from the TRC report—but it could have come from any of the three reports.

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Do human rights have a role in public health work?

What role do human rights have in public health work? Since the early stages of the women's health, reproductive health, and indigenous health movements it has been asserted that public health policies must incorporate human rights norms and standards. Lack of respect for human rights has hampered development in such areas as mental health care and control of sexually transmitted infections.¹

Lately, however, it has been argued that "Human rights based approaches to HIV/AIDS prevention might have reduced the role of public health and social justice, which offer a more applied and practical framework . . . in Africa's devastating epidemic".²

The underlying assumption is that in a human rights approach individual rights are protected at all costs—even despite adverse effects on the public's health. Yet a rights-based approach does not privilege protection of individual rights over the public good. This apparent tension should be addressed to enable the creation of sound public health policies and programmes.

A human rights approach mandates that any public health strategy, whether or not rights are to be restricted, be informed by evidence and openly debated.³ This approach protects against unproved and potentially counterproductive strategies, even those motivated by genuine despair in the face of overwhelming public health challenges.

The introduction of human rights into public health work is not about the imposition of any preordained result, but about processes and their application towards maximum public health gains. For example, a focus on health systems requires attention to their "availability, acceptability, accessibility, quality" and their outcomes among different populations.⁴

These terms have concrete implica-

tions: availability—health care must be offered to the extent possible within available resources, and benchmarks need to be set to guarantee that this goal is reached progressively; accessibility—health facilities, goods, and

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A role for human rights in public health work?

services must be attainable for everyone without discrimination on the basis of such factors as socioeconomic status, community, or disability; and finally, health care must be the highest possible quality and acceptable, culturally and otherwise, to all groups.

At times, public health measures are needed to curb the spread of disease, resulting in restrictions on rights. For example, if a person infected by open pulmonary tuberculosis poses a grave risk to public health by refusing treatment, it may be permissible to isolate that person, and thus lawfully restrict their freedom of movement.

Human rights do not conflict with restrictions, so long as the objectives and the process used to make the decision to restrict rights are clear. For a restriction to be considered legitimate, a government has to address five criteria spelled out in the Siracusa principles adopted by the UN Economic and Social Council (panel).⁵

The rights-based approaches to health, currently underway in many institutions, should be assessed and

validated to ensure clarity in what are understood to be the strengths and limitations of bringing human rights into governmental, non-governmental, and international health work.

Information should be gathered to show how human rights have been relevant in analysis of the health needs of populations or public health problems; in the ways health systems' performance assessments are done; in the processes by which countries or institutions choose public health interventions; and in the implementation and monitoring of interventions—their focus, what they do, and what they do not do.

Bringing health and human rights together in public health also allows the progress, success, or failure of a policy or programme to be assessed against public health and human rights benchmarks. Ultimately, much of the work to bring human rights into public health involves looking at tradeoffs and working within a framework of transparency and accountability towards achieving the highest attainable standard of health.

There is no one-size-fits-all approach. Rights issues and the appropriateness of policies and programmes might be of concern in one setting and one population but not in another. Central to all settings, however, are the principles of non-discrimination, equality, and, to the extent possible, the genuine participation of affected communities: these principles will not undermine but further advance public health.

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Siracusa principles

- First, the proposed restriction has to be provided for and implemented in accordance with the law.
- Second, the restriction has to be directed towards a legitimate objective of general interest, such as preventing further transmission of the HIV virus.
- Third, it must be strictly necessary to achieve the objective in question.
- Fourth, no less intrusive and restrictive means should be available to reach this objective.
- Fifth, it cannot be unreasonable or discriminatory in its application.

The burden of proof falls on those who want to restrict rights; and concrete public health evidence is needed to genuinely respond to the last three criteria.

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Talking points

Improving the health of sex workers

'It seems obvious that health promotion programmes . . . ought not to contribute to mistreatment of sex workers'

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VAMP/Harish Yamgar

Sex workers are discriminated against and stigmatised by many sectors of society, and unfortunately these attitudes can underlie public health research ostensibly aimed at improving their health. In this week's [Health and human rights](#) section, Ivan Wolffers and Nel van Beelen describe how public health programmes often fail to address sex workers' concerns; Bebe Loff and colleagues from the Network of Sex Work Projects discuss the unforeseen effects of the 100% Condom Use Programme; and Kate Butcher writes about why prostitution should not be confused with sex trafficking.

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Can health programmes lead to mistreatment of sex workers?

The 100% Condom Use Programme (100% CUP) is aimed at female sex workers and, as its name suggests, promotes increased condom usage. Supported by both WHO and the Joint United Nations' Programme on AIDS (UNAIDS), the programme was initiated in Thailand in 1989. 100% CUP has been regarded as a success story in the campaign to limit the spread of HIV infection. However, the international Network of Sex Work Projects (NSWP), an informal alliance of sex worker groups with constituent Asian, African, Latin American, and European networks, does not share this view.

It seems obvious that health promotion programmes funded by international agencies ought not to contribute to mistreatment of sex workers. Because sex work tends to be regarded as a behaviour not an occupation—who you are, not what you do—sex workers are often not recognised as legitimate parties to discussions of their conditions of employment. Sex workers are often treated as the object of programmes rather than contributors to them. Yet discussions about sex work without sex worker representation result in an incomplete understanding of the social dynamics of the occupation. It is, therefore, not surprising that programmes such as 100% CUP, developed without consultation with sex worker advocates, have had and continue to have negative repercussions for sex workers.

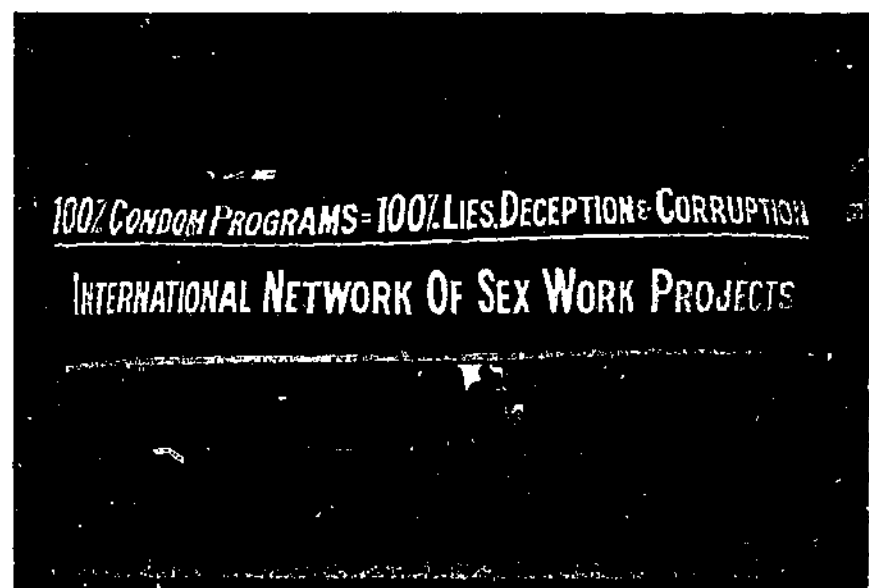
UNAIDS describes 100% CUP as follows: "The main strategy of the programme is to gain the agreement of the owners and managers of all commercial sex establishments to enforce condom use as a condition of commercial sex. Sex workers should be instructed to refuse sex to any customer who refuses to use a condom. If all sex establishments enforce this policy, clients have no choice—they either use condoms or they don't have sex."

At first glance the logic of this approach seems unassailable. However, at the very least, the language of 100% condom use ignores the importance of encouraging non-penetrative sexual activity. 100% CUP discourages the building of more comprehensive sexual skills. This shortcoming is substantial, but there are further concerns. Typically, control of the programme rests with local authorities, police, and brothel owners and managers. A UNAIDS *Best*

Practice publication notes: "Safer sex" is promoted by introducing protective measures such as consistent condom use and modification of risky sexual practices and by reinforcing behavioural change towards adopting these practices. . . . Modifications in the way sex work is organized must be encouraged and, in some cases this may be

tested sex. If workers are then dismissed they may continue working in the more hidden sections of the industry. High-risk services can always be purchased.

From the perspective of the NSWP and their members, claims that the policy empowers sex workers in their interactions with clients are



NSWP protests at Barcelona with banner made by sex workers in Kolkata, India

supported by policy enforcement. Possible approaches to building such support include enlisting sex establishment owners and managers to protect their workers' health and physical safety, working with police to reduce harassment, and promoting self-esteem and workplace solidarity among sex workers."

What has this meant in reality? Some developing country governments now make it compulsory for brothels to register every sex worker they employ, instruct her to use condoms, and ensure that she attends mandatory checks for sexually transmitted infections (STIs). Police and other local authorities can be authorised to enforce this policy, inspecting brothels, sex workers, and documents to ensure compliance. Although free condoms should be provided, this rarely happens in practice. Sex workers have been taken to clinics under military or police escort. They have paid fees to obtain certification showing that they are free of disease, or kickbacks have been paid directly to the authority responsible for inspection of brothels. In some cases, photographs of women are displayed in brothels allowing clients to identify which worker agreed to have unpro-

unfounded. In frustration, the NSWP protested at the 2002 Barcelona AIDS Conference (figure). This action prompted research on 100% CUP in Cambodia that showed its adverse effect on respect for the human rights and health of sex workers."

There are alternative approaches to promoting health in sex workers, such as the Sonagachi project in Kolkata, India. The project began in 1992, and initially was a survey examining social demography, sexual behaviour of sex workers, their clients, and partners, and the prevalence of STIs and HIV infection. Subsequently, an intervention programme was initiated to control the spread of these infections.⁴ An understanding of the sex trade was developed and used to devise strategies to "win friends and neutralise enemies".⁵ Sex workers are now involved in management of the programme. Strikingly, the prevalence of HIV infection among the sex workers in Sonagachi has remained at 5%.⁶

Enabling strategies that build social capital among sex workers, allowing them to organise and lobby for better working conditions, would seem to be a more effective approach than creating new means of abuse, especially in environments prone to corruption.

Unfortunately, abuse seems to have been the outcome of 100% CUP. Ultimately, the sex workers' rights movement seeks resources to enable sex workers to participate in civil society and in decision-making that concerns them. However, as long as commercial sex is seen as degrading and workers as tainted, efforts to improve their working conditions and lives will not succeed. Until this attitude begins to change nothing else will.

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Confusion between prostitution and sex trafficking

In May, 2003, the US government passed the Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, which outlines the areas and support that the US administration is prepared to endorse in the fight against these diseases. The act includes the limitation that "No funds made available to carry out this Act... may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking."

This statement might go unnoticed, but it deserves attention. The juxtaposition of the terms prostitution and sex trafficking demonstrates a belief that both share similar characteristics, and thus reflects moral ideology rather than objective reality.

The distinction between trafficking and prostitution is important because it pivots on individual agency. Trafficking, though variously defined,¹ covers coercion, forced labour, and slavery. Prostitution describes the sale of sex, by no means necessarily without consent or with coercion. At a time when trafficking is increasing, as are international efforts to tackle it, it is critical to clarify the differences between the issues.²

The merging of these issues is not new, nor confined to the USA. In Asia, where human trafficking (both for prostitution and for bonded labour) has a longer history than in Europe, responses by governments and feminist groups alike have often been to call for eradication of prostitution, and therefore trafficking.

But this approach overlooks an important fact: millions of women have made the decision to sell sex, usually but not always, on economic grounds. Selling sex is a pragmatic response to a limited range of options. If you can earn the equivalent of UK£100 in a night, why knit sweaters or sweep floors to earn the same money in a month?

When women's groups call for rehabilitation and rescue of trafficked and prostituted women they argue from their own moral perspective and not that of the women they are seeking to save. The situation is complex, in that a spectrum can exist between trafficking and prostitution, with trafficked girls at one end and women who have decided to work as prostitutes at the other. Some women who have been trafficked may eventually begin to define themselves as sex workers. The longer a woman is involved in the sex industry the more likely this is to be the case; 6 years after being trafficked to India a Nepalese woman told me: "Why would I want to return to Nepal? I have friends here, I make good money. In Nepal what would I do? Look after goats and have no money! I'm good at my job and I know it. I don't want to return to Nepal."

Of course there will be other women and men who may wish to leave the sex industry. The responsibility of public health, development, and human rights workers is to ensure that individuals enjoy the same level of human rights whatever their involvement in the sex industry.

The prominence of debate about sex work and trafficking has grown largely as a result of the HIV epidemic.³ Sex workers, initially identified as a public health threat, embodied in phrases such as "pools of infection" and "vectors of disease", were recruited to promote safer sex. Sex workers around the world have been practising safer sex and educated many of their clients to do the same.⁴ Their importance in responding to the HIV epidemic is evident, but evidence of improved rights for these men and women is harder to find.

Key rights listed in the UNAIDS handbook for legislators on HIV, law, and human rights include:

- Non-discrimination and equality before the law

- Freedom from inhuman or degrading treatment or punishment

- Autonomy, liberty, and security of the person

All over the world these basic entitlements are violated in the context of sex work. It is rare to read of a successful lawsuit made by a sex worker against a rapist, violation from a policeman, or unlawful arrest.

By merging trafficking and prostitution, the agency of sex workers is overlooked. Rather than promoting opposition to prostitution we would do better to promote human rights. The right to resist being drawn into prostitution by trafficking certainly, but so too the right to work with the law's protection from harm, be it rape, violence, robbery, or other violations.

We can expect sex workers to continue contributing to the fight against HIV and thus to public health: it is after all in everyone's interest including their own. We should also expect public health and development professionals to support their so doing without fear for their lives or their safety—in sum, by advocating for the human rights of sex workers.

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Prostitution, public health, and human-rights law

The Optional Protocol to the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), created in September, 1981, is now open for signing and ratification by nations. Should the protocol come into force, women will be given the right to complain to the United Nations (UN) about breaches of the Convention and, in particular, discrimination in the provision of health services. For women who are prostitutes, however, and whose legal status is uncertain, it is unlikely that the Convention will be of substantial benefit.

Prostitutes are entitled to enjoy universal human rights. Because their legal status is complex, and compounded by international human-rights law, prostitutes are rarely in a situation where health protection or promotional activity could be expected to succeed.

The view that linking health policy with respect for human rights will result in a better health outcome is gaining acceptance. But when human-rights instruments are applied uncritically, in ignorance of the larger social picture, measurements of improved health outcomes may be less certain. Rights-based questions about public health should be asked and failings in rights instruments must be confronted.

Prostitutes overwhelmingly work outside the law. This has implications for their health that are hard to quantify. In one Australian study carried out in 1998, the prevalence of sexually transmitted bacterial infections was 80 times greater in 63 illegal street prostitutes than in 753 of their legal brothel counterparts. All the illegal street prostitutes with infections were in the group who had not been screened for infections in the past 3 months, whereas none of those screened in the last 3 months were infected. In legal brothels women are given a strong legal incentive to be screened monthly, and the use of condoms is compulsory. Legally sanctioned encouragement of prostitutes to use condoms or access screening services, both major determinants of the prevalence of sexually transmitted diseases, is impossible because of their illegal status. Occupational health and

safety law is applied to prostitutes in lawful brothels but not to their counterparts on the street.

Vulnerability to contracting HIV has been characterised as "exercising little or no control over one's risk of acquiring HIV infection...vulnerability is magnified by societal factors such as marginalisation or discrimination". This account encapsulates the situation of most prostitutes. In this



Prostitutes are yet to enjoy universal human rights

context rights-based objections to individual programmes such as compulsory testing, for example, have some, but limited, worth. A failure to acknowledge a background of general deprivation of rights undermines the impact of these objections.

International law that deals with prostitution targets trafficking in women for the purpose of prostitution, and counterpoises prostitution with human dignity. The 1949 Convention for the Suppression of Traffic in Persons prohibits the exploitation of prostitution of a person even with the consent of that person. CEDAW asks States to suppress trafficking in women and exploitation of prostitution. Nowhere is trafficking defined.

In May this year the Council of Europe adopted a recommendation which stated that trafficking in human beings for the purpose of sexual exploitation includes the procurement of individuals, even with their consent. Prominence is given to the rehabilitation of the prostitute and punishment of those responsible. This is despite the comment in February this year from Radhika Coomaraswamy, the UN Special Rapporteur on violence against women, that lack of consent should be an element of trafficking.

In a 1998 International Labour Office (ILO) study on prostitution in southeast Asia investigators noted that for adults it was possible to distinguish between forced and voluntary prostitution. But, they asserted, "It is outside the purview of the ILO to take a position on whether prostitution should be legalized. The question of legalization is thorny because the human rights concerns are difficult to disentangle from concerns over morality, criminality and public health threats".

Many prostitutes would not find it difficult to disentangle the human-rights issues. Social history explains the legal emphasis on trafficking and rehabilitation, and constructed similarities to slavery. But this is no longer a sufficient explanation. Perhaps the prohibition of exploitation of prostitution is a protective measure necessary when prostitution is illegal, but substitutes poorly for labour rights. This is not a

basis upon which to carry out a health programme for prostitutes. No international treaties promote the rights of willing workers. The failure to recognise the distinction between forced and unforced prostitution allows the claims of prostitutes' rights groups to be ignored. This expression of international law undermines efforts to reduce the incidence of HIV and AIDS and discriminates against prostitution on the basis of occupation. Anti-Slavery International and the Network of Sex Work Projects argue that the redefinition of prostitution as work is vital if prostitutes are to enjoy equal human rights, in particular, their rights as workers.

If it is possible to conceive that a person can enter prostitution voluntarily as the best of available options, then it is evident that there is a problem in international law. This problem contributes to the vulnerability of prostitutes to disease. It is therefore within the remit of health practitioners to advocate for a critical review of human-rights law. Rights instruments should not contribute to the vulnerability of populations to disease, they should aim to diminish this vulnerability.

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Torture and trauma in post-conflict East Timor

The 25 years of Indonesian military occupation of East Timor were characterised by repeated allegations of human-rights atrocities, few of which were ever investigated or prosecuted by the Indonesian authorities. Following the August 1999 referendum, pro-Indonesian militias, supported in part by the Indonesian military, embarked on a wide scale and largely indiscriminate programme of organised violence and destruction of infrastructure, which required a major international peace-keeping and relief operation.

An inherent part of the response to such humanitarian crises must include assessment of the prevalence of torture and extreme trauma, and attention to the rehabilitation needs of victims. If people do not have the opportunity to process the mental consequences of their traumatic experiences, and to obtain an integrated, balanced perception of their history, social reconstruction becomes extremely difficult if not impossible. Although spontaneous recovery is acknowledged, previous studies of treated and untreated patients with post-traumatic stress disorder (PTSD) have found a doubling of the average time needed to achieve significant remission of symptoms for those who did not receive treatment. Treatment is a critical process that must be incorporated early in the emergency phase of a post-conflict situation.

The International Rehabilitation Council for Torture Victims (IRCT), an independent international health professional organisation, carried out a national psychosocial needs assessment in East Timor in June and July this year. We aimed to assess the extent of torture and trauma and the health impact it had on the population. The study results have provided the basis for

the proposed National Psychosocial Rehabilitation Program.

1033 households in 13 districts of East Timor, an estimated 750 000 individuals, were interviewed. One respondent was selected from each household who was considered to be a reliable informant. A community trauma mapping activity was carried out, with the aim of generating a picture of each district's health system, and of identifying

"998 (97%) respondents said they had experienced at least one traumatic event"

and establishing potential partners and support systems. The questionnaire was designed to ascertain trauma and torture history, PTSD symptomatology, self-perception of health, potential for recovery, and help-seeking behaviour.

Respondents had a median age of 35.5 years and 873 (85%) individuals were aged 14–59 years. 998 (97%) respondents said they had experienced at least one traumatic event. The five most common events were: direct exposure to combat situation (785 [76%]), lack of shelter (658 [64%]), and ill health with no access to medical care (623 [60%]).

351 (34%) were classified as having PTSD, based on a cut-off score of 2.5 or greater in the Harvard trauma questionnaire symptoms checklist. Death of the father or mother was a common occurrence, reported by 320 (31%) and 248 (24%) respondents respectively, and 142 (14%) had lost their spouse during the conflict period. For women, grieving the death of a loved one was often compounded by the dilemma of taking over the sole responsibility for the family.

To get an indirect measure of the effect of trauma on children, respondents were asked if they had children who were either injured or from whom they had been separated. 227 (22%) said yes, and a further 125 (12%) said that they had children who died as a result of political violence. In several provinces there were reports of children having been raped by the militia.

Torture appears to have been widespread. 400 (39%) respondents said that they had been tortured, but a larger number, 587 (57%), said they had experi-

enced at least one of the six forms of torture included in our study instrument. Psychological torture (411 [40%]), physical beating or mauling (336 [33%]), and beating the head with or without a helmet (267 [26%]) were the most common forms reported, and other forms of torture included submersion in water (126 [12%]), electric shock (124 [12%]), crushing of hands (102 [10%]), and rape or sexual abuse (54 [5%]). Many respondents described having been threatened at gunpoint, especially during interrogation by the Indonesian military. 227 (22%) witnessed the murder of a family member or friend. 207 (20%) respondents believed that they would never recover from their experiences, and a further 424 (41%) believed they would only recover with some help.

The problem of under-reporting of torture in population surveys was clearly seen in this study. Asking directly whether the interviewee had been exposed to torture yielded 39% affirmative, whereas the summation over only six specific forms of torture raised the estimate to 57%. This discrepancy may be explained by the reluctance of many victims to raise the subject at all unless asked about it directly. Future studies to assess the prevalence of torture should use instruments that specifically address particular experiences of torture.

Our study also found that East Timorese people look primarily to family members, the church, and the local community for assistance, although they are willing to approach a doctor or community nurse for problems that they perceive as being health related. Psychosocial and rehabilitation programmes are therefore likely to be most effective if they are family and community oriented.

With this in mind, the IRCT is working closely with other organisations to educate primary-school teachers in basic concepts of trauma and psychosocial recovery in children, and to provide support to children and their families. We aim to carry out the programme nationwide during the next 12 months. Giving priority to the treatment of children acknowledges that they are the population group in which the impact of conflict and disaster is greatest. Children can recover rapidly if they receive prompt treatment. By assessing traumatic events and their health sequelae epidemiological studies can play a crucial role in the collective response to humanitarian crises.


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Human rights in psychiatry



The Geneva Prize for Human Rights in Psychiatry was awarded this year to the Netherlands-based organisation—the Geneva Initiative on Psychiatry (GIP). The prize, created 2-years ago on the 50th anniversary of the Universal Declaration of Human Rights, rewards organisations who work to promote human rights in this field. The panel commended GIP for its work to combat the political abuse of psychiatry in the Soviet Union in the 1980s, widely used as a tool of repression. Robin Jacoby, Chairman of GIP, explains "We now have over 100 projects running throughout Central and Eastern Europe—day centres for victims of repression and for patients with chronic mental illness, as well as teaching programmes". Although the organisation now works with local professionals and families to promote the needs of the mentally ill in this region, the issue of political abuse is being revived "since there is growing and disturbing evidence of it from China", says Jacoby. **SH**

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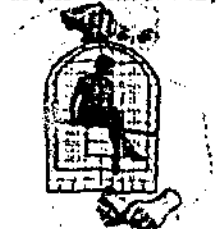
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Talking points

Health and human rights*'Asking a trafficked woman to speak about her experiences means asking her to relive memories of a personal tragedy'***THE LANCET**
Infectious Diseases**Neurology****Oncology**Steady jobs available abroad
No qualifications necessaryYou only pay with your dignity,
your health, and your freedom.

IOM

The trafficking of women and girls into forced prostitution and slavery-like or exploitative conditions is a gross violation of human rights. Chris Beyrer discusses whether or not trafficking should be recognised as a health issue. He notes that concentrating on health issues specific to these women can allow for programmes that meet not only the human rights goal of freedom from exploitation, but also the treatment needs of these women. From a different perspective, Cathy Zimmerman and Charlotte Watts draw our attention to the ethical and safety issues related to meeting with and gathering information from trafficked women, and call for safeguards to ensure that this process does not put women in jeopardy. Bebe Loff and Jyoti Sanghera finish this series by discussing the distortions and difficulties in trafficking data, which are often contaminated with ideological and moral bias.

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Distortions and difficulties in data for trafficking

Research into issues related to trafficking is hampered by a lack of clarity in the way we think about and act with respect to trafficked people. Work in the area is made even more difficult by the paucity of accurate data on the topic.

Despite the definition given to trafficking in international law¹ the term and issues surrounding it remain confused both conceptually and in government policy and practice. Several issues contribute to this confusion. First, researchers, law-enforcement agencies, and non-governmental organisations usually focus on a subset of trafficked people—women and children in sex work. Second, trafficking is rarely discussed without mention of coercion. But what constitutes coercion in the trafficking context? There is no universal, or even readily arrived at, position, which creates difficulties in contextualising and responding to many dilemmas raised by trafficking. Third, the definition of trafficking is complicated by a frequent failure to differentiate between women and children. Issues pertinent to children are sometimes incorrectly applied to adults. Even the Palermo Protocol¹ adopts the indiscriminate phrase “especially women and children” (panel). Further, trafficking is sometimes confused with people smuggling and illegal immigration.

That accurate data on trafficking in all its forms are difficult to obtain is not surprising. Such data, as exist, are often contaminated with ideological and moral bias. UNESCO notes that “(w)hen it comes to statistics, trafficking of girls and women is one of several highly emotive issues which seem to overwhelm critical faculties. Numbers take on a life of their own, gaining acceptance through repetition, often with little inquiry into their derivations. Journalists, bowing to the pressures of editors, demand numbers, any number. Organizations feel compelled to supply them, lending false precisions and spurious authority to many reports.”²

Emotive factors, used effectively since the days of the white slave trade campaigns, make funding easier to obtain for research on trafficking than for the full range of circumstances that exist for migrant workers. Laura Agustin D’Andrea³ makes the point that researchers wanting to study migrant sex work-

A definition of trafficking: the Palermo Protocol¹

- “Trafficking in persons” means the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs
- The consent of a victim of trafficking shall be irrelevant
- The recruitment, transportation, transfer, harbouring or receipt of a child for the purpose of exploitation is considered “trafficking in persons”
- “Child” is any person under eighteen years of age

ers find funding difficult to obtain for work outside the themes of trafficking, HIV/AIDS, or violence against women. She attempts to show how working only within these frameworks distorts the multiplicity of realities that exist for women and the range of responses that might be offered to them. If prevention of abuse and promotion of health in the context of trafficking is to be achieved, then we should work to address difficulties faced by other trafficked people such as domestic servants, workers in the carpet and garment industries, organ harvesters, agricultural labourers, and camel jockeys. Arbitrarily picking out one subset of trafficking as an issue of greater worthiness has a distorting effect.

In the past few years, there has been an upsurge in concern about trafficking, and reports that the crime is growing. Such anxieties have flourished in the post-September 11 climate, which is marked by deepening apprehensions about transnational crime, terrorism, and border security, and a hardening of attitudes to illegal immigrants. Yet, accurate data do not exist to support or refute the concern that the number of people being trafficked has suddenly increased. In fact, many of those post-September 11 worries and corresponding restrictions are increasing the difficulty of coordinated research between countries. Paradoxically, as the need for accurate information becomes more pressing, the chances of obtaining good data are fading.

Discussions about trafficking should be considered against a background of global inequity in which people may make rational decisions to act in ways that might

be illegal, socially unacceptable, or self harming.

Trafficking is the result, in part, of actions by “victims” who sensibly seek a better life for themselves and their families in another country. It is also a response to needs in the labour market in countries of destination.

What should the contribution of health-care professionals be to this issue? First, to ask trafficked people themselves about the problems they face and involve them in finding solutions. Second, to be aware of the health risks that come from being a non-citizen or illegal alien. People in this position may fear deportation and avoid health services in case their status is revealed. Surely the role of doctors and health workers is not to reinforce trafficking myths, but to fully enter into debates about migration and health that are properly located in the setting of human rights and global inequity.

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- 1 UN. Protocol to prevent, suppress and punish trafficking in persons, especially women and children, supplementing the United Nations convention against transnational organized crime. New York: United Nations, 2000. http://www.uncjin.org/Documents/Conventions/dcatoc/final_documents_2/convention_20traff_eng.pdf (accessed Jan 27, 2003).
- 2 UNESCO. Trafficking statistics project. <http://www.unescobkk.org/culture/trafficking/trafficking.htm> (accessed Jan 14, 2004).
- 3 Agustin D’Andrea, L. The (crying) need for different kinds of research. *Research for Sex Work* 2002; June 5: 30–32.

Risks and responsibilities: guidelines for interviewing trafficked women

The trafficking of women and girls into forced prostitution and other slavery-like or exploitative conditions is a gross violation of human rights. So dehumanising is this crime that one 17-year-old Romanian woman who was trafficked to the UK and forced to sell sex, explained that, while being sold from country to country, and client to client, she felt like a "piece of meat with two eyes".¹

The WHO *Ethical and Safety Recommendations on Interviewing Trafficked Women* released in October, 2003, addresses many ethical and safety issues related to meeting with and gathering information from trafficked women.

Although written for researchers, service providers, and journalists, the recommendations have relevance for health professionals, especially those who treat migrant women. Increasingly, reproductive health specialists, mental health professionals, and family doctors report that they know or suspect that women in their care have been exploited by traffickers. Encounters with such women are complex both medically and ethically.

The recommendations build on existing WHO guidelines for undertaking research with women who have experienced partner violence, and the collective experience of researchers and service providers working with trafficked women.

Even with the best of intentions, professionals who aim to gather

information from an extremely vulnerable group such as trafficked women can place not only the woman, but also themselves, at risk of physical or psychological harm. Ten guiding principles are provided for people interviewing trafficked women (panel 1); the aim is to keep danger to a minimum and increase the likelihood of gathering accurate information.

The first principle is "do no harm." Although a standard responsibility for research, in the case of trafficked women the concept has far-reaching implications; even approaching a woman to request an interview can cause problems. Contact with strangers may raise suspicions about the intentions of a woman in an exploitative situation. Will her traffickers think she is planning to escape? Will she reveal information about them? Talking with a woman who has left the trafficking situation also poses risks. Inquiries by outsiders can undermine any attempt to keep her experiences secret from family or community. For these reasons, people planning to interview trafficked women should not only be well informed about the dynamics of trafficking in general, but also have specific knowledge of the individual situation.

Asking a trafficked woman to speak about her experiences means asking her to relive memories of a personal tragedy, which can cause trauma and extreme reactions (panel 2). Interviewers should be able to offer women referral to appropriate assistance. Therefore, two of the strongest messages in the WHO recommendations are, whenever possible, to interview women once they are clearly out of the exploitative situation, and to always work closely with organisations that are knowledgeable about trafficking and can provide assistance.

Another recommendation is "Listen to and respect each woman's assessment of her situation and risks to her safety". Seeing a woman in an extremely abusive environment can incite some interviewers to take action on the woman's behalf. However, in the past, such well meaning actions have left women in worse situations than before. Trafficked women, like others in violent situations, should be consulted about their own safety, and timing for any change. Although contacting police might seem

Panel 2: Alexandra's story

I was a teacher in the Ukraine. Within my first 2 years at work I was shot in the shoulder and my front door was set on fire—probably because I am ethnic Moldovan. A friend offered to help me leave for a nanny job in the UK. I accepted. Damek arranged my documents and travel to the UK. When we arrived at the border, I changed my mind about going. Damek slapped me hard and made me continue on; he said that he could kill me. In London, Damek told me that I would be working as a prostitute and he raped me to show me that I would have no choice. The next night I escaped dressed only in my nightclothes. Eventually I found help. 5 months later, I discovered I was pregnant and had syphilis. My baby was born with syphilis and needed special treatment. I now sleep with a knife under my pillow in case Damek comes for me. When I am feeling very bad, I imagine killing myself. The psychologist I saw didn't seem to really listen to my story and told me that I would feel better as soon as my asylum application cleared. I don't really think so.

sensible, in some countries police are in collusion with traffickers. In other cases, police and immigration authorities will immediately deport the woman without providing appropriate assistance—potentially sending the woman back into the hands of traffickers.

Trafficking of women is a violent crime with everchanging dynamics as traffickers seek to stay ahead of the law. Risks associated with gathering information can be great. The collection of reliable and accurate data must include safeguards to ensure that this process does not put women in jeopardy.

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Panel 1: Ten guiding principles for the ethical and safe conduct of interviews with women who have been trafficked

- Do no harm
- Know your subject and assess the risks
- Prepare referral information. Do not make promises that you cannot fulfil
- Adequately select and prepare interpreters and co-workers
- Ensure anonymity and confidentiality
- Get informed consent
- Listen to and respect each woman's assessment of her situation and risks to her safety
- Do not retraumatise a woman
- Be prepared for emergency intervention
- Put information collected to good use

1 Zimmerman C, Yun K, Watts C, et al. The health risks and consequences of trafficking in women and adolescents: findings from a European study. London: LSHTM 2003. <http://www.lshtm.ac.uk/hpu/staff/czimmerman.html> (accessed Jan 15, 2004).

2 Zimmerman C, Watts C. World Health Organization recommendations for interviewing trafficked women. London: LSHTM/WHO, 2003.

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Talking points

Sexual violence in war

'It is clear that impunity for violence against women continues'

In this week's [Health and Human Rights](#), various writers explore the issue of sexual violence during conflict. Helen Durham and Bebe Loff begin by describing the symbolic hearing in Tokyo last month which sought to gather evidence of the horrific experiences during the Second World War of Japan's so-called "comfort women". As a gift from Emperor Hirohito to his troops, these women were systematically raped and tortured throughout their detention. Although rape is a commonly used strategy in war, it often remains hidden and is poorly addressed by humanitarian agencies. The lack of interest shown by the international community remains unacceptable, and there is a clear need for a firmly established international legal framework so that perpetrators of such abuses can be brought to justice.



Sando Moore

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Panel 3: Comparison of clinical features of fourth disease, SSSS, scarlet fever, and rubella

Clinical features	Fourth disease	SSSS	Scarlet fever	Rubella
Incubation period (days)	9-21 days	2-4 weeks	2-6 days	13-21
Scarlatiniform rash	All	All	All	No
Exfoliation or desquamation	Most	93%	Late	Rare
Nikolsky's sign or denudation	Yes	Yes	No	No
Vesicobullae	NS	69%	Rare	No
Conjunctivitis	Yes	59%	No	Often
Tender skin	Some	53%	No	No
Fever (>38.3°C)	Some	52%	Yes	Some
Perioral rash	NS	38%	No	No
URI prodrome	NS	29%	No	Some
Tonsillopharyngitis	Most	24%	Yes	Some

NS=not stated.

Dukes would mention the presence of an outbreak of pemphigus had once occurred at the time of the fourth disease outbreak. The incubation period of 9 days to 3 weeks is an important discriminator between fourth disease and scarlet fever. The incubation period of 9-21 days seems extended for bacterial illnesses, typical for a viral illness and identical to that of rubella. In the only mention made of incubation period in either of the modern papers, Margileth⁸ reported three siblings that had staphylococcal disease in 2-4 week intervals, which is consistent with the 1896 report of Dukes.⁴ An outbreak of pemphigus acutus in 1897 also described infection occurring 2-3 weeks apart in siblings.¹² The incubation period of fourth disease, then, is consistent with that of known staphylococcal exotoxin disease.

In an interesting article using a standard, modern approach to outbreak investigation, Morens and Katz¹⁰ maintain that there are epidemiological flaws in Dukes' report. They argue that in the 1896 outbreak, Dukes' described patients with a history of scarlet fever but in whom the fourth disease more closely resembled rubella, and in the second outbreak the disease more closely resembled scarlet fever but the patients had a prior history of rubella and not scarlet fever. Unfortunately, Dukes did not go into great detail regarding the clinical manifestations of the outbreak among 31 patients in 1896, so it is impossible to tell which disease this outbreak more closely resembled. The 1900 outbreak did resemble scarlet fever more than the previous description of 1894, but with some differences: (1) although the tongue was more furred than a usual case of fourth disease, it did not peel, as is so characteristic of scarlet fever; (2) there was no throat pain, which is usually a significant portion of the discomfort in cases of scarlet fever;¹⁴ and (3) there was an absence of albuminuria in his patients but "very frequent" in cases of scarlet fever. A comparison of Dukes' patients, SSSS, scarlet fever, and rubella is provided in panel 3.

Corroborating evidence of the role of *S aureus* in fourth disease is the appearance of another staphylococcal toxin disease around the same time. Ritter von Rittershain¹⁴ described exfoliative dermatitis of newborn babies in 1878, proven to be caused by *S aureus* by Winternitz in 1898.¹⁵ Pemphigus acutus and bullous impetigo were also quite common at the turn of the century, and *S aureus* was found to be the cause of pemphigus acutus by Escherich, Almquist, and Strelitz.^{16,17}

That fourth disease disappeared for several decades after it was first described is not unusual for a disease caused by *S aureus*. Staphylococcal scarlet fever was first described in America in 1927,¹⁸ and then not again until 1942.¹⁹ Staphylococcal exotoxin disease did not return in large numbers until the 1960s to 1970s when it was reported by Melish and Margileth and reviewed by Bass.²⁰ SSSS became rare again during the 1980s and is seen only sporadically now. The disappearance and re-emergence of staphylococcal disease may be due to reporting bias, but appears to be cyclical and excuses fourth disease for its temporary absence after it was described.

In summary, the already persuasive argument by Powell is bolstered by the report of tender skin in fourth disease patients, other diseases now known to be due to staphylococcus occurring around the same time, and evidence that staphylococcal toxin disease does have an incubation period of 2-4 weeks in household contacts, as was the case with Dukes' patients. After careful consideration of the evidence, one could conclude that Filatow, Dukes, and Powell were right: the "measles type" of rubella is German measles, the "scarlet fever variety" of rubella is the fourth disease, and fourth disease, like SSSS, is caused by exotoxin producing *S aureus*.

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Health and human rights: women and sexual violence

Supporting local efforts to document human-rights violations in armed conflict

At the end of 1999, 56 of the 188 AUN member states were involved in violent conflicts, resulting in 35 million refugees and internally displaced people, mostly women and children. Many were victims of deliberate and systematic attacks including sexual assault. The civil conflict in Liberia began in December, 1989, after 10 years of ethnic tension and violence, during which seven different fighting factions struggled for control of the country. Because the fighting occurred mainly in rural areas, nearly three-quarters of the population were forced to flee their villages. Civilians were subjected to illegal detention, strip searches, beatings, torture, rape, and murder. In 1996, Liberia had the largest percentage of uprooted people of any country in the world.

In the past decade the international community has begun to recognise and document sexual violence against women and girls during conflict. Documenting sexual violence and human-rights violations against women presents a unique challenge that requires special documentation methods. Reporting the experience of rape and sexual abuse will affect the woman and her community differently according to the attitudes of the individual, her family members, and her culture. Although a woman may be willing to report the killing of her family members, she may be reluctant to admit that she was raped. To document sexual violence accurately requires an intimate understanding of attitudes, languages, and regional practices.

Women's Rights International (WRI) was founded with the specific purpose of developing methods that can accurately document and address human-rights violations against women. The organisation works with rural women in countries at war or who are living under state-sponsored violence, using participatory action-oriented research. The women who are affected by a certain issue choose the research questions, design the survey, and collect the information themselves. In 1994, WRI began a collaboration with the Women's Health and Development Program (WHDP) at the Mother Patern College of Health Sciences in Monrovia, Liberia, to document the experiences of women, including sexual violence and coercion, during the

Japan's "comfort women"

It was not until 1993 that the Japanese government stopped denying its involvement in the creation of comfort stations—establishments that saw the systematic rape, torture, and in some cases murder, of approximately 200 000 so-called comfort women. Women from Asia and the Netherlands, many of whom were girls at the time, had been a gift from Emperor Hirohito to his troops during the Second World War. Numerous attempts by the women to claim justice for their abduction and brutal treatment through the Japanese courts have failed, including a recent case brought by 46 Filipino women. Last month, to continue to put pressure on the Japanese government, the Violence Against Women in War Network (VAWW-Net Japan), the Korean Council for the Women Drafted for Military Sexual Slavery by Japan, and the Asian Center for Women's Human Rights (ASCENT) convened the women's international war-crimes tribunal on Japan's military sexual slavery. At this symbolic hearing in Tokyo, 78 former comfort women from countries including North and South Korea, Peoples Republic of China, Taiwan, Philippines, Malaysia, Indonesia, and the Netherlands gave evidence and demanded accountability.

The evidence-gathering process took many forms. In Manila in the Philippines, 30 elderly women told their stories through an interpreter. With tears rolling down their faces they exposed the pain and humiliation of their experiences more than 50 years ago. As young girls they had been forced into army brothels where they were raped by as many as 60 soldiers from the Japanese imperial army each day. Their stories were stark testimony to the horror experienced by those forced into sexual slavery. The women had recently been rejected by their families for speaking out. One woman told of her devastation after her 30-year-old daughter refused to speak to or see her on learning the details of her sexual abuse by the military for 5 months during the 1940s. One survivor from Korea told of how she became pregnant as a result of multiple rapes. The soldiers cut her fetus out with a bayonet and removed her uterus. Another, an Indonesian woman, was 16-years old when taken from her home with 80 others and kept in one room to "service" the soldiers. She explained to interpreters that every Friday a doctor would examine her, and that once the examination was complete the doctor would rape her. The tribunal was told that at the end of the war, in order to hide evidence of one of the stations, women had been grouped there and the station bombed. Two Japanese veterans and six expert witnesses also provided testimony. Prominent international lawyers including Gabrielle Kirk McDonald, previously president of the International Criminal Tribunal for the former Yugoslavia, served as judges and prosecutors. The judges indicted Emperor Hirohito for these war crimes.

In addition, on Dec 11, there was a 1-day public hearing in Tokyo on crimes against women in recent conflicts. This hearing, coordinated by Women's Caucus for Gender Justice, brought together women who have survived violations in recent and ongoing wars and conflicts. Women presented testimonies from many countries including Sierra Leone, Burundi, Colombia, Vietnam, Somalia, and Korea. One 25-year-old woman from Chiapas, Mexico, spoke of going to a public hospital to give birth in August, 1999, where the doctor advised her that a caesarean section was necessary. She later found that she had been sterilised. A widow with five children from Sierra Leone told of how her town was attacked by rebel forces in December, 1999, and how she had escaped into the bush with her children. They were without food for 3 days and on the fourth day ten masked men raped her while swearing their allegiance to the rebel leader. They left her bleeding, helpless, and separated from her children. It is clear that impunity for violence against women continues.

Sexual assault has always occurred in armed conflict and for many years was seen merely as an inevitable consequence of war. In the last few years the ad hoc international criminal tribunals for Rwanda and the former Yugoslavia have set a strong precedent that rape is a war crime and a crime against humanity. By contrast, the Second World War international prosecutions in Nuremberg and Tokyo were almost silent on sexual crimes against women. Current developments in the ad hoc tribunals are welcome and it is heartening that the proposed international criminal court includes ample reference to sexual crimes.

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war. During ongoing conflict, a team of Liberian health workers designed, wrote, and carried out a population-based survey, interviewing 205 randomly selected women in urban neighbourhoods, markets, camps for internally displaced people, and high schools in Monrovia. They found that nearly half the women they interviewed had experienced physical or sexual violence and coercion by soldiers and fighters.¹ Because they designed the survey themselves, the Liberian women were able to draw on their own experiences and understanding of violence against women during the war to document important risk factors and characteristics of sexual violence. For example, the team knew that when a woman was detained by a fighter and forced to cook for him, that detention was



The refugee camp in Liberia, 1995

often associated with sexual violence. The survey data showed that being forced to cook was a significant risk factor, providing statistical evidence for what the Liberian women knew about human-rights violations during the war. Additionally, Liberian women knew that there were many interpretations of the word "rape", and that if they simply asked women if they were raped they would not have accurately documented every instance of sexual violence. Instead they used Liberian English to ask women about forced sex. Finally, the Liberian women knew that sexual violence during the war occurred along a continuum, with forced sex at one extreme, voluntary relationships with fighters at the other extreme, and sexual relationships in exchange for economic support and safety falling somewhere in between. In their survey they asked about the entire continuum, documenting a broad spectrum of physical and sexual violence and coercion by soldiers and fighters.

Collecting information and developing programmes during armed conflict presents significant safety risks to everyone involved. Security problems, military curfews, and other complications interfere with a project undertaken in the middle of a war. These complications should not prevent information from being collected, but they do impose the need for additional security precautions. The Liberian

team decided to document what was happening to Liberian women during the war, but they did not feel it was safe to identify perpetrators. The team took special precautions to protect their own safety and the safety of the women they interviewed. They chose not to document the identities of individuals, fighting factions, or details of when and where violent events occurred, but to establish a record of the scope and scale of physical and sexual violence against women. This type of information has been used in other conflicts to establish the need to prosecute rape in international tribunals. In the former Yugoslavia, for

example, evidence of rape on a massive scale was based primarily on data that did not identify perpetrators. Those data prompted the UN Commission on Human Rights in 1993 to pass the first resolution to identify rape as a war crime.

The collaborative partnership between WRI and WHDP has developed innovative ways to support Liberian women in organising a programme to address the effects of physical and sexual violence in their lives. The first workshop involved 11 traditional birth attendants in a displaced people camp in Liberia in 1994. As a result of the workshop, these women formed a group to promote mutual understanding, support, and willingness to speak for one another's rights. They organised the women in the camp to elect a woman as camp leader, something that had never happened before. When a woman's husband died and her brother-in-law tried to take her house, as is customary by tribal inheritance law, they collectively went to the chief and persuaded him to let the woman keep her house. In April, 1996, fighters attacked the camp and the occupants fled. Several weeks later, the women returned to the camp to find that their garden had been demolished and their stick and thatch houses had been looted. However, within a year the women's group had grown to include several hundred women who were addressing immediate concerns such as violence against women in the camp.

During ongoing armed conflict the international community focuses its resources on emergency humanitarian aid, supporting food distribution and

emergency medical care. Active armed violence and a government that is unstable or in constant upheaval create a difficult context for documenting human-rights violations and for developing programmes to address war violence. Small international non-governmental organisations, however, can work directly with local groups to collect information and establish programmes during war. When information on human-rights violations is collected immediately it is more accurate and more useful to local and international agencies.² In addition, the protracted nature of many conflicts makes it ethically irresponsible to wait until the conflict is over to set up programmes for people who could have benefited from them earlier. Local groups should retain control of decisions about the purpose for collecting data, what data are collected, and when and where the data are disseminated. Donor partners and international organisations that support local programmes must be aware that it could be many years before local programmes can safely release some of the information they collect. A delay in providing information to international partners could be crucial for protecting the local programme, but may conflict with the needs and expectations of international organisations and donors.

Supporting local efforts results in a programme that is meaningful and sustainable. The Liberia project started developing and implementing its programme in 1994, 5 years into the civil war. The project remains active today and has functioned virtually uninterrupted for 7 years. The WHDP team has now travelled to nearly half the counties in Liberia to carry out their 2-week workshops to promote consciousness raising, problem solving, and community organisation around the issue of violence against women. Using a participatory approach to collecting information about human-rights violations requires enduring commitment and carries substantial risks, but also has the potential for positive, lasting, and sustainable changes at the local level.

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Responding to rape

Sexual violence has long been used as a strategy in war. Widespread rape has been documented in the former Yugoslavia, Rwanda, Bangladesh, Uganda, Burma, and Somalia. It is a highly effective means of terrorising entire communities: because of the emphasis most cultures place on the sexual virtue of women, the rapist is able to humiliate and demoralise. The impact is multiplied when the woman becomes pregnant. In Rwanda after the 1994 genocide, as many as 5000 babies were born to rape victims. These children became known as the *enfants mauvais souvenir* (children of bad memories) and there have been reports of abandonment and infanticide.

The issue of rape, however, often remains hidden and is poorly addressed by humanitarian agencies. This is partly a result of under-reporting. In Freetown, Sierra Leone, Médecins Sans Frontières (MSF) found the prevalence of rape among women to be 14%, but intake of rape victims in rape counselling centres in Freetown indicate that rape is much more common;

one MSF mental health worker commented that "being raped is like being bitten by a mosquito, it's that frequent."

Rape victims will weigh their need for care against possible stigmatisation within the family or society, or retribution from the aggressors. Health staff are often ill-equipped to tackle the issue, and therefore reticent to explore it. Staff should be trained in recognising and dealing with victims of rape, and time should be taken to establish a rapport and provide a safe and confidential environment for disclosure.

An adequate response requires clear protocols and a multidisciplinary approach. A full history of the event and a physical examination should be obtained. Antibiotic prophylaxis should be prescribed when possible. HIV prophylaxis is more complex: its use is often restricted by the high cost of the drugs. Emergency contraception should be available, and depending on the laws of the country, an abortion can be offered. Reconstructive surgery may be needed. When indicated, and with consent, a forensic examination should be done according to local capacity.

Mental-health support, where available, should be integrated into the medical services. Because rape in wartime usually happens together with other traumas and losses, and to avoid stigmatisation, these services should focus on a broad range of psychosocial problems. All patients should be offered a medical certificate, as a testimony to the event, and for eventual legal action. However, victims should be supported regardless of whether they wish to report the assault.

International human-rights law now clearly recognises sexual violence as distinct from other forms of torture. Thanks to the testimony of many courageous women, the International Criminal Tribunals for Rwanda and the former Yugoslavia have successfully prosecuted cases of rape as a grave crime against humanity, and as part of the act of genocide. The statute creating the new International Criminal Court will allow prosecution of perpetrators of systematic sexual violence. So far, however, the statute has been signed by 139 countries but ratified by only 27 (<http://www.iccnw.org/index.html>).

Such legislation has not, however, translated into increased protection for women. Recently in Kosovo, the media eagerly sought out victims of rape, to be used as part of the propaganda to justify NATO intervention. This resulted in a further erosion of women's dignity while doing little to remove the risk. Meanwhile, rape continues unchecked in many forgotten conflicts: Amnesty International recently reported that all sides to the conflict in the Democratic Republic of Congo are using sexual violence "to spread terror among the populations, and to destabilise community identity". In late 1999, MSF spoke out against the systematic rape of displaced women returning home to Brazzaville—1600 rape victims presented at Makeleke hospital, Brazzaville, over 8 months. These denouncements were met with almost no interest from the international community. It would seem that rape in war has become too banal to provoke a response. Nevertheless, until an international legal framework is firmly established, ad-hoc advocacy efforts, informed by medical ethics, human rights, and humanitarian law, will remain crucial in preventing sexual violence in war.

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Sexual violence in Sierra Leone

9 years of civil war in Sierra Leone have unleashed widespread and systematic sexual violence against women and girls. This violence has included gang rape, sexual slavery, and assault. The rebel factions use sexual violence to terrorise the civilian population—to humiliate and punish them, and ultimately to control them. Sexual violence in this war is intended to break taboos and undermine cultural values. Human Rights Watch has documented cases of fathers being forced to watch the rape of their daughters, and middle-aged women being raped by boys as young as 11. Girls have been raped during sacred coming-of-age rituals.

In July, 1999, the Sierra Leonean government and rebels signed a peace accord giving amnesty to all sides in the war. Some forms of human-rights abuse dissipated after the accord—but sexual violence continued, unabated. Now, since the peace accord collapsed in May, 2000, there has been a substantial increase in women being raped by forces loyal to the Sierra Leonean government.

The largest faction among the government's Civil Defense Forces is the Kamajors, who believe that their potency as a warrior depends on sexual abstinence. But in recent years, the Kamajors have been moved away from their native areas in the south and east and given more responsibility for national security. Now separated from their traditional chiefs, they have let discipline flag, and grown more inclined to commit sexual violence.

The victims of sexual violence can suffer serious health consequences. We have documented two rape victims who suffered a prolapsed uterus, and several cases of serious injury in women who had objects inserted into their vaginas. The incidence of sexually transmitted diseases is very high among the victims of sexual violence, although the HIV/AIDS infection rate in this population is not known. Sierra Leone has no programmes available to test for the infection. Sexual violence is among the most serious, and is possibly the most prevalent, human-rights abuse now underway in Sierra Leone. But surprisingly it is not a focus for the foreign authorities working in the country. The UN is currently providing some human-rights education to Sierra Leonean police units, and the British army is training 3000 members of the Sierra Leonean army on the laws of armed conflict and the protection of children, but no one offers any specific training to any military or police force in Sierra Leone on women's rights.

We have called for the establishment of an internationally supported tribunal to bring to justice the perpetrators of war crimes and other abuses in Sierra Leone. That tribunal has been slow in coming. But if and when the UN finally sets up such a court, rape, sexual slavery, and sexual mutilation must be judged as crimes against humanity and war crimes. They cannot be viewed as anything less.

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or dance. These types of activities depend on identifying motivated leaders.

In responding to HIV, we need to ensure that we respect people's right to self-determination, confidentiality, privacy, information, and non-discrimination. In these settings there are often calls for mandatory HIV testing. This needs to be resisted, not only because it is an ineffective public health strategy, but also because it breaches these rights. Research and treatment also need to incorporate these principles. Because health care service providers who discriminate against people with HIV are potent generators of stigma in the community, so they need

accurate information and antidiscrimination policies.

Relief agencies that have been present during an emergency are in a good position to integrate HIV prevention and care efforts into their health, education, and social activities when the situation becomes stable. Agencies have recognised that their workers need guidance in prioritising and implementing responses to HIV—for example, the International Rescue Committee is currently preparing a manual for their field staff. In addition, efforts to prevent conflict, and to resettle those displaced as soon as possible, are obviously fundamental to addressing the vulnerability of refugees.

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Compulsory detention: limits of law

On March 16, a man was convicted for the first time in the UK for intentionally infecting his partner with HIV. He was sentenced to a 5-year term of imprisonment. The prosecution was criticised by AIDS groups who suggested that it would not deter similar behaviour in the future, and could well lead to unwarranted complacency among people engaging in risky sexual behaviour. Elsewhere, criminal prosecution for actual or attempted HIV transmission has also been criticised for unfairly targeting racial and sexual minorities and for its potential to further marginalise people with HIV. Those opposed to the involvement of the criminal law have not necessarily considered the sometimes less transparent, though potentially equally draconian, activities of public health officialdom. In the now 20-year-old debate on HIV and human rights, some civil libertarians have preferred the use of criminal law to the application of public health powers. Criminal law commonly requires a public trial and procedural protections for an accused. These requirements are found less often in public health law.

The power to isolate and detain carriers of infectious disease is a traditional feature of public health law. In many jurisdictions, the powers remain largely as they were more than a century ago, giving full decision-making authority to a public health bureaucrat. Some have argued that granting the authority to isolate carriers entails great risks to civil liberty. We suggest that protecting others from serious harm is a sufficient justification, in principle, for detaining an individual until the danger can be eliminated. Where a serious disease is still low in prevalence, or is approaching elimination, the case is even stronger because the benefits of preventing each case are quite high. In practice, the crucial issue is whether the conditions that would justify detention are actually present. Unfortunately, those who are detained under these laws are often at the social margin—the homeless, street workers, intravenous drug users, the mentally ill, and intellectually disabled. These populations have more exposure to disease, fewer resources for coping, and are more likely to be perceived as uncooperative. The focus of coercion on the poor and mentally ill also accounts for the fact that criminal and mental health laws have been used to achieve detention. It may be more convenient to prosecute a sex worker under criminal law and keep him or her out of circulation for a while than to initiate what may be a cumbersome public health process. This is particularly so because many jurisdictions have done

away with their infectious disease hospitals, and sanatoria thus have no place to detain an individual. Criminal law may sometimes be used because neither public health nor mental health authorities want charge of a difficult individual, and so pass on the case to the police.

Not surprisingly, HIV and tuberculosis have provided occasions to rethink the criteria and process for detention. Some jurisdictions have amended their laws to explicitly require that there is a significant risk to others involved—ie, a person cannot be detained at the discretion of an official solely because they are infected with a disease. These jurisdictions will often require graded responses to the risk posed. The least restrictive approaches must be used to deal with behavioural threats—for example, support in the community in preference to isolation and detention. The individual is provided with legal counsel and the right of review before a neutral judicial officer. Legal procedures that afford the detained individual an opportunity to present facts, and that are transparent to the public, are desirable developments. Although sometimes resented by health professionals, such systems can effectively harmonise human rights values and public health needs.

But even in these jurisdictions, legal and public health systems may cooperate too well. The chief source of evidence to the court will be a physician or health official. Decisions will turn to medical determination of the risk to others. Judicial officers will usually defer to this evidence, and will often share the cultural biases of fellow professionals in assessing the risk posed by a person of significantly lower social status. Properly seen, the issue is not whether compulsory detention can be justified in theory, but whether it can be fairly deployed in practice. Where an HIV-positive homeless and mentally ill person comes to the attention of health officials and the courts there is the danger that the risks will be overstated, the recalcitrance of the individual exaggerated, and the range of less intrusive responses ignored. In these cases, the principle of protecting the many from the serious risks of the few is sound, but misapplied on the facts. Clear legal criteria and fair transparent procedures are vital for a just public health detention system. Equally necessary is continued awareness of the social distance between those most at risk of disease and those in charge of controlling it.

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Expert Opinion

How much is patent protection threatened by drug costs?

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A recent article in the Wall Street Journal began by stating

'As public-health groups urge wider use of generic drugs to lower the cost of treating AIDS and other diseases in developing countries, US trade negotiators – prodded by the drug industry – are taking the opposite stance in new trade pacts, seeking to strengthen protections for costlier brand-name drugs.' (1)

As the impact of AIDS deepens, the demand for treatment will continue. The use of patent law in limiting access to drugs is now continually subject to challenge by civil society, governments and international organisations. In the face of an incomprehensible number of humans confronting untimely death as a result of AIDS and other treatable diseases, there is no doubt that something must change. The questions are simply what, when and how.

Analogies with the Holocaust of the Second World War are striking. As with World War 2, and the millions murdered in the concentration camps, to those in the industrialised world it is impossible to grasp the immensity of what is happening. To say millions are dying is meaningless. Yet the story of one person or a few is intelligible. If a current affairs programme were to follow a mother in Africa each night from the moment she was diagnosed to her death, this would probably generate more sympathy and pressure for change than any horrific mortality report published by UNAIDS.

Controversy generated over the impact of patents is centuries old. Countries have swung between promotion of the implementation of intellectual property laws and revoking them. Although to some, laws may appear immutable, in fact, regulatory environments change regularly, sometimes in advance of public opinion but more commonly in response to it. It is probably naive to suggest that a single factor, such as drug costs, will result in significant reform of patent law. In any social or legal controversy there are always a great many questions to consider.

In the case of the future development of patent law, the practices and image of the pharmaceutical industry will naturally be at issue. Anticompetitive activities ranging from excessive secrecy regarding a product (something patents were intended to remedy), to conspiracies between companies to price fix have been continuing problems (2). Current concerns about off-label use, such as in the case of GlaxoSmithKline and Paxil® (and potential civil litigation and criminal prosecution) have and will contribute to damaging perceptions of the industry (3). Amongst other related issues is the failure to publish unfavourable studies regarding a product, and the practices of drug company employees in wooing medical practitioners, in order to promote their product. Although it receives less publicity other criticisms of the industry involve the lack of development of new drugs and the inattention to the diseases of the developing world. For example, in 2000, even though the US Patent Office granted 6730 pharmaceutical patents, the FDA only registered 27 new chemical entities (161).

In addition as a germane article in the New York Times noted

'The pharmaceutical industry earns nearly two-thirds of its profit in the United States, as drug prices in the rest of the industrialized world are largely controlled by governments. Those profits rely almost entirely on laws that protect the industry from cheap imports, delay home grown knockoffs, give away government

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Box 1. Flexibility of the Trade Related Aspects of Intellectual Property Rights agreement.

- **Compulsory licensing:** during a national emergency a government may issue a licence for the production or purchase of a drug for domestic use without the approval of the patent holder. Patent holders will normally receive compensation
- **Parallel importing:** drugs will be imported from a country where they are available at a cheaper price rather than from the patent holder

medical discoveries, allow steep tax breaks for research expenditures and forbid government officials from demanding discounts while requiring them to buy certain drugs.' [102]

It is not well understood that governments (not only that of the US) provide a range of different supports and protections, such as those described, for the pharmaceutical industry. Patents are merely one of these.

The same article went on to note that 57% of respondents to a poll conducted in the US said that drug prices are 'unreasonably high' and an equal share said that the drug industry should be increasingly regulated by the federal government. Some respondents equated the pharmaceutical industry with the tobacco industry. A former researcher for Bristol-Myers Squibb was quoted saying that surging prices invite government controls. In response, Pfizer Inc. has said that it will provide discounted drugs to the working poor and anyone without health insurance [102].

At an international level, it is possible to see compromises on patent law and access to drugs being reached then undermined. The Doha and Cancun World Trade talks concerning intellectual property, were a breakthrough of sorts but were rendered less so with the US embarking upon a series of 'free trade' negotiations. In summary, the Doha Ministerial meeting resulted in a consensus that the multilateral agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) should be interpreted in a manner that allows government members of the World Trade Organization (WTO) to protect public health [4]. The right of WTO members to fully use the provisions in the TRIPS Agreement, which provide flexibility for this purpose, was affirmed. Such flexibility includes compulsory licensing and parallel importing (Box 1). It was recognised that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Therefore, the Council for TRIPS was instructed to find an expeditious solution to this problem before the end of 2002. In Cancun, in 2003, it was agreed that member countries could export pharmaceuticals made under a compulsory licence provided numerous requirements were met [5]. The decision has force until such time as TRIPs is formally amended. Although Canada has amended

its law to permit this, and Malaysia and Mozambique have said that they would be issuing compulsory licences, benefit from this new arrangement has yet to be demonstrated.

Despite these negotiations, to which the US was party, the US has exerted pressure on countries during the 'free trade agreement' negotiations to reform their intellectual property laws in order to provide greater protection for the pharmaceutical industry. In its bilateral negotiations with Thailand, for example, the US raised concerns regarding Thai intellectual property law [103]. As was noted by Kamon Uppakaew of the Thai Network of People Living with HIV/AIDS 'Scaling up access to treatment in Thailand will be challenging enough without additional barriers to obtaining generic versions of newer, patented medicines for HIV and other diseases.' [104] Similarly, so-called TRIPs plus standards are being demanded in 'free trade' negotiations with Ecuador, Colombia and Peru. The US has also stipulated that systems regulating drug availability and pricing be made more open to challenge by the industry such as in the case of Australia [6].

As mentioned earlier, responses to the present situation now emanate not only from activist groups such as Medecins Sans Frontieres, Oxfam and Health Gap but also from the World Health Organization, UNAIDS and the United Nations Office for the High Commissioner for Human Rights. In its latest report, UNAIDS noted that

'Access to antiretroviral treatment and other HIV-related disease care remains abysmally low. Five to six million people in and middle-income countries need antiretroviral treatment immediately. However, the World Health Organization (WHO) estimated that only 400,000 people at the end of 2003 had access to it. This means that nine out of ten people who urgently need HIV treatment are not being reached.' [7]

The report further acknowledges that some gains have been made in the affordability of drugs and attributes this largely to the work of advocates. United Nations Secretary-General, Kofi Annan is quoted

'People no longer accept that the sick and dying, simply because they are poor, should be denied drugs that have transformed the lives of others because they are better off.' [8]

Prof. P Hunt, the Special Rapporteur of the United Nations Commission on Human Rights on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, issued a statement after a recent visit to Peru. It was almost entirely concerned with the trade negotiation between the US and Peru. He said

'I am deeply concerned that the US-Peru trade agreement will water-down internationally agreed health safeguards, leading to higher prices for essential drugs that millions of Peruvians will find unaffordable ... The US-Peru trade agreement must not restrict Peru's ability to use the public health safeguards enshrined in TRIPS and the Doha Declaration ... If the final agreement has the effect of restricting access to essential drugs it will be

inconsistent with Peru's national and international human rights obligations [105].

Despite recognising that patent regimes are not the sole source of difficulty, United Nations human rights bodies are increasingly cognisant of the impact of patents in either driving up prices for pharmaceuticals or in ensuring their unavailability to those most in need. In June 2004, the Committee on Economic, Social and Cultural Rights strongly recommended that Ecuador take its human rights obligations into account when negotiating the US-Ecuador trade agreement. The Committee on the Rights of the Child recently adopted a similar position when recommending that El Salvador 'systematically consider the best interest of the child when negotiating trade-related intellectual property rights' [106].

Pressure to reform the patent system is mounting. Pharmaceutical companies know they have an image problem and are not entirely impervious to pressure. However, responses in the form of charity are not regarded as being sufficiently

reliable so as to be satisfactory. Initiatives, such as the Global Fund on HIV, Tuberculosis and Malaria and the World Health Organization 3X5 Campaign, attempt to meet treatment needs. But this also relies upon willing donors, and is far from sufficient. The undermining of international agreements such as those reached in Doha and Cancun must eventually lead countries to question the benefit of being party to organisations, such as the WTO. Why have international agreed standards for patent law been placed in a negotiating position that requires the imposition of a more restrictive standard? Furthermore, no democratic government, not even that of the US wishes to be seen to be in the pockets of any single force regardless of their influence. Balances must always be struck. History has demonstrated that the powerful do not relinquish their power voluntarily. It must be wrestled from them. Drug prices, among other concerns, have already resulted in some reform of the patent system. It may be that more is to come.

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Patents on Drugs: Manufacturing Scarcity or Advancing Health?

Bebe Loff and Mark Heywood

Respect for and promotion of the human rights of people with HIV/AIDS is now an entrenched component of the global response to HIV. However, as the global HIV epidemic has turned into a global AIDS epidemic, and as the death toll mounts, one area of human rights — the right to health care — has become fiercely contested. In particular, the degree to which patents on medicines impede what the United Nations High Commissioner for Human Rights has described as the “human right” of access to essential medicines is receiving close scrutiny.¹ The controversy generated by a recent article that argues, “in Africa patents and patent law are not a major barrier to treatment access in and of themselves,”² is indicative of the intensity of the debate.³ But more importantly, advocacy for the human right to health, and to treatment in particular, is pitting developing country interests against those of the rich world and research-based pharmaceutical companies. Advocacy for access to treatments is leading to careful moral and legal scrutiny of patents taken out on medicines, new attempts to define the boundaries to intellectual property, and calls for a renegotiation of world trade rules.

However, in the hullabaloo, the need to present practical evidence of the impact of patents on health and access to medicine is sometimes neglected. This article attempts to fill that gap by examining some of the consequences of international trade law and intellectual property law for the prophylactic or curative treatment of ill health in general and HIV in particular.

The fact that AIDS and later HIV were first diagnosed in industrialized countries, such as the United States, and the relatively rapid development of treatments for HIV has helped to bring these issues to the fore in a way that arguably other

illnesses have not. This is because while treatments for HIV were designed in and for a profitable first world market, the greatest need for them is now in developing countries — where they are largely unaffordable. Treatments for HIV have also suddenly created a new group of patented “essential medicines”⁴ (particularly antiretrovirals) that are still highly profitable in rich countries but desperately needed in poor countries. Early this year this contention was borne out by the addition of all the current antiretroviral drugs to the World Health Organization’s Model Essential Drugs List.⁵

In the context of drugs needed for the treatment of HIV, we attempt to illustrate how, despite the acknowledgment of other factors named by the World Health Organization (WHO) as influencing access to medicines (such as reliable health infrastructure and supply systems, sustainable financing, and political commitment), the effect of price in limiting access to life-saving drugs is significant. This article argues that the patent status of a medicine (as well as other essential medical technologies including diagnostic tools that measure viral load and CD4 counts) is the major determinant of that medicine’s price — not traditional economic factors such as demand, active ingredient costs, or even research and development costs. Once again, we reiterate that there is absolutely no doubt that there are other significant factors that can limit access to treatment, but the purpose of this article is to address the consequences of patents and the commercialization of intellectual property related to human health. Medicines and political commitment to a public health-care infrastructure that can deliver them are obviously linked. But rather than pitting one against the other, we would argue for an analytical separation of the two issues, and a recognition that the demand for upgrading public health-care systems (and properly appreciating the obstacles to this) may represent a separate agenda both politically and developmentally.

PATENTS AND PHARMACEUTICALS

Patent law is a "rather artificial, highly complex and somewhat refined subject."⁵ Patents are a legal reward provided by the state for the disclosure and working of a new and useful invention. They result in monopoly rights over a process or product for a given period. In the words of the United Nations Committee on Economic Social and Cultural Rights, the legal recognition that is given to intellectual property is a "social product" that has a "social function" — namely, "to provide incentives for inventiveness and creativity from which society benefits."⁶

The debate over the consequence of patenting essential products, including medicines, is not new. Historically, some inventors and courts have deemed certain discoveries in the fields of medicine and surgery too valuable to be subject to a patent, recognizing the inherent inconsistency between monopoly rights and goods that might have significant health effects. This is true of ether and its effect in surgery, penicillin, medical applications of radium, and the polio vaccine. In the recent case of *Bristol-Myers Squibb v. FFI Faulding*, Justice Finkelstein stated, "The important question: 'is it ethical to patent a pharmaceutical substance or a method of medical treatment?' admits of no satisfactory answer."⁷ He noted that Dr. Squibb is reported to have said, "I do not myself think that anything should be patented by either physician or pharmacist."⁸

This dilemma led to the development of divergent approaches, with some countries choosing to exempt medicines from all or part of patent law. In countries like Canada and Australia, patent regimes were moderated by mechanisms to control prices, or to facilitate local production under compulsory licenses.⁹ In countries such as India, Thailand, and Brazil, other legal means were found to allow competitors to circumvent the negative effects of patents by allowing the patenting of medical products but not processes, or vice versa. In Brazil, for example, Bermudez and colleagues note:

Pharmaceutical products and processes were patent-protected until 1945, when a change in legislation excluded inventions that contained food or pharmaceutical substances obtained by chemical means or processes. Additionally, another change in 1969 excluded patent protection completely for pharmaceuticals.¹⁰

Such approaches had dramatic effects on the capacity of local industry to manufacture medicines, albeit with different effects on the actual availability of medicines to people in need. In India, for example, 20 years after the enactment of the Patents Act of 1970, the share of Indian firms in the domestic pharmaceutical market had risen from 25 percent to 70 percent of bulk drugs and 80 percent of formulations. According to Lanjouw:

Of the top ten firms by 1996 pharmaceutical sales, six are now Indian firms rather than subsidiaries of foreign multinationals. Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country.¹¹

Two rationales underlay these approaches, both arguably rooted in governmental acceptance of its responsibility for protecting and improving health. The first was to make medicines affordable, the second to stimulate local industry (sometimes state-owned) in order to move toward greater self-sufficiency in medicines.

INTELLECTUAL PROPERTY LAW — ITS INTERNATIONALIZATION AND ENFORCEMENT

Regrettably, this pluralistic approach to the patenting of medicines, possible under treaties of the World Intellectual Property Organization (WIPO), is now being sacrificed. During the nineteenth century, countries became increasingly interested in international cooperation in the field of intellectual property and negotiated bilateral treaties. These agreements laid the foundation for the Paris Convention of 1883, resulting in a union for the protection of industrial property, including patents, and numerous treaties. Eventually, WIPO was formed in 1967, becoming a United Nations agency in 1974.

Nevertheless, significant domestic variation in intellectual property law remained. The enforcement mechanism for WIPO treaties was ultimately to bring an appeal to the International Court of Justice.¹² However, countries placed reservations on dispute resolution clauses, meaning that in reality there were no effective means of international enforcement of patent law.

Faced with the impossibility of enforcing its intellectual property rights under the WIPO treaties and the growing economic value of intellectual property, the United States began to look for an alternative system for more effectively policing intellectual property entitlements. In 1974, the U.S. Congress established a private sector advisory committee system to ensure that its trade policy reflected its commercial and economic interests. The Advisory Committee for Trade Negotiations, chaired by the chief economic officer of Pfizer in 1981, was critical in promoting the idea of linking trade negotiations and implementation of intellectual property law. This led to the United States amending its own trade legislation in 1984, enabling it to impose sanctions on countries that did not respect U.S. intellectual property.

During the 1980s, the U.S. government, under fierce political pressure from U.S.-based pharmaceutical companies, directed resources to internationalizing its domestic standard of patent law, thereby giving its companies the possibility of truly global markets. But for over a decade, as efforts were turned to negotiating a new international patent agreement, concurrently this stick was wielded with

great effect to protect the "property" of U.S. companies in foreign markets.¹¹

In Thailand, for example, the 1979 Patent Act, which allowed pharmaceutical processes to be patented, but not products or ingredients, led to sustained threats of trade sanctions from the United States over a number of years, eventually leading to the Act's amendment in 1992 and 1998. Under the first amendment to the Patent Act, pharmaceutical processes became patentable, patent protection was extended from 15 to 20 years, and powers of compulsory licensing were weakened. Under the second amendment, local working requirements were removed and the Pharmaceutical Patent Review Board was abolished.¹² Brazil faced similar pressures.

PATENTS AND THE WORLD TRADE ORGANIZATION

At the end of the Second World War, the idea for an international trade organization emerged, along with a proposal for a conference to discuss multilateral reduction of trade barriers. The first proposal was not pursued, but the second resulted in the General Agreement on Tariffs and Trade (GATT). The purpose of GATT was to promote trade liberalization and a number of "rounds" of GATT negotiations took place.

By the time the Uruguay Round of discussions commenced, GATT was regarded as insufficient to meet the needs of the world trade environment. From 1986 to 1994, the United States, supported by Europe, Canada, and Japan, examined how trading principles could be extended into areas not previously included, such as (and completely inappropriately) intellectual property. In contrast to WIPO, where developing countries had a greater impact due to their number, industrialized countries, because of their economic power, dominated the GATT negotiations.¹³

Between 1986 and 1989, developing countries refused to negotiate a trade agreement on intellectual property. Industrialized countries argued that such an agreement would result in more foreign investment, technology transfer, and the promotion of local research and development. It was also erroneously thought that the United States might limit the unilateral imposition of trade sanctions and rely on the international system, but this was belied by continuing threats of sanctions against countries such as South Africa and the Philippines after the World Trade Organization (WTO) agreements came into effect. Eventually, there was a trade-off in which developing countries were to obtain access to markets for their textile and agricultural products and intellectual property was to be incorporated into the world trade regime.¹⁴

The result of this process was the Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations, signed April 15, 1994 at Marrakesh, Morocco.¹⁵ The Act established the WTO and included the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).¹⁶

Thus, trade law was significantly expanded, covering not only goods, but also services and intellectual property. TRIPS will, no doubt, have its greatest impact in the area of pharmaceutical products.

Agreement on Trade-Related Aspects of Intellectual Property

The law contained in TRIPS is in its embryonic stage and the next few years will be crucial in determining the balance between the competing interests of health and profits. The TRIPS agreement creates minimum standards to be observed in drafting national law, but its overall result is the expansion of U.S. standards of intellectual property law to developing countries, where its benefits are questionable.

Defenders of TRIPS point out that the agreement's stated objectives are to enforce intellectual property rights in the interests of both producers and users "in a manner conducive to social and economic welfare, and to a balance of rights and obligations."¹⁷ In this regard, Article 8 states that WTO members may adopt measures necessary to protect public health consistent with the terms of TRIPS.¹⁸

In a mechanism known as compulsory licensing,¹⁹ third parties may exploit patents for a limited period if the proposed user has made efforts to obtain a license to produce the product on reasonable commercial terms and these efforts have been unsuccessful. The patent holder is to be given adequate recompense. Article 31 waives the requirement of obtaining authorization from the patent holder on reasonable commercial terms in cases of national emergency.

These are two potentially important windows that can be kept open in the interests of public health. However, the lack of skilled intellectual property lawyers in some countries will most likely result in law that does not take full advantage of the provisions of TRIPS and in unworkable patenting systems. This will be to the advantage of more powerful nations and to the detriment of health—a conclusion that is shared by the United Nations Commissioner on Human Rights, whose report recognizes:

The various links [in TRIPS] with the subject matter of human rights — the promotion of public health, nutrition, environment and development — are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement.²²

A matter that was not stated but is of exceptional importance is the 20-year period of market exclusivity now required by TRIPS. Professor Jagdish Bhagwati of Columbia University and Special Adviser to the United Nations on Globalization noted in an interview on Australian radio that this lengthy period is supported by very few economists.²³ Indeed, a grow-

ing number of prominent economists, including Joseph Stiglitz, winner of the Nobel Prize in 2001, senior economists from the World Bank, and Jagdish Bhagwati, have begun to see "patent protectionism" as unfair, inefficient, and inconsistent with a free trade agenda.²⁴

The World Health Organization believes that "an infectious disease crisis of global proportions is today threatening hard-won gains in health and life expectancy."²⁵ This historical coincidence between the globalization of patent protection on medicines and the globalization of certain diseases, driven by the HIV/AIDS pandemic, has meant that the early years of TRIPS have been fraught with conflict.²⁶ Changes in domestic legal frameworks to make laws TRIPS-compliant (or the specter of such changes in countries such as India) have led to greater patent protection on medicines, and higher prices, at a time when there is unprecedented demand for medicines — particularly, but not exclusively, medicines under patent that treat AIDS. In the argument about the actual impact of stronger intellectual property protection, a complex group of discussions is often conflated to the detriment of being able to arrive at firm conclusions. However, we would assert that the core conflict is between those who argue that:

- the monopoly over a market bestowed by a patent harms health by making medicines unaffordable, versus
- the ability to profit from research is an essential guarantee for further research into new and better medicines. Patents, therefore, keep the wheel of research and invention in perpetual motion.

South Africa

South Africa has a population of 44 million people, the majority of whom live in dire poverty. However, it is atypical of poor countries because it has a sizeable middle class, previously mostly white people who benefited from apartheid, that has created a market for first world health care and brand name medicines. Consequently, medicines in this market are heavily patented and highly priced. Unfortunately, many of the medicines that are highly priced to maximize profit in the private sector are needed equally in the public sector, where ill health creates a large market based on need, but poverty restricts the market because of affordability. Consequently, the high price of patented medicines is a relative barrier to health care in the private sector, but an absolute barrier to health care in the public sector.

As in other countries, the HIV/AIDS epidemic and the price of AIDS medicines have brought this conflict to the fore. Last year, the world watched as multinational pharmaceutical manufacturers and the South African government (with vocal and visible support from groups such as the Treatment Action Campaign (TAC) and Médecins Sans Frontières)

battled in a court case over intellectual property rights. Ironically, except for its intent to create a legal framework for parallel importation, this case actually had little to do with any real threat of depriving patent rights. The law in question (the Medicines and Related Substances Control Amendment Act, 1997) was primarily aimed at regulating other means by which pharmaceutical companies leverage prices, particularly "perverse incentives" that encourage doctors to continue to prescribe expensive brand-name medicines whose patents have expired, even when there are cheaper generic alternatives.

However, largely as a result of the successful intervention of the TAC as an *amicus curiae* (friend of the court), the media focus turned to the price of AIDS drugs and the patent power of the companies that manufacture them as justification for the South African government's duty to take legislative measures to improve access to health care. The legal arguments in *Pharmaceutical Manufacturers Association v. President of the Republic of South Africa*²⁷ are not the subject of this article. But what is significant is the manner in which the shaming of the companies led to rapid and deep drops in the prices of patented antiretroviral medicines. At the beginning of 2001, triple therapy had cost approximately 3,500 rand (U.S. \$450) per month. By June 2001, the price of the same medicines had dropped to approximately 1,000 rand (U.S. \$125) per month.

This may be indicative of the size of the surplus that was being extracted from these medicines by the patent holders before they faced a challenge. It is instructive that South Africa has not been alone in experiencing deep, but apparently arbitrary price reductions. Richard Stern, director of the Agua Buena Human Rights Association in Costa Rica, writes how in Honduras the price of antiretrovirals dropped by 85 percent in 2001, while in Nicaragua their price remained stable at approximately \$5,000 yearly for most cocktails.²⁸

As a result of price reductions, there has been a marked expansion in the number of South Africans who are being treated with antiretroviral medicines, either through medical insurance or out of pocket. Some analysts suggest that whereas the number of people using these medicines had previously been static at around 10,000, the price reductions make possible an expansion of up to 150,000 people who will be receiving treatment within the next two years. The benefits for health are demonstrated through the records of Medscheme, South Africa's largest private medical insurance scheme, whose Aid for AIDS program shows large reductions in hospitalization costs for the patients receiving these medicines.²⁹

Here then is clear evidence of the link between price and access. Patent status is relevant because it is the primary determinant of price; and in South Africa — as Attaran and Gillespie-White demonstrate — thirteen out of the fifteen registered antiretroviral medicines are under patent.³⁰ In re-

cent years, South Africa has gone through a tortuous process of high level political denial about HIV, which has also manifested itself in governmental opposition to the use of antiretroviral medicines by people dependent on public health services. As a consequence, the primary beneficiary of price reductions so far has been the private sector. But this should not blind us to the fact that the South African public health sector has the most developed and expansive infrastructure in Africa — with the potential to scale up treatment to reach tens of thousands of poor people. If drug prices were to come down even further, it would begin to allow discussion and calculation of the opportunity costs, cost savings, and cost benefits of using the same medicines in the public health system. But further significant price reductions are unlikely unless the patents of these medicines are challenged. This requires a political commitment to the rights of people with HIV/AIDS, which is where the lessons of Brazil become instructive.

Brazil

It is important to acknowledge the differences between Brazil and South Africa, particularly the different scales of the HIV/AIDS epidemic and the fact that Brazil is largely urbanized, whereas in South Africa nearly 50 percent of the population still lives in rural areas.

However, there are also significant similarities: Both are middle income countries, and in certain areas, both are able to record high levels of commitment to health, indicative, we would argue, of the capacity of the public health infrastructure to treat HIV if there was political commitment and if medicine was affordable. For example, both countries have high rates of immunization against measles and tuberculosis (TB), and high percentages of births attended by skilled staff.¹¹ The most relevant difference between South Africa and Brazil is that, in the latter, there is a political commitment that has made it possible to demonstrate the relationship between patents, prices, and the number of people on treatment.

Since making a decision in 1996 to ensure access to antiretrovirals for "100 percent of identified HIV patients in the country,"¹² Brazil has repeatedly asserted its right to take legal measures to ameliorate the abuse of patent powers by excessive pricing. Initially, this was done by generic production of those antiretroviral medicines that were not patent-protected locally before Brazil's intellectual property law was made TRIPS-compliant in 1995 (before this, inventions involving medicines were excluded from being patented). This included drugs such as Zidovudine, patented by Glaxo Wellcome, and Pfizer's antifungal Diflucan.

The benefits of Brazil's policy to locally produce generic medicines have been internationally recognized. According to UNAIDS, "The annual cost of double therapy with nucleoside analogues decreased on average by 80%

between 1996 and 2000.... For triple therapy with two nucleosides and one protease inhibitor, the cost reduction was 36% over the same period...."¹³ Similarly, the United Nations High Commissioner on Human Rights noted approvingly that generic production of antiretrovirals had saved the Brazilian government an estimated \$230 million.¹⁴ Another positive consequence of generic competition in Brazil has been a drop in the prices of patented medicines as multinational companies aimed to compete with local manufacturers.¹⁵

Despite pressure from the United States, the Brazilian government drafted its intellectual property law to ensure that the allowance in TRIPS for countries to use compulsory licensing was exploited.¹⁶ Since the law was passed, the government has been prepared to use it, or threaten to use it, with significant results. Last year, Brazil negotiated a price reduction of almost 70 percent for the antiretroviral drug Efavirenz (patented by Merck). When similar negotiations failed to bring about a satisfactory result, it threatened to issue compulsory licenses for Nelfinavir, a protease inhibitor patented by Pfizer but licensed to Roche. This threat brought about a price reduction of 40 percent (from \$1.07 per pill to 64 cents per pill).¹⁷ This elasticity in pricing is yet another example of the lack of transparency in the real costs of drug development.

Important to our argument is the way in which lower drug prices, achieved through the production of non-patent-protected drugs or threats to implement compulsory licensing provisions in Brazilian law, made possible a bold HIV/AIDS treatment program, which — despite other challenges to its success — has quickly become the largest in the world with demonstrable health outcomes. Again, the report of the United Nations Commissioner for Human Rights deserves quotation:

In terms of the enjoyment of Brazilians' right to health, there has been a reduction in deaths due to AIDS by 50 per cent over the last four years. Further, there has been a reduction of 80 per cent in cases of hospitalization due to opportunistic diseases with a reduction in the appearance of the most serious opportunistic diseases tuberculosis (by 60 per cent), cytomegalovirus (by 54 per cent) and Kaposi's sarcoma (by 38 per cent).¹⁸

A clearer illustration of the links between patents and prices would be hard to find. Finally, contrary to those who argue that where health infrastructure is lacking, treatment is not possible (and thus discussions of patents and price are irrelevant), in Brazil affordable medicines provided the incentive to create the infrastructure for their optimal use. Thus, according to the Brazilian Ministry of Health, in 2001 it was anticipated that 422,000 viral load tests and CD4 T-lymphocyte counts would be conducted.

Thailand

Brazil is not the only country in the world where it is possible to evince this kind of evidence. In Thailand, a country relatively high on the United Nations Development Programme's Human Development Index (HDI), 95 percent of the population has access to what the WHO currently defines as "essential drugs," suggesting that both health infrastructure and political commitment to health exists.³⁹ But the contrast between general access to medicines and access to the patented medicines needed to treat the Thai HIV/AIDS epidemic could not be starker. According to Oxfam, "Less than five per cent of people living with HIV/AIDS have access to the anti-retroviral medicines.... The main reason for this is the high cost of drug therapy."⁴⁰ Neither the government nor the consumer can afford the cost of treatment. After an evaluation of the government program to provide antiretrovirals to the poor by the Thai Government and the World Bank, it was decided that "free treatment was not cost-effective when compared to prevention programmes."⁴¹ The scheme ended other than limited provision of AZT to prevent mother-to-child transmission.

Other difficulties related to the structure of the patent regime in Thailand — difficulties arising from pressure from the United States both before and after the TRIPS agreement — have resulted in additional and unnecessary delays in generic products getting to the Thai market.

Like Brazil, although by virtue of a different history of variations in patent law, the Thai Government Pharmaceutical Organization has been able to produce generic versions of a number of patented medicines and create price (and consequently access) differentials. Fluconazole and Ciprofloxacin, two drugs that play an important role in treating HIV-related opportunistic infections, are available as generics. In the case of the former, there is a 95 percent price differential between the brand name and the generic; in the case of the latter, the differential is 62 percent.⁴² Unfortunately, though, of antiretrovirals, only Zidovudine, Stavudine, and Didanosine are available off-patent. This allows some Thai patients to access this regimen of triple therapy, but leaves a sword of Damocles hanging over those who fail on this regimen, or cannot tolerate it and are dependent on substitution with a drug still under patent and available only at a much higher price. In the words of the President of the Thai Maw Chao Ban Foundation (Rural Doctors), "Those who can't afford treatment either take herbal remedies or pray."⁴³

DISCUSSION

Pharmaceutical companies frequently suggest that it is not patent law that limits access to drugs, but lack of funds with which to purchase these drugs — or systems to distribute them. The proof offered for this contention is that in countries with a low level of patent protection, such as India, poor people do not have access to drugs.⁴⁴

Apart from being a very selective example, this is to take a narrow interpretation of the historical and current impact of intellectual property law. It is also to take a short-sighted view of the meaning of access to drugs.

India is a country of more than a billion people, 70 percent of whom live in rural areas, with only 31 percent having access to "adequate" sanitation facilities. To equate India's intellectual property regimen with its general health crisis is simply untenable, and as we noted in our introduction, we do not assert that redressing the single issue of intellectual property law will revolutionize health care. While the price of many medicines in India is drastically lower than in many other countries, and this undoubtedly increases the possibility of access to health care for many (uncounted) people, it obviously cannot undo the general crisis of human development that exists in that country.

It should nevertheless be noted that patent law also has structural effects on the development of economies and is more suited to states with well-established industry. It is likely that strengthened patent law in developing countries may in fact deepen the crisis of development, as it causes technology and capital to flow back to patent holders — who are predominantly located in industrialized countries. The World Bank, for example, found that in 1997 patent applications in high income countries numbered more than 2.5 million, whereas in East Asia and the Pacific they numbered 290,630 "and in sub-Saharan Africa only 392,959, with only 38 of those filed by residents."⁴⁵

Intellectual property law, therefore, primarily serves to protect a handful of dominant multinational corporations. The monopoly market power provided by the grant and extension of a patent inhibits the growth of generic industries. As intellectual property law extends its reach, developing countries will be unable to copy products using reverse engineering. There is thus no obvious reason that TRIPS should lead to an investment in research and development in developing countries. There also is no obvious reason (or evidence) why TRIPS should encourage research into drugs for diseases whose main impact is in developing countries where there is no economic market for these medicines.

The examples we have provided of South Africa, Brazil, and Thailand point to a number of conclusions. Firstly, the speed at which prices have been reduced under pressure or in the face of generic competition strengthens the assumption that the price of the drug and its cost of production have little direct relationship. Secondly, significant price reductions of patented medicines in these (and other) countries have had no visible impact on the global profitability of research-based companies. GlaxoSmithKline, for example, reported that in 2001 its sales of pharmaceutical products amounted to \$24.8 billion (a 15 percent increase measured in sterling over 2000). The antiretroviral medicine Combivir had sales of \$872 million.⁴⁶ This casts a question mark over allegations that generic competition will deplete resources

for research and development. Is this argument not in reality a veiled threat of an investment strike by companies whose real losses will in fact only be negligible? Thirdly, the connection among patents, price, access to medicine, and health is confirmed by tangible evidence of larger numbers of people on treatment and improved health outcomes as prices decrease. Simply asserting that a lack of funds is the reason for limited access to drugs has other obvious flaws. As we have discussed, in South Africa, a country that could afford to provide general treatment for HIV were it not for blanket patenting, drugs are only available in the private sector.

The Doha meeting

In the late 1990s, a movement to mitigate the worst effects of TRIPS and to try to strengthen and create a countervailing set of state duties emerged from developing countries, often led by Brazil, South Africa, and India. The battle has popped up from time to time in the World Health Assembly, particularly at the time of discussion of the Revised Drug Strategy,⁴⁷ and in other forums. But in 2001, it received a renewed impetus from the South African court case, leading to better coordination between developing countries, better technical support from nongovernmental organizations, and high-impact lobbying of industrialized countries. This revival of concern about TRIPS found its clearest expression at a meeting of the Ministerial Council of the WTO that took place in Doha, Qatar November 9–14 of last year.⁴⁸

It is arguable that the anthrax scares that followed the terrorist attacks in the United States on September 11 also created a changed international mood, leading to greater sensitivity to the centrality of access to medicine to health. As demand grew in the United States and Canada for drugs to combat anthrax, the pharmaceutical company Bayer was forced to sell Ciprofloxacin at a substantially reduced rate after threats that both countries would otherwise issue compulsory licenses. The parallels with the demand for AIDS medicines were unavoidable.

Consequently, by the time of the Doha meeting, it would have appeared unconscionable for the United States or Canada to deny other countries the right to determine what constituted a public health emergency. The Ministerial Declaration on the TRIPS Agreement and Public Health produced by the meeting recognized that TRIPS does not prevent countries from taking measures to protect public health and that WTO members are entitled to use TRIPS provisions for this purpose. The declaration states:

- (b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) Each member has the right to determine what constitutes a national emergency or other cir-

cumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.⁴⁹

The declaration extends until January 2016 the obligation for least developed countries (such as India, but not Brazil, Thailand or the Philippines) to fulfill their obligations under TRIPS. It also recognizes the difficulty countries with insufficient manufacturing capacity face in making effective use of compulsory licensing provisions. Thus, the Council for TRIPS is instructed to find an expeditious solution to this problem before the end of 2002.

This represents a theoretical advance on earlier consideration of the rights and obligations of developing countries. Whether this also facilitates greater access to drugs, particularly after 2016, is yet to be seen. Indeed, within four months of the Doha meeting, the United States already retreated from what might have been the clear intent of the meeting, arguing for a time-limited conditional moratorium on WTO challenges in these circumstances.⁵⁰

PATENTS AND HUMAN RIGHTS

In the first chapter of the World Health Organization's *World Health Report 2000*, a number of poignant comments are made about human health that are cause for reflection, and beg the question as to whether health — or factors that directly affect health — should not be the subject of more explicit and enforceable human rights protections. The report notes that health is an "inalienable asset" that "is subject to large and unpredictable risks, which are mostly independent of one another."⁵¹ Drawing an analogy between health insurance and car insurance (!), the report points out:

If a car worth \$10,000 would cost \$15,000 to repair after an accident, the insurer would pay only \$10,000. The impossibility of replacing the body, and the consequent absence of a market value for it precludes any such ceiling on health costs. Since the poor are condemned to live in their bodies just as the rich are, they need protection against health risks fully as much.⁵²

The need to protect the "inalienable assets" of the poor from health risks as much as those of the rich goes to the heart of the crisis exacerbated by the strengthening of intellectual property law globally. The question is to what extent national human rights law has the power to do this — and to what extent international human rights law will lend support to national autonomy on this question.

On the one hand, the right to health, including medicines needed for health, as a human right that can be demanded of the state has been quite broadly established. Jurisprudence worldwide is replete with cases where this right has been asserted. On the other hand, the right of governments to take measures to make medicines more affordable and thereby allow them to fulfill their duties is more contested — even though more countries are trying to claim this right.⁵¹

The history of modern human rights law provides contrasting insight into the extent of the legal "right" to intellectual property in an international context, and which right trumps when this right is in conflict with arguably more fundamental rights. This is the heart of the question addressed by the report of the United Nations High Commissioner that we have referred to repeatedly in this article.

Article 15 of the International Covenant on Economic, Social and Cultural Rights provides that states recognize the right of all:

- (a) to take part in cultural life;
- (b) to enjoy the benefits of scientific progress and its applications;
- (c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [she] is the author.⁵²

The conceptual approach of Article 15 reflects an unresolved debate concerning whether intellectual property ought to be considered a right. Some states argue that no such protection is required and that intellectual property protection merely reflects the elitist privileges of the literary and scientific community. All should be able to share in the benefits derived from the advances in science. Eastern Bloc countries argue that the right to benefit from scientific advancement should not be confused with rights to property.

While intellectual property was ultimately included as a right, what exactly is protected by this right is left unclear. One interpretation is that in order to fit the normative pattern of human rights, the right to intellectual property must be rooted in the human dignity of the author of the work.⁵³ Such a right should be distinguished from other legally protected rights, such as commercial rights and the rights of corporate entities. Once property ownership moves from an individual to a commercial body, these rights should be sourced to secondary laws outside human rights, such as, in this case, TRIPS.

As Audrey Chapman has stated:

Ultimately, a human rights approach requires that intellectual property protection serve the objective of human well-being, to which the international human rights instruments give legal expression. Human rights are inalienable and universal

claims belonging to individuals, and in some situations, to communities, but never to corporations. Human rights are understood to exist independently of recognition or implementation while intellectual property rights are granted by the State according to criteria defined by national legislation. In contrast with human rights, which establish permanent and irrevocable entitlements, intellectual property rights are temporary; they exist for a limited period and can be revoked, licensed or assigned to someone else.⁵⁴

These debates received renewed impetus last year as a result of the actual clashes between intellectual property rights and rights to health. In April 2001, for example, the United Nations Human Rights Commission approved a resolution, sponsored by Brazil, titled *Access to Medication in the Context of Pandemics Such as HIV/AIDS* (from which the United States was the only country to abstain).⁵⁵ In June 2001, the High Commissioner for Human Rights published a report on *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, and in December 2001, the United Nations Committee on Economic, Social and Cultural Rights issued a statement on human rights and intellectual property, which includes the unambiguous assertion that "[a]ny intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party."⁵⁶

Human rights bodies inside and outside the United Nations now argue that the regulation of the global economy must not be divorced from global social problems. Intellectual property law should be considered within the body of international human rights law and be implemented consistently with human rights such as the right to health, to nondiscrimination, and to development. A new international legal architecture could be constructed that both makes bodies like the WTO accountable for their actions and builds within them a consciousness of human rights. Thus, citing Chapman with approval, the United Nations High Commissioner points out that "a human rights approach ... would explicitly place the promotion and protection of human rights, in particular those in ICESCR [International Covenant on Economic, Social and Cultural Rights], at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement."⁵⁷

CONCLUSION

There is no doubt that many factors contribute to health. These include access to food, clean water, general sanitation, and shelter. Social measures to reduce vulnerability are

equally crucial. Both prevention and treatment programs and services are necessary, as is research directed toward diseases affecting those in developing countries. To suggest that any of these measures may be sacrificed is to take a simplistic view of a highly complex world.

But it is equally simplistic to suggest that intellectual property law as now partnered with world trade law is not a significant factor in determining who has access to what drugs. This law was clearly designed to ensure that control over patented drugs would rest in the hands of their manufacturers, predominantly American pharmaceutical companies. This has, in general, not been balanced by other considerations, such as health and development. Under present world trade law, patent laws cannot be structured to suit the requirements of domestic economic conditions. The impact of patent law on health is significant and needs to be addressed. However, it must not be considered in a vacuum. It must be judged against and made accountable to other arguably more pressing ethical and legal considerations.

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3. The term "essential medicines" is used here to connote the necessity of particular medicines to the survival of a large proportion of people in the developing world. It is not intended in the specialized way that "essential drugs and medicines" are defined for purposes of the list generated by the World Health Organization (WHO). A broader definition, with the Essential Drugs List criteria based on health need rather than current prices, is advocated. This is in keeping with the recommendation of the WHO Expert Committee on Essential Drugs in November 1999, which stated, "Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford."
4. Expert Committee on the Selection and Use of Essential Medicines, *Summary of Recommendations*, 12th Expert Committee on the Selection and Use of Essential Medicines Meeting, Geneva, April 15-19, 2002, available at <<http://www.who.int/medicines/organization/paredl/expertrecommend.shtml>>.
5. *Commissioner of Patents v. The Wellcome Foundation* [1983] N.Z.L.R. 385, at 398.
6. Committee on Economic, Social and Cultural Rights, United Nations Economic and Social Council, *Human Rights and Intellectual Property*, Statement by the Committee on Economic, Social and Cultural Rights, E/C.12/2001/15 (December 14, 2001): paras. 4 and 6.
7. *Bristol-Myers Squibb Co. v. FH Faulding & Co. Ltd* [2000] FCA 316, available at <<http://www.ipcr.gov.au/SUBMIS/docs2/Sub11AttA.pdf>>.
8. *Id.*
9. In an affidavit filed in support of the Treatment Action Campaign in *Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa*, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998), Professor Colleen Flood of the University of Toronto mapped how patent law in Canada evolved since 1923 with the "expressly stated goal of making food and medicine affordable to the public" (at para. 4). To facilitate this, various legal devices, including compulsory licensing and administrative mechanisms (a Patented Medicines Prices Review Board), were established. However, in common with developing countries, Canada has been pressured to strengthen intellectual property protection. In Australia, the government negotiates with industry as a monopsonist purchaser and is thus able to provide drugs to the community at greatly reduced prices under a Pharmaceutical Benefits Scheme.
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11. J.O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'," Oxford Intellectual Property Research Centre, *Electronic Journal of Intellectual Property Rights*, WP 07/99 (originally published August 10, 1999), available at <<http://www.oiprc.ox.ac.uk/EJWP0799.html>>.
12. See, for example, Article 28 of the *Paris Convention for the Protection of Industrial Property* (March 20, 1883, as amended on September 28, 1979), available at <<http://www.wipo.int/clea/docs/en/wip/wip02/en.htm>>.
13. According to Audrey Chapman, Brazil, Ecuador, India, Pakistan, South Africa, and Thailand were among the countries subject to trade threats. A.R. Chapman, *Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c)*, E/C.12/2000/12 (November 27, 2000): at para. 33, cited in Robinson, *supra* note 1.
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15. M. Ryan, *Knowledge Diplomacy, Global Competition and the Politics of Intellectual Property* (Washington D.C.: Brookings Institution Press, 1998): at 12.
16. J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge, England: Cambridge University Press, 2000): at 83.
17. *Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations*, April 15, 1994, available at <http://www.wto.org/english/docs_e/legal_e/03-fa.pdf>.
18. *Agreement on Trade-Related Aspects of Intellectual Property* (April 15, 1994), available at <http://www.wto.org/english/tratop_e/trips_e/agt0_c.htm>.
19. *Id.* at Article 7.
20. One such measure might be the use of parallel importation, a legal mechanism on which TRIPS allows countries to determine their own law. Parallel importation means that once the patent holder has sold its product, it has exhausted its rights over the product and the new owner may sell it to others. As pharmaceuticals vary dramatically in price internationally, this is a useful provision that is widely used in the European Union. It has also been exploited successfully by the Philippines govern-

ment to buy patented medicines from India at prices lower than they were being sold in the Philippines. However, in 2016, when all countries are to become members of the WTO, there will be limited benefit to parallel importation as there will be less variation in the price of patented medicines between countries as a result of the elimination of generic competition.

21. Compulsory licensing involves the licensing of companies that are not the inventors (patent holders) of a medicine to produce and sell that medicine. It means a deprivation of certain rights ordinarily granted to patent holders. Its benefit in the context of medicine is drastically lower prices. Compulsory licensing is of no effect when there is no domestic industry, as TRIPS does not allow the export of medicines produced under compulsory license. This leaves poor countries without their own industry at the mercy of donor agencies and multilateral organizations. Contractual agreements sometimes suggested as an alternative legal route for obtaining pharmaceuticals would be subject to the contingencies created by unequal bargaining power.

22. Robinson, *supra* note 1, at para. 22.

23. Jagdish Bhagwati, interview by Geraldine Doogue, *Life Matters*, Australian Broadcasting Corporation (March 12, 2002).

24. M. Weishrot, Center for Economic and Policy Research, *Rich Country Protectionism Puts WTO on the Slow Track* (November 16, 2001), at <http://www.cepr.net/columns/weishrot/rich_country_protectionism.htm>. James Love, director of the Consumer Project on Technology, states simply, "market incentives for health care R&D are not efficient." See J. Love, *Flying for Health Care R&D: Carrot and Sticks*, paper prepared for the *Médecins Sans Frontières Drugs for Neglected Diseases Working Group* (January 2001): at 1.

25. World Health Organization, *Removing Obstacles to Healthy Development*, Report on Infectious Diseases, WHO/CDS/99.1 (Geneva: World Health Organization, 1999): at § 1.1, available at <<http://www.who.int/infectious-disease-report/pages/textonly.html>>.

26. *Id.* In this context, it is often argued that the difference between (a) the cost of producing the developed drug and (b) the cumulative costs of research and development that go into bringing a successful new medicine to the market make downward pressures on drug prices (by whatever means) unsustainable — and ultimately counterproductive to the future development of new drugs. However, this argument is difficult to dissect because of the dearth of transparency regarding the actual costs of research and development, marketing and the costs of providing the developed drug alone. Typical of the rhetoric on the cost of development is a recent claim by PhRMA that \$800 million is required to bring a drug to market, where only one product results from a pool of more than 5,000 new chemical entities. See PhRMA Special 301 Submission, Priority List Watch Countries, 2002. These claims by pharmaceutical companies are, to put it mildly, contested. Actual costs are difficult to obtain. James Love, for example, has pointed out how these claims originate from a 1991 study by Joseph DiMasi, which estimated the cost of new drug development at \$231 million. But Love points to "several misunderstandings" regarding subsequent estimates based on DiMasi's work, including the fact that these figures were:

estimates of the costs of doing both the early discovery and pre-clinical work, the clinical trials and FDA regulatory approval. For many drugs, the U.S. government paid for either the pre-clinical or clinical work. In those cases the companies' costs were lower. In addition, these figures were largely based upon adjustments for both risk and huge cost of capital assumptions, and not on actual expenditures on R&D.

James Packard Love, Affidavit (April 9, 2001): at paras. 37–38, filed in support of the Treatment Action Campaign in *Pharma-*

ceutical Manufacturers Association of South Africa v. President of the Republic of South Africa, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998).

27. *Pharmaceutical Manufacturers Association of South Africa v. President of the Republic of South Africa*, No. 4183/98 (High Court of South Africa, Transvaal Provincial Division February 18, 1998).

28. R. Stern, *AIDS Treatment Access in Latin America: The Year in Review*, Consumer Project on Technology (January 7, 2002), at <<http://www.cptech.org/sip/health/aids/stern01072002.html>>.

29. S. Laverack, presentation on the Aid for AIDS program, Cape Town, June 2001. "Significant sustained cost savings have been achieved primarily by reduced expenditure on hospitalisation," *id.*

30. See Attaran and Gillespie-White, *supra* note 2, at 1892, who make the strange assertion that "the data suggest that patents in Africa have generally not been a factor in either pharmaceutical economics and anti-retroviral drug treatment access (South Africa, with its larger affluent market, is an exception)." In addition to its "affluent market," where 22 million people live below the poverty line (?), South Africa has one tenth of the global total of people living with HIV.

31. United Nations Development Programme, "Human Development Indicators," *Human Development Report 2001* (New York: Oxford University Press, 2001): at 159.

32. National AIDS Drug Policy, Ministry of Health, Secretariat of Health Policies (2001). Also according to the National AIDS Drug Policy of the Brazilian Ministry of Health, "Congressional Bill 9113, of 13 November 1996, guarantees every patient access, free of direct costs, to all the medication required for his/her treatment, including protease inhibitors."

33. UNAIDS, *Report of the Global HIV/AIDS Epidemic*, UNAIDS/00.13E (June 2000): at 102, available at <http://www.unaids.org/epidemic_update/report/Epi_report.htm>.

34. Robinson, *supra* note 1, at para. 52.

35. See E. 't Hoen and S. Moon, *Médecins Sans Frontières, Pills and Pocketbooks* (July 18, 2001), at <<http://www.msf.org/content/page.cfm?articleid=1A25BDD8-64D1-4B40-BA2C06C23BEAFFCE>>. 't Hoen and Moon write, "Lessons can be learned from Brazil where the price of AIDS drugs fell by 82% over five years as a result of generic competition. The prices of drugs that had no generic competitor remained stable, falling only 9% over the same period." See also World Health Organization, World Trade Organization, Norwegian Foreign Affairs Ministry, and Global Health Council, *Report of the Workshop on Differential Pricing and Financing of Essential Drugs* (April 2001): at 7, available at <http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wholereporthosbjorworkshop-fin-eng.doc>: "It was noted that within the year prior to the workshop, a combination of corporate responsiveness, domestic production, and competition have led to substantial reductions in the price of HIV/AIDS drugs."

36. Law No. 9.279 of May 14, 1996, to Regulate Rights and Obligations Relating to Industrial Property; Article 71 states: "In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee do not satisfy such need, a temporary non-exclusive compulsory license to exploit the patent may be granted *ex officio*, without prejudice to the rights of the owner of the patent."

37. On August 22, 2001, the Brazilian Ministry of Health announced its intention to "break the patent of the drug Nelfinavir"; it was pointed out that a Brazilian government laboratory "has succeeded in producing the drug at a saving of 40% over that charged by Roche. This will mean a saving of \$8 million

reals per year." Brazilian Ministry of Health, *Official Note* (August 22, 2001), available at <<http://lists.essential.org/pipermail/pharm-policy/2001-August/001410.html>>.

38. Robinson, *supra* note 1, at para. 58.

39. See United Nations Development Programme, *supra* note 31, at 159. It is also significant that Thailand occupies a relatively high position (99 out of 191) in terms of general health system attainment and performance. See World Health Organization, *World Health Report 2000* (Geneva: World Health Organization, 2000): at Annex Table 1, "Health System Attainment and Performance in all Member States," at 152-55.

40. Oxfam, *The Impact of Patent Rules on the Treatment of HIV/AIDS in Thailand*, Thailand Country Profile (March 2001): at 1.

41. *Id.* at 2.

42. *Id.* at 5.

43. *Id.* at 3.

44. See Attaran and Gillespie-White, *supra* note 2.

45. Robinson, *supra* note 1, at para. 25, citing World Bank, *World Development Indicators 2000* (Washington, D.C.: World Bank, 2000): at Table 5.12.

46. J.P. Garnier, presentation at the *Lehman Brothers 5th Annual Global Healthcare Conference*, Orlando, Florida, February 26, 2002, available at <http://corp.gsk.com/financial/lehbrothers_26feb2002.htm>.

47. World Health Assembly, *Revised Drug Strategy*, WHA52.19 (May 24, 1999), available at <http://www.who.int/gh/IIB_WHA/PDF/WHA52/ResWHA52/e19.pdf>.

48. The Ministerial Conference is the highest decision-making body of the WTO and it can make decisions on all matters under any of the WTO agreements, including the TRIPS agreement.

49. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (adopted November 14, 2001): at para. 5, available at <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>.

50. Inside U.S. Trade, "EU and U.S. Split over Scope of TRIPS Exceptions for Public Health" (March 8 2002), available at <<http://lists.essential.org/pipermail/ip-health/2002-March/002756.html>>.

51. World Health Organization, *supra* note 39, at 4.

52. *Id.* at 4.

53. Reference has already been made to the Medicines and Related Substances Control Amendment Act, 1997, in South Africa. In 2001, the government of Kenya passed a new Industrial Property Bill which, according to Médecins Sans Frontières, represented a landmark victory, includes rights concerning parallel importation, compulsory licensing, and a Bolar provision. Médecins Sans Frontières, Press Release (May 10, 2001), at <<http://www.msf.org/content/page.cfm?articleid=D2BCAC7D-8881-4391-83ACD5D23BDBED2A>>.

54. General Assembly, United Nations, *International Covenant on Economic, Social and Cultural Rights* (adopted December 16, 1966): at Article 15.

55. See Robinson, *supra* note 1.

56. Audrey Chapman, American Association for the Advancement of Science, "New Projects Focus on Intellectual Property and Human Rights," *Report on Science & Human Rights*, XXII, no. 1 (Winter 2002), available at <<http://shr.aaas.org/report/xxii/ip.htm>>.

57. Washington File USIS, "United States Abstains from Vote on AIDS Drugs Resolution: Measure to Increase Access Is 'Flawed,' Ambassador Says," April 23, 2001, available at <<http://www.aegis.com/default.asp?req=http://www.aegis.com/news/usis/2001/US010405.html>>.

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59. Robinson, *supra* note 1, at para. 22.

Debate that "This house believes the essential drug concept hinders the effective deployment of drugs in developing countries"

Patents and access to essential drugs

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Abstract

This paper provides a brief overview of historical developments in patent law including its recent incorporation into world trade law. The impact of patents on access to essential drugs will be discussed. The relationship between intellectual property rights and the right to health will be considered.

Keywords: chemotherapy, drugs, patent law, Essential Drugs List

Introduction

Many factors contribute to the ability of a community to gain access to drugs. These include a functioning public health infrastructure and skilled health service providers. This paper will not address these issues. In so far as patents create a monopoly over a drug for the manufacturer and contribute to the price of pharmaceuticals they are independently worthy of analysis. Elsewhere it has been argued that patents are not a significant factor in determining access to a drug (Attaran & Gillespie-White, 2001; Boelaert *et al.*, 2002; Goemaere *et al.*, 2002; Selgelid *et al.*, 2002); a view not accepted here and the subject of another paper by Loff & Heywood (2002).

Controversy over monopoly rights

Controversy over patents, their morality and overly broad application is not new. Patents have been known to English law since the fifteenth century. Queen Elizabeth I consolidated their use in order to stimulate the importation of inventions and privilege industrial ventures of certain individuals whether they be new or not. General monopolies, distinguished from patents for inventions, were granted to individuals and groups under the power of Royal Prerogative. They could not be challenged under common law. It is worth noting, in the light of contemporary debates in an environment in which a patent is regarded as a right of the inventor, that patents were conceived as a privilege granted by the monarch not a right of the recipient.

Abusive monopolies, granted for all variety of odd purposes, gave rise to such discontent that in 1601 the Queen was forced to issue 'A proclamation for the reformation of many abuses and misdemeanours committed by patentees'. In her last speech to the Commons, the 'Golden Speech', on 30 November 1601, Elizabeth stated: she had granted monopolies in good faith and that they would not be permitted to harm her subjects.

In 1624 the Statute of Monopolies was passed making monopolies null and void, except those granted for inventions. It stated that, for a patent to be valid it must possess seven features:

1. It must be for a term of twenty-one years or under.
2. It must be granted to the true and first inventor.
3. It must be in respect of new manufactures.
4. The privilege must not be contrary to law.
5. It must not be mischievous to the State by raising the price of commodities at home ('In every such new manufacture that deserves a privilege, there

must be Urgens necessitas, and evidens utilitas.' — urgent necessity and evident utility).

6. The privilege must not be to the hurt of trade.
7. It must not be generally inconvenient (for example it should not put men out of work).

The law takes into account the needs of the domestic market and notably contains a reference to pricing.

In 1846, when discussing the requirement for utility in the invention, Hindmarch on Patent Privileges stated that this '... seems also to mean that the excepted grants must not be for the sole making of any thing which is to be used for any purpose which is illegal, or 'contrary to law', such as implements for house-breaking, picking pockets, locks, etc. Such grants, however, it is clear would be void, not only on the ground of want of public utility, but also because they are contrary to the policy of the law; and indeed it would be absurd if, by one law, patents might be granted to reward persons for providing the means of violating any other law' (Hindmarch, 1846). It is interesting to reflect on this statement in the context of the present debate about the primacy of human rights law over intellectual property law. This will be discussed below.

Considerations of morality, equity and lawfulness were core parts of the jurisprudence concerning patents. In the American case, *Morton v. New York Eye Infirmary* (1862) Morton had discovered that a known agent (ether) had the effect of rendering a patient motionless and insensible during an operation. He obtained a patent for this discovery and brought proceedings against the Infirmary for infringement. The trial court declared the patent to be invalid. On appeal to the Second Circuit Court of Appeals, the decision was affirmed. The Circuit Court accepted that though the discovery 'rank[ed] among the great discoveries of modern times; ... its value was too great to be estimated in dollars and cents'. This ruling held firm in the USA until 1952 when a court allowed a claim for a medical procedure (*Becton-Dickinson v. Scherer*, 1952).

During the drafting discussion preceding the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights there was extensive debate as to whether intellectual property should be considered a right. The Eastern bloc objected to a provision on intellectual property being part of an article dealing with a right to benefit from scientific progress. Others asserted that the rights of authors and scientists should be protected. Chapman (2000) asserts that this history suggests that the rights of authors and creators were viewed as not simply good in them but were understood as essential pre-conditions for cultural freedom and participation and scientific progress.

In the case of *Bristol-Myers Squibb Co. v. F H Faulding & Co. Ltd* (2000), the Honourable Justice J. J. Finkelstein began his judgement by saying '(t)he important question: is it ethical to patent a pharma-

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ceutical substance or a method of medical treatment? admits of no satisfactory answer'. He noted that Dr E. R. Squibb himself is reported to have said 'I do not myself think that anything should be patented by either physician or pharmacist'. Finkelstein went on to refer to a case in 1983 in New Zealand (*Commissioner of Patents v. Wellcome Foundation*, 1983). In that case Judge McMullin held there was much to be said for developing the law to allow the grant of patents for methods of treatment of human illness. Human suffering may be alleviated. Research may be encouraged by the knowledge that what is discovered or invented will be protected from competition and assured of a reward. But the grant of a patent is the grant of a monopoly. In recognition of this, patents legislation aims to balance the desirability of encouraging technological advances against the restrictions or abuse which may result from monopolies. He said a shift in emphasis favouring one interest would be achieved only at the expense of the other.

The Parliament of the UK had considered this matter in the words of section 41 of the Patents Act 1949. It provided that the Comptroller of Patents should endeavour to secure the availability of medicines and surgical and curative devices to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. The 1977 Act provides for Crown use of patented inventions including the production or supply of specified drugs and medicines. The Crown may provide compensation to the patent holder but the Comptroller is not normally involved in such matters.

It is not only the content of patent law but also the mechanics that have been the cause of concern. Charles Dickens' short story *A Poor Man's Tale of a Patent* describes Old John's travails when trying to obtain a patent for his invention (Dickens, 1850). At the end Old John states, 'I went through thirty-five stages. I began with the Queen upon the Throne. I ended with the Deputy Chaff-wax. Note. I should like to see the Deputy Chaff-wax. Is it a man, or what is it?' Some reforms were made to the system, but not sufficient for Dickens who continued to satirize it in his novel *Little Dorrit* (Dickens, 1857). It was during this period that calls to end the patent system were at their peak, but not just because of the cumbersome application process. It was understood that patents should not be granted too readily since this would create a proliferation of undeserved monopolies and work to the disadvantage of scientific innovation.

Unlike the arguments about corruption of royal patronage during the era of Elizabeth I, the opponents of patents in the nineteenth century saw them as anti-competitive, opposed to the operation of the free market. It was thought that industry no longer needed this sort of support. Switzerland and The Netherlands did indeed do away with their patent systems. However, by the time of the Great Depression, protectionism further enshrined patents as an important legal mechanism believed to support the development of local industry (Dutton, 1984). Those who have analysed the role played by patents in the market more recently, independent of the debate over access to essential drugs, have not been of one mind as to its benefits.

How might patents impact upon access to essential drugs in resource poor settings? The answer requires some basic familiarity with modern law and its administration.

Patents and world trade law

During the nineteenth century countries negotiated bilateral intellectual property treaties. The inefficiency of a country-by-country approach led to the Paris Convention of 1883 resulting in a union for the protection of industrial property including patents. Subsequently, in 1967, the World Intellectual Property Organization

(WIPO) formed, becoming a UN agency in 1974. Despite the existence of WIPO treaties, countries maintained independent patent regimes. In addition, treaties entered into by State members did not require agreement to the dispute resolution processes so there was no effective means of enforcement of patent law between countries. By the 1980s the USA, the nation with the most to gain from enforcement of patent law, found this unsatisfactory and began to look for an alternative system (Braithwaite & Drahos, 2000).

In parallel, at the end of the Second World War (1939-45) as part of the Bretton Woods discussions (which resulted in the formation of the International Monetary Fund and the World Bank) a proposal was made for a conference to discuss reduction of trade barriers. This resulted in the General Agreement on Tariffs and Trade (GATT). A number of 'rounds' of GATT negotiations took place. By the early 1960s, it was recognized that special policies were required for developing countries. A decision of the Tokyo Round (1973-79), made it possible to give tariff concessions to developing countries. But most developing countries were not able to take advantage of this because of their limited trading capacity.

By the time the Uruguay Round of discussions commenced (1986-94) the USA had begun to exert pressure on other member nations with respect to their patent regimes (Braithwaite & Drahos, 2000). Prior to the Uruguay Round, 50 States did not issue patents for pharmaceuticals including some developed countries such as Portugal and Spain. Between 1986 and 1989 developing countries refused to negotiate a trade agreement on intellectual property. However, industry complained stressing financial losses and the lack of dispute resolution processes. Industrialized countries argued, on what basis it is hard to know, that such an agreement would result in more foreign investment, technology transfer, and promotion of local research and development. This was despite the fact that at the time 4% of research and development took place in the developing world. It was also erroneously thought that the USA might limit the unilateral imposition of trade sanctions and rely on the international system. Eventually there was a political trade-off in which developing countries were to obtain access to markets for their textile and agricultural products, and intellectual property was incorporated into the world trade regime (Velasquez & Boulet, 1999).

The result of this process was *The Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations* signed on 15 April 1994 at Marrakesh, Morocco. The Act is a 'framework convention' and established the World Trade Organization (WTO). It consists of a number of Agreements including the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Thus, world trade law was significantly expanded, now covering not only goods but also services and intellectual property and it had a permanent institutional base enabling resolution of disputes, the WTO. The overall result of the linkage of intellectual property law to trade law is the expansion of intellectual property law into countries in which its benefits are the subject of great controversy and the extension of the reach of pharmaceutical companies to enforce rights that were previously non-existent.

TRIPS and essential drugs

TRIPS law is new. It creates minimum standards to be observed in drafting national law. The next few years will be crucial in determining the balance between competing public interests, at its most basic—access to drugs and compensation to industry. At present few drugs on the Essential Drugs List (EDL) are under patent. Patents themselves are not part of the criteria used in determining whether drugs will be added to the list. However, the criteria for addition to the list state

'The cost-benefit ratio is a major consideration in the choice of some drugs for the list'. Therefore whether or not a drug is under or off patent will be a factor, if only indirectly. As new and important drugs are developed the issue of access to them must be addressed and patents are clearly part of the package of issues that must be considered.

Article 8 sets out the principles of the TRIPS Agreement. It states that members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. However, this Article, and the reference to public health has been given the most limited interpretation.

A Ministerial Declaration produced in Doha in November 2001 attempted to provide some guidance on the interpretation of TRIPS (WTO, 2001). The Declaration was made in an environment influenced by the events of 11 September 2001. At that time both the USA and Canadian governments had threatened to introduce compulsory licences for the supply of ciprofloxacin to treat anthrax, and the back down by 39 pharmaceutical companies in their action against the South African government. Under TRIPS it is permissible for countries, according to strict conditions, to issue licences to domestic third-party manufacturers for the production of pharmaceuticals still under patent.

The Doha Declaration stated that TRIPS does not prevent countries from taking measures to protect public health and that members of the WTO are entitled to use TRIPS provisions, which provide flexibility for this purpose. The Declaration also stated that countries have the right to grant compulsory licences for the production of needed drugs and determine the grounds upon which such licences are granted. It confirmed that countries have the right to determine what constitutes circumstances of extreme urgency, including public health crises such as those relating to HIV/AIDS, tuberculosis, malaria and other epidemics (WTO, 2001).

It recognized the difficulty countries with insufficient manufacturing capacity face in making effective use of compulsory licensing provisions. Thus, the Council for TRIPS was instructed to find an expeditious solution to this problem before the end of 2002. This deadline has passed. The USA has retreated from the agreement and any resolution seems somewhat distant (Anonymous, 2002).

During April 2002, the WHO Expert Committee on the Selection and Use of Essential Medicines, recommended that the following antiretroviral medicines be placed on the EDL: nucleoside reverse transcriptase inhibitors (abacavir, didanosine, lamivudine, stavudine and zidovudine); non-nucleoside reverse transcriptase inhibitors (efavirenz and nevirapine); and protease inhibitors (indinavir, lopinavir/low-dose ritonavir, nelfinavir, ritonavir and saquinavir) (WHO, 2002). The Committee added 'Selection of two or three protease inhibitors from the Model List will need to be determined by each country after consideration of local treatment guidelines and experience, as well as the comparative costs of available products' (WHO, 2002). It is important that, for those essential drugs that are subject to a patent and for new drugs to be included, that TRIPS as interpreted by the Doha Declaration be relied upon in the drafting of effective national laws. It may, however, be predicted that such laws will be subject to local and international challenge.

TRIPS and the right to health

Although TRIPS forms part of international law it must be enforced so as to minimize conflict with other areas of international law. Here Article 12, the right to the highest attainable standard of health contained in the International Covenant on Economic Social and

Cultural Rights will be examined. This right may be found in numerous conventions, declarations and charters and references to it are often made.

During 2000 the UN Committee on Economic Social and Cultural Rights (UNESCO, 2000) produced a General Comment providing guidance as to what is expected from States when demonstrating their fulfilment of this right. The obligations of States are said to include the provision of a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health. This includes making available essential drugs as defined by the WHO Action Programme on Essential Drugs to all without discrimination. By placing the antiretroviral drugs described above on the EDL, the Expert Committee has clearly identified that, despite their patent status and expense, their availability should be thought of as a right. How this is to be achieved is less clear.

Article 12.2(d) obliges States to create conditions that would assure to all medical service and medical attention in the event of sickness. The General Comment includes the provision of essential drugs as part of this obligation. The Committee drew attention to the obligation of all States parties to take steps both individually and through international assistance and cooperation, especially economic and technical, toward the rights in the Covenant generally and the right to health in particular. States are required to facilitate access to essential facilities, goods and services in other countries, wherever possible and give aid where required. These words appear in the General Comment: 'States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact on the right to health. Similarly, States parties have an obligation to ensure that their actions as members of international organisations take due account of the right to health'. Later on it states 'States parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political or economic pressure'.

The regulation of the global economy ought not to be divorced from global social concerns, including potential conflict with international human rights law. A consciousness of not only the rhetoric of rights but of the system of law that is human rights should be encouraged within the WTO. As noted, a strong argument may be put, on the basis of the General Comment, that lack of access to essential drugs is a breach of the right to health. This is not a loose use of the language of rights, but a highly tenable interpretation of the meaning of this particular right that should be introduced as often as possible into dispute resolution both in the WTO and national courts.

A human rights approach to intellectual property would no doubt subordinate this time limited corporate interest to inalienable and permanent rights such as the right to health. This view has been acknowledged with approval by bodies within and outside the UN (United Nations High Commissioner for Human Rights, 2001).

Price control mechanisms

If the present intellectual property regime is to continue, it is important that there be some mechanism for analysis of cost-effectiveness of a product and price control. Schemes for regulating the price of pharmaceuticals, such as those operating or being considered in Australia, the UK, Canada, The Netherlands, Italy, Portugal, Sweden, Norway and Finland, are options. However, some sections of the pharmaceutical industry

have aggressively defended their positions with tactics that have been widely criticised. These have included legal challenges and threats to governments, advisory bodies and individuals in Canada, USA, UK and Australia.

With respect to the imposition of price controls, the International Federation of Pharmaceutical Manufacturers' Associations has recommended that local innovation be encouraged by avoiding price control, either directly or indirectly. They argue 'Price controls tend to reduce supply and damage incentives for the research and development based industry, as well as negatively affecting the development of GMP-based local generics industry...' (Bale, 2000). However if existing drugs are unavailable the industry argument is of less force.

Conclusions

Essential drugs have a special status amongst the multitude of the world's drugs. The fact that they have been termed 'essential' dictates a degree of urgency in their provision. Access to essential drugs has been deemed a human right.

Governments are clearly entitled to build public interest considerations into their patent law and must make full use of the legal flexibility contained in TRIPS. Countries must take the time to formulate carefully balanced patent law to facilitate access to essential drugs. Board members hearing of disputes at the WTO should be encouraged to develop broadly based jurisprudence that takes into account the special nature of access to essential drugs. The impact of patent law on health is significant and must be balanced by other critical considerations.

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In an attempt to broaden the current debate over proposed revisions to the Declaration of Helsinki we define vulnerable subjects as those lacking basic rights, and examine the ethical risks inherent in research on such subjects. We then propose special ethical criteria for the conduct and publication of research on vulnerable subjects.

The Declaration of Helsinki, CIOMS and the ethics of research on vulnerable populations

DEBORAH ZION¹, LYNN GILLAM²
& BEBE LOFF³

For the past 30 years, human subjects research has been directed by the principles set out in a central document, the Helsinki Declaration of Helsinki. This statement on research ethics was put together in 1964 by the World Medical Association in an effort to ensure that medical research would follow ethical rules of practice and be of benefit to both researchers and research subjects. However, this document has recently come under considerable scrutiny. The goal of the declaration is presumably to protect the subjects of biomedical research from abuse and exploitation, but now it seems that the declaration may not be adequate to this task. It has not coped well with new challenges posed by clinical trials conducted by first world researchers in developing countries, particularly trials related to HIV/AIDS, a disease that has forced a reconsideration of many of our fundamental legal and bioethical tenets¹. This is perhaps not so surprising, given that the Declaration of Helsinki was drafted over 30 years ago by a first-world elite, mainly in response to problems particular to that time.

Reviews of the declaration, including the review now underway, have occurred within the most narrow of formal frameworks. The debate so far has been far too polarized. It has been characterized by two opposing arguments about the standard of treatment that should be required for subjects in the control arm of a randomized trial (either the 'best-proven method of treatment' or the 'highest attainable and sustainable treatment or method'), without any sustained attempt to consider the broader social and ethical issues. No real opportunity for the transformation of social relationships in the context of research has been offered.

It is time to reframe this debate, and explore other ways of thinking about the issues—ways that find some middle ground and relate more directly to the research subjects concerned. Here, we investigate some of the fundamental issues. We examine the ethical risks inherent in medical research conducted by people who are distant in economic, social and cultural terms from the participant communities from which the subject are recruited. We propose special ethical criteria that need to be met for research on these vulnerable populations. Then we suggest that, given the complexity and importance of the ethical issues in this sort of research, articles reporting results should include an 'ethical methodology' section as a standard requirement for publication.

Framing the ethical problem

Medical research takes place within a complex web of power relations, in which subjects—particularly subjects who are economically disadvantaged—are easily exploited. The sociopolitical environment in developing countries also compounds this possibility. Individual subjects are rendered passive because they rely on the presence of a research project for basic goods and services that would not otherwise have been available to them.

The Declaration of Helsinki does not address this type of

exploitation. It is addressed to some extent in the commentary accompanying the Council for the International Organizations of Medical Science International Ethics

Guidelines for Biomedical Research Involving Human Subjects, which states that "lack of alternative means of obtaining medical care or other expensive necessities" is one characteristic of those vulnerable to exploitation. But this recognition needs to be developed into a more comprehensive understanding of exploitation and vulnerability, which would then directly inform research practice. When working with such impoverished subjects, we must ask whether truly ethical research is even possible.

The following approach should be taken: Recognize that some subjects or populations require special ethical consideration and rigorous ethical accountability. These special groups are 'vulnerable populations' because they lack basic rights and liberties that make them particularly open to exploitation. They are often communities in the developing world, but this in itself is not a determining factor. Vulnerable populations can and do exist in developed countries as well. Our analysis of 'vulnerable populations' differs somewhat from other accounts, which often focus on particular groups like prisoners, children or incompetent adults—subjects who are frequently unable to make autonomous decisions. In fact, any population or group within a society must be considered vulnerable if they lack basic rights and freedoms that form an essential part of choosing the basic course of their life.

What are 'basic rights'?

The question of rights is always complicated in discussions of different cultures, and is further complicated by unequal power relations. Nonetheless, the political theorist Henry Shue has gone some way in distinguishing which rights should be universalized. He suggests that such rights are distinguishable from others, not because they are more important, but because they are foundational². Shue describes rights to goods like food and basic health care as primary, not because they are "more valuable or intrinsically more satisfying" than other rights, but because the enjoyment of such basic rights is necessary for other rights to exist. Similarly, certain kinds of political liberties such as the right to free speech, freedom of choice and freedom of movement can also be seen as fundamental. Thus Shue's 'basic rights' are a kind of foundation on which other rights are built.

Any population deprived of 'basic rights' should be regarded, for the purposes of medical research, as a vulnerable population, analogous to groups traditionally recognized as vulnerable in this setting, such as prisoners. Special justification should be required for medical research involving participants from these vulnerable populations in developing countries, just as it is for prisoners and other groups in developed countries.

The CIOMS guidelines—particularly guidelines 8 and 10—go some way to affording such protection. However, they do not go far enough. Moreover, these guidelines themselves are being reconsidered.

COMMENTARY

Specific issues for vulnerable populations

Vulnerable subjects must be treated with great care because they are prime candidates for exploitation. Desperate circumstances may lead these subjects to make decisions that are not in their own best interests, all things considered, even if researchers genuinely believe that the research is beneficial. The research may not address the most pressing needs of the local population, or may have detrimental long-term consequences, even if the researchers do not foresee or intend this. That is not to say that such subjects may not enjoy some benefits as the result of a first-world trial. But such trials may distract from important local issues, and the benefits gained are defined externally, rather than by the subjects themselves.

Informed consent

It is often believed that informed consent by the subjects makes trials ethically acceptable, even when they have some troubling features. However, when the subjects come from a vulnerable population, informed consent does not accomplish this.

It is already well recognized that cultural misunderstanding may abrogate the possibility of obtaining meaningful consent¹. However, there is a more sinister dimension to the problem of informed consent. One African researcher recently asked, "In an environment where the majority can neither read nor write and is wallowing in poverty and sickness, hunger and homelessness, and where the educated, the powerful, the rich or the expatriate is a semi-god, how can you talk of informed consent?" (<http://hivinsite/ucsf/edu/topics/women/2098.33fo.html>).

Oyewale Tomoori's observation demonstrates the vital connection between exploitation and autonomy, the value on which the requirement for informed consent is based. In many accounts of informed consent, the rationality of the subject is enough to ensure his or her autonomy. However, this kind of account ignores the important connection between autonomy and freedom. It seems farcical to suggest that subjects who are deprived of basic rights like food, or who live under regimes where the most fundamental liberties are denied to them, can be considered to be autonomous simply because they are rational. Thus, the conditions that make exploitation likely also inhibit the possibility of proper informed consent.

Conditions under which research might be ethically acceptable

Given all these difficulties, it may seem that medical research on vulnerable populations could never be ethically justifiable. However, to take this view would have substantial consequences. Although it would protect the most vulnerable individuals and their communities from the sort of exploitation described above, it would also prevent them from receiving the benefits of any research that really does address their particular needs. If some research projects could be beneficial from the perspective of the subjects themselves, is there a way of conducting them that is genuinely non-exploitative, and thus is truly ethical? Is it possible to frame standards in such a way that truly ethical research is permitted, whereas research that is not ethical is prevented?

One way this might be achieved is through the use of a process of special justification when vulnerable subjects are involved. Some elements of an appropriate process are included in the CIOMS guidelines, but under these guidelines, there is still room for vulnerable populations to be exploited. Thus, the following conditions would need to be met for research on a vulnerable population to ethically acceptable.

1. The research itself should directly address real health needs thought to be important by the subjects themselves (as indicated in CIOMS guideline 8). The CIOMS guidelines suggest that review by an ethics committee familiar with local customs would be an adequate safeguard. However, consultation with local ethics committees or national governments does not take into account the problems of corruption, and unequal power relations within and between different communities. Therefore, a sophisticated form of community consultation is required, which takes into account the complexity of such power relations within communities, especially pertaining to gender, sexuality and ethnic minorities. This is particularly pertinent when researchers are external to the community from which the subjects are to be recruited.

2. Medical research should not proceed on vulnerable groups unless the research is specifically related to inherent characteristics of that group (and not related, for example, to the needs or preferences of the researchers), and these characteristics are crucial to the internal research design (that is, the research only makes sense when the participants have these characteristics). This would include, for example, research on a disease that only affects a particular population. This requirement is much stronger than the current CIOMS statement that "persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities." Our requirement focuses on the characteristics of the actual target research population and its needs, rather than on other possible research populations. This, we believe, is the correct focus, ethically speaking.

These stringent justifications are particularly controversial at present because some commentators have suggested that trials in developing countries that could be done elsewhere also develop infrastructure and training for later trials. Such concerns are important, but in our view do not outweigh the problem of exploitation.

3. A process should be set in place to determine that subjects are not consenting from desperation, and genuinely understand the nature of the research and its potential risks and benefits. This is again a more stringent requirement than the CIOMS guidelines, which only require that informed consent is genuinely sought, rather than actually achieved. Clearly, developing an effective process would not be easy, but it is an ethical necessity, and we look forward to future discussion in the literature about means of achieving it.

4. The research should project contain an undertaking to analyze the long-term consequences of the project, through trial debriefing and follow-up studies. This kind of investigation should include any negative effect the original project has had, such as the distraction of local researchers from indigenous health problems.

It is by no means obvious that these conditions could in fact be met. It is likely that many research projects now ongoing in developing countries would fail to meet them, despite the good intentions of researchers. The sorts of changes required would involve a substantial shift in philosophy and methodology, with financial consequences for those funding the research. A high degree of partnership and common purpose between researchers and participants would be required. But any medical research that does meet these conditions would offer real benefits in a manner genuinely respectful of the people asked to participate in it, and would be ethically acceptable. Medical research that does not meet these conditions, no matter how well-intentioned, would not be ethical, and should not proceed.

Accountability and publication

The Declaration of Helsinki at present requires that research not conducted according to its provisions should not be published. Research that does meet its provisions, however, is customarily published without comment. The intention here is commendable: to ensure that researchers do not gain any reward for conducting research that is unethical. However, this practice creates the impression (and is probably based on the assumption) that the issue is 'black-and-white': a research project is either ethical or not, and either way, there is no particular need for anyone to comment. But given the complexities of conducting research in developing countries, described at length here, this view is really somewhat inadequate.

The publication of research conducted in developing countries or on vulnerable populations should always be accompanied by a discussion of the relevant ethical issues. Questions of ethics will inevitably arise in such research, and it is appropriate to require evidence that researchers have given explicit and careful consideration to them, in just the same way that explicit description and justification of the scientific methodology of the research project is required. This can never be a matter of simply stating that the relevant guidelines have been followed. Whatever set of guidelines is ultimately adopted to govern medical research in this setting will necessarily be cast in general terms, and will require interpretation and application to the local setting. The sorts of ethical tensions described above will always need to be worked through, and evaluation of the reasoning behind the chosen resolution ought to part of the part of the process of peer review and publication.

Journal editors, then, should routinely require that every paper reporting the results of medical research in this context contain a section on ethical methodology. This would give the issue much more prominence than the occasional refusal to publish, and in addition would help to build up a body of expertise in dealing with ethically complex research settings that

is in the public domain and, thus, widely accessible. It would also avoid the problem, emphasized by the controversy over the vertical transmission trials, that post hoc justifications for ethically contentious research are often unconvincing and do little to allay concerns. Editors would naturally reserve the right to refuse to publish research that they believed to be egregiously unethical, but this would remain a rare event.

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Global health problems require global solutions, and public-private partnerships are increasingly called on to provide these solutions. But although such partnerships may be able to produce the desired outcome, they also bring their own problems. A first-of-its-kind workshop in April, hosted by the Harvard School of Public Health and the Global Health Council, examined the organizational and ethical challenges of partnerships, and ways to address them.

Public-private partnerships for public health

Recently, many organizations in public health have declared partnerships with private-sector organizations. Academic institutions have created partnerships with private companies for specific research activities, such as the development of new treatment therapies. The World Bank has announced that it will encourage partnerships as part of its comprehensive development framework. The new director-general of the World Health Organization (WHO) has stated that she will promote partnerships with the private sector. Non-governmental organizations have established relationships with private for-profit firms. Private foundations are supporting and joining partnerships, exemplified by the surge of activities from the Bill and Melinda Gates Foundation. Similar trends are apparent for many international health issues, particularly in efforts to expand access to drugs and vaccines in poor countries¹⁻⁴.

The trend is clear and widespread. But why has the issue of public-private partnerships become so prominent on the international

MICHAEL R. REICH

policy agenda at this time? One reason is that new public health problems are being

pushed onto the international policy agenda by non-governmental organizations that have gained influence in the past 30 decades. These problems often involve issues of health equity between the rich and the poor of the world. Médecins sans Frontières, for example, has helped focus global attention on access to essential drugs in poor countries. Neither public nor private organizations are capable of resolving such problems on their own. Traditional public health groups are confronted by limited financial resources, complex social and behavioral problems, rapid disease transmission across national boundaries and reduced state responsibilities. At the same time, private for-profit organizations have come to recognize the importance of public health goals for their immediate and long-term objectives, and to accept a broader view of social responsibility as part of the corporate mandate. Pharmaceutical companies, for example, have become involved in a number of high-visibility drug

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Ethics

The Declaration of Helsinki and research in vulnerable populations

Bebe Loff and Jim Black

Mooted changes to the Declaration on the agenda of the World Medical Association have sparked a vigorous debate on international research issues. The medical, research and ethics communities in Australia need to participate more broadly in this debate.

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For editorial comment, see [Stockhausen](#)

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Introduction The Nuremberg Code, which was formulated to prevent a recurrence of the horrific medical experiments carried out on humans during World War II, is unwavering in its commitment to the primacy of the human subject. It states that any person who is a research participant "should be so situated as to be able to exercise free power of choice" and that "(t)he experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."¹

The Declaration of Helsinki² was the World Medical Association's (WMA's) response to the Nuremberg Code and its goal was to safeguard research subjects. However, in declaring the need to weigh the importance of the research objective against the risk to the subject (Article I.4), the Declaration was seen as a subtle retreat from the Code.³ Some fear that changes to the Declaration currently under consideration by the WMA would substantially "water down" the basic principles of ethical human research.

The Declaration does not specifically deal with international collaborations. In 1993, the Council for International Organizations of Medical Sciences (CIOMS) developed the *International ethical guidelines for biomedical research involving human subjects*,⁴ which address issues pertinent to the conduct of research in developing countries.

Despite the existence of the Declaration and other documents, it is apparent that the application of safeguards to protect research subjects is far from uniform, especially among impoverished or marginalised people.^{5,6}

Proposed revisions to the Declaration of Helsinki

A number of revisions are currently proposed to the Declaration to make it

more relevant to researchers (some of whom, it has been suggested, commonly breach its provisions).⁷ Those who oppose the amendments fear that research participants will be made more vulnerable to harm in order to make research more efficient and perhaps expedient (see Box).⁸

Two proposals have generated a great deal of discussion and controversy. One concerns the abolition of the distinction between "therapeutic" and "non-therapeutic" research. The other (the main focus of this article) relates to provision of the best proven treatment and to use of placebo-controlled trials.

"Therapeutic" v "non-therapeutic" research

The introduction to the Declaration requires that

"a fundamental distinction . . . be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research".

Article II.6 states that in "therapeutic" research

"The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient."

Article III.2 states that in "non-therapeutic" research

"The subjects should be volunteers -- either healthy persons, or patients for whom the experimental design is not related to the patient's illness."

Robert Levine, Professor of Internal Medicine at Yale University School of Medicine, argues that these Articles together rule out "all rational research on the causes of diseases or on their pathogenesis or pathophysiology".⁹ He notes that clinical trials may include both therapeutic and non-therapeutic agents.⁷ Others believe the division between therapeutic and non-therapeutic research to be firmly entrenched in research guidelines developed since and influenced by the Declaration and to be well understood in practice.⁹

"Best proven treatment" v "highest attainable treatment"

The changes proposed to Article II.3 (see Box) have generated extensive debate. Opinions are polarised between those in favour of the "best proven treatment or method" and those for the "highest attainable and sustainable treatment or method". The problem with the "best proven treatment" approach is that it may prevent valuable research being done, as treatments and services will not be readily available in resource-poor settings and may not be provided by researchers and their sponsors. The problem with the "highest attainable treatment" goal is that it may lead to a marked decline in care -- there are no clear criteria for establishing what level of treatment is acceptable or firm safeguards for applying it.

The problem in resource-poor countries

Perhaps the real issues to be debated are how best to enable people to make

meaningful choices and how to ensure that they are not treated poorly and without respect because of their circumstances. What should be examined are the problems created in some societies by a lack of fundamental civil and economic rights, and whether this advantages proposed research projects.

To assume that all would like to be treated as people in affluent countries would, and to rely on this judgement as a basis for formulating an encompassing ethical ideal, is, *to some extent*, misguided. Classic egalitarian premises, upon which comparable rights documents, such as the Universal Declaration of Human Rights,¹⁰ are based fail to take account of subcultures and their priorities. Indeed, issues like gender and race are still inadequately addressed in these documents, in which the tacitly assumed "universal person" is the European white heterosexual male.¹¹ This difficulty is accentuated when privileged cultures interact with others. Is it true to say that standards appropriate for industrialised countries are equally relevant to others? If not, what are we left with?

Ruth Macklin, Professor of Bioethics at the Albert Einstein College of Medicine in New York, has analysed ethical concerns in international research according to the concept of justice.¹² She states that a prominent feature of justice is that no one group should "receive disproportionate benefits or bear disproportionate burdens",^{12a} a corollary being that like cases should be treated alike. One side argues that if the study is unethical in one place it is unethical in both. The other argues that risk-benefit ratios are different in resource-poor countries and therefore require a different response and, further, that if the benefit is actually to accrue and only to accrue to the developing country, this is ethically significant.¹² Her conclusion in this debate is that both sides can claim that their arguments observe the ethical requirement of justice.

Advocates of placebo-controlled trials in resource-poor countries cite local support and participation in defence of their views. Thus, in the case of trials of less expensive regimens to prevent vertical transmission of HIV, Edward Mbidde, a Ugandan physician, said in a now oft-cited statement, "(t)hese are Ugandan studies, conducted by Ugandan investigators, on Ugandans ... for the good of their people".¹³ It would be too simple a response to discount this comment entirely as being no answer to a breach of ethical standards.¹⁴

Yet, even when a host country agrees to allow drug trials, substantial ethical difficulties remain. One of us (J B), after working for 10 years as a clinician in Mozambique (where the local provincial health service budget was about \$US3 per capita per year), believes that the basic rights of potential trial participants in some parts of Africa may be so compromised that refusal to participate is not an option:

"This is the sort of health service where every clinician finds him or herself from time to time looking at the pharmacy cupboard and wondering how to divide the remaining three vials of penicillin between the five patients in the ward who need it. (Whether to give starting doses to everyone in the hope that the promised new supplies will arrive, or just give it to one seriously ill child, for whom at least it represents a curative course.) From that perspective, enrolling patients in a clinical trial will always look attractive, no matter how unethical that research may turn out to be."

¹³ Almost any reward, even bars of soap or transistor radio batteries, is likely to ensure trial participation.

Perhaps international collaborations, particularly those involving complex drug trials, should not be conducted where there is this degree of poverty. Speaking at the same symposium,¹⁵ Pascale Allotey, Lecturer in International Programs at the Key Centre for Women's Health, Melbourne University, made the point that the possibility of enhanced services or cashflow to a community will mean that community leaders will very likely agree to trials taking place, as, ostensibly, will community members. However, they may resent doing so. Fears of a diminished standard of care as a result of withdrawal from a trial are quite real in these circumstances.

Where to from here?

Are genuinely consensual relations possible between the research community and participants who otherwise have little or no access to healthcare or other basic rights and liberties? Can structures and criteria be implemented that promote dialogue and recognise diversity of approach, but discourage abuse of trial participants?

The following suggestions were offered to the participants in the aforementioned symposium¹⁵ for consideration, and most agreed that more discussion was required to flesh out what these ideas might mean in practice (the suggestions are not entirely new and are broadly consistent with the CIOMS guidelines and draft UNAIDS guidelines¹⁶):

(a) Where a population does not possess basic economic or social rights it should be regarded, *prima facie*, as one whose members' capacity to freely consent is gravely impaired. Research studies in such populations, especially those involving randomised trials, require special justification. An exception might be where the research goal is to work out how to apply a proven technology: for example, an assessment of whether open or covered buckets are more suitable water containers in a refugee camp (Associate Professor Michael Toole, Macfarlane Burnet Centre for Medical Research, personal communication).

UNAIDS guidelines¹⁶ state that, in international collaborative programs, strategies should aim to balance inequalities by involving members of affected communities from very early on in the design and development stage, and by imposing a number of safeguards around the process of informed consent.

(b) A research protocol should describe the conditions that might make a research population vulnerable to exploitation and the steps that will be taken to overcome them.¹⁶ *The UNAIDS guidelines impose this requirement on research protocols. We further propose that these steps should be described in publications derived from the research, in order to give the issues greater prominence and to further this discussion.*

(c) *In planning research in populations severely deprived of civil and political rights, agreements with governments and ethics committees are insufficient. This is especially the case when governments have demonstrated grossly repressive or corrupt behaviour, or where ethical review systems can not be regarded as independent. Research should not take place in these circumstances. This recommendation should be distinguished from ethical guidelines applying to research in emergency or refugee settings.*

(d) Thorough community-based consultation is required to determine local views, needs and priorities. Researchers need to establish what local research priorities exist (although, in many deprived populations, any problem area could be seen as a priority). This includes, in particular, consultation with people who have little power or are ostracised for whatever reason. Ethnographic studies could be conducted in advance of a proposed project to determine actual rather than supposed local attitudes, and debriefing could be required after completion of a trial (Deborah Zion, Centre for Human Bioethics, Monash University, personal communication). Including nationals on committees, or agreement by host governments and ethics committees, are not substitutes for community consultation.

(e) An analysis should be made, in advance of a project, of the long-term consequences of the intervention. Long-term considerations should certainly include, but not be limited to, sustained access to a trial drug. One of the possible adverse consequences to consider would be the diversion of local researchers and healthcare providers into projects that are not local initiatives. Consistent with current ethical standards, if there is no prospect of benefit to the community in its terms the research should not be undertaken. At the very least, a memorandum of understanding should be prepared before the commencement of any international collaboration, indicating what each party - community, government, research institution and sponsor -- expects prior to, during and as a consequence of the trial.

Conclusion

Angela Harris, Professor of Law at the University of California, Berkeley, has stated that modern human rights standards are at once indispensable and inadequate.¹² The same may be said for ethical guidelines on medical research. The solutions are not clearcut. The WMA meeting in Tel Aviv, Israel, in October 1999, at which the Declaration of Helsinki was reconsidered, issued the following brief statement:

"The meeting heard of widespread support for retaining the existing structure of the Declaration of Helsinki. It was agreed that the working group set up to consider amendments to the Declaration should report back with a proposed revision at next year's annual General Assembly meeting in Edinburgh, Scotland (3 October 2000)."

It is to be hoped that the Australian medical research community and other interested groups will debate the issues and arrive at a consensus.

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Some proposed revisions to the Declaration of Helsinki

Current statement

I.8: Reports of experimentation not in accordance with principles laid down in this Declaration should not be accepted for publication.

Proposed revision: Variances from these principles should be explained and justified in the report. Editors are obligated to consider carefully the justification for any variances from these principles in deciding whether to accept or reject the report for publication.

Current statement

I.10: ...the informed consent should be obtained by a physician who is not engaged in this investigation and who is completely independent of this official relationship.

Proposed revision: In some cases of this type, it may be preferable if the informed consent were to be obtained by a qualified person who is not engaged in the investigation, independent of the dependent relationship, or both.

Current statement

II.3: In every medical study, every patient, including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.

Proposed revision: In any biomedical research protocol every patient-subject, including those of a control group, if any, should be assured that he or she will not be denied access to the best proven diagnostic, prophylactic or therapeutic method that would otherwise be available to him or her.

Current statement

II.3: This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

Proposed revision: This principle does not exclude the use of placebo or no-treatment control groups if such are justified by a scientifically and ethically sound research protocol. When outcome measures are neither death nor disability, placebo or other no-treatment controls may be justified on the basis of their efficiency.

Current statement

II.5: If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.

Proposed revision: When permitted by applicable law, the requirement for informed consent may be waived by the independent research ethics committee. Such a waiver may be appropriate in research that presents little or no threat to the rights and welfare of research subjects as exemplified by use of anonymous tissue samples for research purposes and in certain other types of research in such fields as epidemiology and policy evaluation. It may be justified in research in emergency situations in which patient-subjects have temporary or enduring loss of decisional capacity and interventions or procedures must be initiated before informed consent can be obtained from patient-subjects or their legally authorised representatives. In the latter case the research ethics committee may require special procedures to protect the rights and welfare of subjects.

Violence



Echo of a Scream by David Alfaro Siqueiros

Museum of Modern Art, New York, USA

Violence in public health and preventive medicine

James Gilligan

"When a man is suffering from an infectious disease, he is a danger to the community, and it is necessary to restrict his liberty of movement. But no one associates any idea of guilt with such a situation. On the contrary, he is an object of commiseration to his friends. Such steps as science recommends are taken to cure him of his disease, and he submits as a rule without reluctance to the curtailment of liberty involved meanwhile. The same method in spirit ought to be shown in the treatment of what is called 'crime'."

Bertrand Russell

A consensus on the causes and prevention of violence has been emerging over the past few decades among investigators of this subject from virtually every branch of the behavioural sciences. All specialties, independent of each other, have identified a pathogen that seems to be a necessary but not sufficient cause of violent behaviour, just as specifically as exposure to the tubercle bacillus is necessary but not sufficient for the development of tuberculosis. The difference is that in the case of violence the pathogen is an emotion, not a microbe—namely, the experience of overwhelming shame and humiliation. And just as people's vulnerability to tuberculosis is influenced by the state of their body's defence mechanisms, so their vulnerability to violence is influenced by the state of their psychological defence mechanisms.

These defences include the degree to which violent individuals have developed the capacity for an emotion that is antagonistic to shame, and inhibits the violence toward others that shame stimulates, namely, guilt and remorse. And this is a capacity that the most violence-prone individuals and groups notably lack. In addition, their vulnerability or sensitivity to any given experience of shame—the likelihood that they will be so overwhelmed by it as to become violent—is strongly influenced, to a statistically significant degree, by whether or not they possess internal sources of pride and self-esteem, such as

education, or external sources of esteem from others, such as wealth or other sources of high social status.

Shame has forty synonyms: feeling slighted, insulted, ridiculed, rejected, disrespected, dishonoured, disgraced, or demeaned; feeling inferior, inadequate, incompetent, weak, ugly, unintelligent, or worthless; suffering "loss of face", "narcissistic wounds", or an "inferiority complex". There is increasing agreement among students of this subject that people, especially men, engage in violent behaviour when, and only when, they do not perceive themselves as possessing sufficient non-violent means by which to undo the feeling of shame and humiliation.

These conclusions about the aetiology of violence enable us to understand how to engage in its primary prevention. The first principle is to stop the causes—namely, shaming and humiliating people by subjecting them to hierarchical social and economic systems characterised by class and caste stratification, relative poverty, and dictatorship. Violence is caused by the feeling of shame, which is the feeling of inferiority; and inferiority is a relative concept. Thus making one group of people inferior to another in terms of relative wealth or power is a recipe for increasing the level of violence.

Worldwide, the most powerful predictor of the murder rate is the size of the gap in income and wealth between the rich and the poor. And the most powerful predictor of the rate of national or collective violence—war, civil insurrection, and terrorism—is the size of the gap in income and wealth between the rich and poor nations. For the same reasons, the nations with the lowest murder rates are those such as Japan, the nations of Western Europe, Canada, Australia, and New Zealand, which have the highest degrees of social and economic equity. And the nations with the lowest frequencies of national violence are those that have both political democracy and relative national wealth—Japan and the western democracies. Primary prevention can also be described in more positive terms: ensuring that people have access to the means by which they can achieve a feeling of self-worth, such as education and employment, and a level of income, wealth, and power that is equal to that which other people enjoy,

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Violence in research

Bebe Loff

Article 7 of the International Covenant on Civil and Political Rights states: "No-one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." Human history makes it understandable that torture and medical research should be joined conceptually in this internationally accepted Covenant, which entered into force on March 23, 1976. However, the phrasing might not have occurred to us today. Indeed, one can imagine the objections that might be raised if such a proposal were to be put forward anew: research is not torture; to combine these thoughts is to inappropriately impute evil intentions to well-meaning researchers; or, the purpose of research is to benefit humanity—occasionally something may go wrong but this does not justify a *prima facie* presumption that experimentation and cruel or inhuman treatment are associated.

It is, of course, the findings of the Nuremberg doctors' trials and subsequent Code that made the statement seem so acceptable to its signatories, if not the medical profession. Medical research is placed within the realm of torture and punishment, and only the "free" agreement of the participant can defend what is otherwise a breach of a fundamental right. So despite its utilitarian value, the goal of research cannot be placed ahead of the exercise of free will. It is the complexity and subtlety of what it means to truly respect human rights and treat research participants with dignity, beyond consent, that will be explored here. Human-rights documents, broadly including, for the purpose of this discussion, codes prescribing ethical standards for research such as the Helsinki Declaration, operate within a liberal discourse of universality. Their espoused universality may, in reality, have little to do with protecting the human dignity of some populations. The egalitarian statements contained within these documents may result in a failure to take account of subcultures and their priorities even within nations. By way of comparison, human-rights instruments have long been criticised for their "gendered" and "European" expression and content. The impact of this bias must surely be exacerbated when privileged groups interact with others.

By focusing on statements of rights we find ourselves in polarised debates in which we can either agree or disagree with a standard—as is amply demonstrated by the current bitter dispute about the proposed revision of the Helsinki Declaration. In some instances this may be

valuable, in others greater capacity for dialogue and contextualised analysis will be more revealing of the significant ethical issues.

Even within the conservative discipline of the law, judicial statements interpreting universally agreed rights may be lengthy and encapsulate a number of shades of opinion. Why do we imagine that codes governing research should be amenable to only one construction when the conditions of individuals are so varied? In international research collaborations, are genuinely non-exploitative relations possible between the research community of the "north" and participants of the "south"? Can we put in place protections that are not naïve, yet promote exchange of views, recognise diversity of approach, and avoid injustice? How can we honour the valuable intent of the Nuremberg and Helsinki documents without falling prey to shortcomings induced by a positivist or "single-minded" outlook? This is not an appeal to ethical relativism, rather a quest to identify and implement what might have been intended by the drafters and for procedural inclusivity.

UNAIDS has published a guidance document entitled *Ethical Considerations in HIV Preventive Vaccine Research*. In it, UNAIDS attempts to deal with some of the issues that have discredited the research community. Let us leave to one side the requirement that researchers provide to participants the highest attainable standard of care in the host country, which is certain to be controversial. The guidelines demand that an exhaustive dialogue should take place. The fifth guidance point states: "To ensure the ethical and scientific quality of the proposed research, its relevance to the affected community, and its acceptance by the affected community, community representatives should be involved in an early and sustained manner in the design, development, implementation, and distribution of results of HIV vaccine research." One would want to be sure that this process involved the most ostracised groups and not only the empowered. Of course the value of such a dialogue is limited in communities where deprivation is great. Research should not take place in such instances. With this proviso, surely the guidance point is well made.

The guidelines further demand a collaborative process involving strategies to capacitate host communities so that they can practise meaningful self-determination. Is this asking too much? Probably some of the current generation of researchers would say that it is, or, at least, that they do not have the right skills. Yet to object to these proposals is tantamount to saying that it is permissible to do research in a community whose diverse voices cannot be heard and responses transparently provided. Without wishing to rely upon extreme language, this seems like a form of violation and gives a contemporary resonance to the wording of Article 7.

"In international research collaborations, are genuinely non-exploitative relations possible between the research community of the 'north' and participants of the 'south'?"

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Africans discuss ethics of biomedical research

Cape Town, South Africa, provided the scenic backdrop for the Third Global Forum on Bioethics in Research held on Feb 21–23, which was followed by the Pan-African Bioethics Initiative (PABIN).

The forum provides a venue in which developing countries have significant input into the ethical debate on international collaborative research sponsored by industrialised countries and done in developing countries. Two thirds of the 110 delegates came from developing countries. Of the 40 countries represented, half were African. The forum is sponsored by the US National Institutes of Health and the Medical Research Councils of South Africa and the UK, WHO, and other international agencies. This year's forum was organised by the UK's Medical Research Council.

The meetings focused on some of the key issues in international collaborative research. These include whether current ethical guidelines constrain or promote post-trial access to drugs, devices, or vaccines; the difficulties in creating ethical guidelines and review processes in developing countries; the standard of care to be provided during trials; traditional medicines; genomics and global health; and culture and informed consent. Participants suggested that we need to move from the discussion on the content of ethical guidelines to their implementation.

Churchill Lukwiya Onen, from the Princess Marina hospital in Botswana, discussed concepts of justice in relation to post-trial access to drugs and devices. He noted that "differences in our interpretation and difficulties in translating research principles into realities must be urgently and amicably resolved".

A comprehensive picture of the difficulties of doing HIV vaccine trials involving women in South Africa was provided by Douglas Wassenaar of the University of Natal. Women in sub-Saharan Africa carry 82% of the global burden of HIV infection. Their vulnerability to infection is, not surprisingly, affected by their status. This in turn is affected by sexual practices including the decreasing age of sexual debut, dry-sex practices—where foreign material is placed in the vagina to lessen lubrication and create more friction, male refusal to use condoms, a higher incidence of untreated STDs, female inability to behave assertively, transactional sex, and acceptance of multiple partners for males. There has

also been an increase in child rape because of the belief that intercourse with a virgin will provide cure STDs.

He noted that fostering voluntary consent is a new ethical agenda in some communities and "would be perceived as a subversive and politically destabilising action". Women's experiences of consent are likely to be severely compromised and it is these women who may be candidates for

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Medical research need to be responsible

HIV trials. Like Onen, Wassenaar called for a transition from aspirational ethical codes to their practice relying on "emancipatory informed and sensitive social-scientific research and action... built on the voices of women".

Godfrey Tangwa of the University of Yaounde, Cameroon, talked about the second scramble for Africa and how the continent presents the biggest and most attractive laboratory for western researchers. Where ethical review committees exist they are inundated with applications. He highlighted the lack of regulation of research in some African countries, and called for the establishment of strong regional and national regulatory frameworks. This would also enable developing countries to make informed contributions to discussions about international guidelines.

With the greater involvement of genomics in drug development Peter Singer of the University of Toronto, Canada, posited that this science has the potential to increase the global pharmaceutical divide and increase health inequities. This effect, he said, was not unavoidable but much activity was required now. An opinion leader network should be created across different sectors: government, industry, NGO/patient organisations, scientists, and health-care leaders. Participants should familiarise themselves with the current state of genomics technology and frameworks for analysing ethical and legal issues. He called for a Commission on Global Genomics Governance to make recommenda-

tions for genome-related issues and activities. He asserted that there was an opportunity for pharmaceutical companies to become positive players.

The forum was treated to a visit to the South African Medical Research Council where the meeting heard from Motalepula Gilbert Matsabisa. He discussed traditional medicines and a scheme being developed by the Council to try to ensure that any benefit derived from knowledge acquired from local communities about traditional medicines would be shared by those communities.

PABIN is part of the Strategic Initiative for Developing Capacity in Ethical Review, a worldwide collaborative of institutions and people interested in promoting ethical review. It was established within the tropical disease research division in WHO. The intention behind PABIN is to "share understandings of good ethical practices between African experts and international organisations involved in research in Africa" and the meeting continued discussion of the issues raised during the forum.

Participants from African countries discussed the difficulties they face in creating rigorous ethical review processes. The lack of regulation of ethical review and unavoidable conflicts of interest arising amongst the small number of people with the skills to be members of ethics committees were consistent themes. Formal academic training in ethics is limited and, in many countries, non-existent.

Donna Knapp van Bogaert of South Africa talked about the challenges of corruption, which she said thrived in environments of poor governance, and were exacerbated by poverty. She described the politicisation of research, noting that in some states research could only proceed if it was authorised by a particular individual. People may be appointed to boards for factors unrelated to their knowledge or experience. It may be exceedingly difficult to act as a whistleblower, she said.

While the challenges of creating ethical guidelines and processes for research are significant in industrialised countries, fundamental issues arise for developing countries who may not have sufficient resources to create the infrastructure for ethical research. All participants agreed that it is crucial that support continues for initiatives such as PABIN.

Bebe Loff

Healthcare rationing, patient rights and the law

Bebe Loff and Jennifer W Majoor

We need frank discussion of healthcare rationing in Australia

EVERY DAY IN AUSTRALIA, healthcare services and providers make resource allocation decisions on grounds that are not necessarily transparent or public. These implicit resource allocation decisions include, for instance, a hospital going on ambulance bypass or condoning long elective surgical waiting lists. Explicit healthcare resource allocation decisions in Australia are made by the legislature; the more widely recognised instruments of this resource allocation are the Medicare Benefits Schedule and the Pharmaceutical Benefits Schedule. Further rationing decisions, although not commonly perceived as such, are contained in the Australian Health Care Agreements, which establish the Commonwealth's contribution to the maintenance of State and Territory public hospital services.

In Australia, courts play only a minor role in resource allocation, and usually intervene only when healthcare negligence or discrimination is alleged. The impact of negligence litigation has been much debated and need not be discussed here.¹ Victoria's IVF legislation was challenged last year in *McBain v State of Victoria* on the grounds of discrimination.² The law in Victoria did not allow access to IVF services for single women; women had to be married or living in genuine de facto circumstances. The Federal Court found this aspect of Victoria's legislation to be invalid. The few examples of court interference in Australia that do not fall within negligence or discrimination relate to overservicing^{3,4} or challenges to decisions of the Pharmaceutical Benefits Advisory Committee (PBAC).⁵ For example, in the Federal Court last year, in the case of *Pfizer v Birkett*, Pfizer challenged the decision of the PBAC to deny a subsidy for Viagra (sildenafil). In her judgment, Matthews J noted:

I should commence by emphasising the limited role of this Court in reviewing the decisions of administrative decision-makers. It is not the function of the Court to review the merits of these decisions. Its role is to ensure that administrative decisions are reached according to law, that proper procedures are followed and that appropriate considerations are taken into account. Unless a decision is so manifestly unreasonable that no reasonable decision-maker could have made it, the Court will not intervene in the fact-finding process or otherwise explore the merits of the case.⁶

Pfizer is currently appealing the court's decision to uphold the PBAC's ruling.

Should a particular individual or group not have access to new drugs or services, there may be an opportunity for redress through the courts, on a range of grounds such as we have described.

The situation differs in the United States. On 13 Jul 2000, the US Supreme Court handed down its decision in the case of *Pegram v Herdrich* (Box).⁷ Although this case arises out of the context of managed care, it is of interest to us because the US Supreme Court gave its imprimatur to rationing within healthcare.

Two main issues are embodied in this case. The first is primarily a legal one that pertains to the interface between state and federal law in the United States and is not relevant to our discussion. The second issue is a complex ethical and medicolegal one and relates to the trade-off between clinical risk and cost-containment strategies. In June 2000, the American Medical Association stated in a press release that the case "provides a compelling argument for a strong patients' bill of rights".⁸ In effect, the organisation was suggesting that an independent mechanism is necessary to protect patient health and minimum entitlements because HMOs can not be trusted to do so. Of course, not all would agree with this view.

Are there implications of *Pegram v Herdrich* for Australia? On the legal front, as noted in *Pfizer v Birkett*,⁵ Australian courts are loath to interfere in resourcing decisions of government bodies unless a decision is "so manifestly unreasonable that no reasonable decision maker could have made it"; an example of such a decision would be failing to provide medical services to prisoners. The avenue for consumer redress in matters of healthcare rationing, regardless of recommendations resulting from coronial inquiries or other expert sources, would tend to be political rather than legal. For instance, long elective surgery waiting lists attract media attention rather than litigation based upon delays in treatment and resultant harm. Legislating for the rights of healthcare consumers might alter this position, as courts might then be empowered to measure provision of services against statutory criteria.

We suggest that individual medical practitioners have both a fiduciary duty to the patient and a responsibility to use resources efficiently and effectively. These two duties are often felt to be mutually exclusive, and doctors often resent the reality of limited resources in healthcare. In general practice, constraints are imposed by both the pressure of the waiting room and the Medicare system. In hospitals, resource constraints may be forced by limiting staff or supplies. There are more complex issues that arise in rural, remote and Aboriginal healthcare. Rationing is a fact of life for Australian medical practitioners, but, unlike doctors in US managed care or the UK fundholding system, Australian

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***Pegram v Herdrich* (Supreme Court of the United States)**

Lori Pegram, a doctor employed by a health maintenance organisation (HMO), examined Cynthia Herdrich. Herdrich was experiencing abdominal pain. Six days later, Dr Pegram found a six by eight centimetre inflamed mass in Herdrich's right iliac fossa. However, rather than ordering an ultrasound of the area at the local hospital, Dr Pegram decided that Herdrich should wait eight days so the procedure could be performed at a clinic operated by the HMO, more than 50 miles away. Before the day of her ultrasound appointment, Herdrich's appendix ruptured.

Herdrich successfully sued Dr Pegram under state law for medical malpractice. She also brought an action against the HMO under the federal Employment Retirement Income Security Act of 1974,⁷ stating that the HMO was in breach of its fiduciary duty of care to plan members. The basis of this claim was that the HMO had deprived plan beneficiaries of proper medical care on financial grounds and retained the resulting savings in what could be thought to be a conflict of interest.

The US Supreme Court found unanimously that "since inducement to ration goes to the very point of any HMO scheme, and rationing necessarily raises some risks while reducing others (ruptured appendices are more likely; unnecessary appendectomies are less so), any legal principle purporting to draw a line between good and bad HMOs would embody, in effect, a judgement about socially acceptable medical risk". This the Court preferred to leave to the US Congress. Thus simply because the owners of the HMO provided an end-of-year distribution to themselves of profits derived from the difference between subscription income and expenses of care and administration, this was not a sufficient basis for the Court to find against them.

doctors have been protected from having to acknowledge openly their role in it.

Our medical practitioners fear that US-style managed care and health maintenance organisations (HMOs) will be imported into Australia. Successful campaigns have already been waged defeating the possibility of private insurance companies extending their influence over clinical medical decision-making.⁹⁻¹¹ The recent amendment to the *National Health Act 1953* (Cwlth) relating to medical purchaser provider agreements provides that such agreements must maintain the medical practitioner's medical freedom within the scope of accepted clinical practice to identify

appropriate treatments in the rendering of professional services to which the agreement applies".¹² *Pegram v Herdrich* will undoubtedly be cited in future discussion as an example of the ills of HMOs and their mandate to reduce expenditure. However, although HMO-style managed care has been avoided in Australia, the healthcare system is still subject to cost-containment strategies to accommodate increasingly scarce resources. Although rationing within the Australian healthcare system is not discussed openly, it is implicitly understood that rationing occurs. We need more frank public debate on how we manage our resources rather than sporadic and superficial media attention.

Pegram v Herdrich highlights that cost-containment can have a price and, if that price is quality of care, the system is in trouble. There is no doubt that there is a need to transparently and scientifically measure and monitor the effects of managerial financial decision-making and its impact on clinical outcomes. This should be done against clearly defined and agreed criteria. This applies to both the public and private sectors, whether managed care exists or not. The scientific evaluation of clinical outcomes and quality of care is a continuing challenge that we should not shy away from on the basis of difficulty, medical dominance, or the mistaken view that this is a wasteful effort by the "bean counters".

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that men cannot get an erection and ejaculate under duress. However, it is well-recognised that males can be physiologically sexually aroused by emotions including anger, fear, and pain.² It is also believed that someone who had been raped would not be emotionless when describing the experience. In the initial description of the (female) "rape-trauma syndrome", victims were said to exhibit one of two styles, the "expressive" and the "controlled". In one study³ 79% of male rape victims were classed as "controlled"—calm, controlled, or subdued. The other common myth is that the guards, not being homosexual themselves, would not want to commit homosexual acts. Again, however, the evidence suggests that the motivation for sexual assault of men is the demonstration of complete control over

the victim,² and that the perpetrators do not perceive themselves or their acts as homosexual.⁴

Torture is defined by the UN as the deliberate infliction of physical and psychological pain by or with the acquiescence of a person acting in an official capacity, with one of several intentions including the intimidation of the victim or third parties. It is an aggravated form of degrading and inhuman treatment. Sexual abuse in detention is always torture. Rape is an attack dominated by feelings of power and anger, rather than being primarily an expression of sexual desire.

We believe that sexual abuse of Tamil men in detention is common in Sri Lanka. Although in this sample the proportion was 20%, the true number is probably higher as some will not have reported it.

Sri Lanka is a signatory to the UN Convention against Torture, and as such must prevent, investigate, and punish all cases of torture. The authorities in Sri Lanka must take action now to stop the torture, sexual assault, and rape of detainees.

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Aboriginal reconciliation still a long way to go

The Australian Council for Aboriginal Reconciliation was set up a decade ago with a 10-year mission to deal with unresolved issues between Aboriginal and non-Aboriginal Australians. On May 27, 2000 a national document of reconciliation was launched. Instead of a celebration, the event may only signal further deterioration in the relationship between Aboriginal people and the Australian government.

In the Northern Territory recent mandatory sentencing provisions state that for a third offence, no matter how trivial, the penalty is 1 year in prison. These laws apply to juveniles aged 15-17 years and adults. Aborigines constitute only 28.5% of the Territory's population comprise, but 70% of the prison population.

For his second offence—stealing oil and paints worth Aus\$40—Johnno Warramarra was sentenced to 28 days in detention. His first offence had been the theft of a pen and felt-tip pens worth Aus\$50. His parents were dead and his Aunt had died shortly before of kidney failure, an endemic problem in the Aboriginal community. The magistrate was unable to exercise discretion. Johnno Warramarra committed suicide in the detention centre. An Aboriginal woman, Margaret Nalyirri Wynbyne was convicted of stealing a can of beer. She was sentenced to 14 days in prison, which meant that she was separated from her breastfeeding child.

Australian diplomats were instructed to negotiate a watering down of impending UN condemnation on this issue. A critical report was

to have been issued finding that Australian law breached a number of conventions. After meetings with UN agencies, a document was released without the concluding findings.

The Committee on the Elimination of Racial Discrimination subsequently issued a damning report, commenting both on sentencing laws and the government's watering down of native title laws. This caused the government to institute a review of its participation in the UN treaty system.

The Commonwealth government also recently chose to argue at a Senate Committee hearing that there had never been a "stolen generation". This term, long in use in Aboriginal English to refer to past child-removal practices, was adopted by the 1997 National Inquiry into the Separation of Aboriginal and Torres Strait Islander Children from Their Families. As an explanation, Senator John Herron said that according to the best estimates from the Australian Bureau of Statistics only 10% of a generation, not a whole generation of Aboriginal children, had been removed from their parents as part of a government programme of forced assimilation. This argument also reflects a broader position being promoted that these child-removal policies were benign in intent, which has been gaining currency in one of Australia's more influential right-wing journals. Despite this, the anguish of many Aboriginal families who witnessed or suffered the devastating effect of child removal was palpable in the Australian media in the days after the release of the Senate Committee submission. Not even an outpouring of

Aboriginal grief moved the Prime Minister, who eventually apologised for upsetting people through the presentation of the argument (but not for its content). He continues to refuse to apologise on behalf of the Australian government for the removal of Aboriginal children arguing that his government and the Australian people cannot be held accountable for mistakes of previous generations.

The Prime Minister initially refused to intervene in the mandatory sentencing debacle. This reluctance was surprising in light of the recommendations from the 1991 Royal Commission into Aboriginal Deaths in Custody to develop strategies to divert Aboriginal offenders from the prison system. With mounting party pressure from government moderates, and rumoured unfavourable public polling, negotiations eventually took place with the Chief Minister of the Territory. The Federal government finally offered to provide the Territory with funds for a diversionary programme to be implemented by police so juveniles are not sent to court after a first offence.

The Prime Minister's first public act when elected was to launch, alongside his Minister for Aboriginal Affairs, a stinging attack on the "Aboriginal industry". Since that time relationships with indigenous Australians have deteriorated. It is difficult to foresee any reconciliation.

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The sexual abuse of men in detention in Sri Lanka

To estimate the frequency and consequences of the sexual abuse of men in detention in Sri Lanka, we reviewed records of all Sri-Lankan men who had been referred to the Medical Foundation for the Care of Victims of Torture between January, 1997, and December, 1998. Those on whom medicolegal reports had been written were identified and the necessary information extracted. For the purposes of this paper, sexual abuse comprises assaults to the genitals, non-consensual sexual acts, and objects pushed through the anus. Rape was classed as non-consensual anal penetration with a penis.

Medicolegal reports were written by 17 doctors that supported the allegations of torture in Sri Lanka made by 184 Tamil men who had been referred during this period. During the interview and examination, an assessment was made about the demeanour of the patient, and the reliability of his history. 74 (40%) were aged between 25 and 30 at the time of the analysis, so they would have been several years younger when they were detained and tortured by the Sri-Lankan authorities, principally the army. 25 (13%) were younger than 25 when they were first seen at the Medical Foundation, 71 (38%) were aged 30–40 years, and 14 (6%) were older than 40. There was no significant difference in the proportion of each age-group who said they had been sexually abused.

Of the 184 men, 38 (21%) said they had been sexually abused during their

detention. Three (7%) of the 38 said they had been given electric shocks to their genitals, 26 (68%) had been assaulted on their genitals, and four (9%) had sticks pushed through the anus, usually with chillies rubbed on the stick first. One said he had been forced to masturbate a soldier manually, three had been made to masturbate soldiers orally, and one had been forced with his friends to rape each other in front of soldiers for their "entertainment".

Of the men who said they had been sexually abused, 11 reported being raped as part of that sexual abuse; this represents 5% of the total number of men on whom reports were written. The men who had been raped were much younger, on average, than the men who said they had not been raped. This suggests that the soldiers choose the younger and more vulnerable men to rape.

Of the 38 men who had been sexually abused, only four (10%) had scarring of the genitals, and none of them were found to have significant scarring around the anus. Since there are very rarely any physical signs caused by acute sexual assault of men,¹ it is not surprising that there were so few men with physical signs of their sexual abuse. The injuries were: thickening and tenderness of final 1–2 cm on urethra of a man who described a soldier pushing an object inside his penis; a scar on the base of shaft of penis of a man who said that soldiers had repeatedly slapped a heavy desk drawer shut on it; an irregularly

defined defect in the foreskin of a man who said that soldiers had tied some string around his penis and pulled, tearing off a piece of his foreskin; and a cigarette burn on the scrotum of a man who said that soldiers had stubbed cigarettes out on his genitals.

Of the 184 men, 45 (24%) described a range of psychological symptoms that included difficulty getting to sleep, waking with nightmares, jumpiness and irritability, behaviour to avoid being reminded of the detention, and depression. These are all symptoms of post-traumatic stress disorder (PTSD). 29 (15%) men had many of the symptoms of PTSD, but not enough to be consistent with the full diagnosis. Of these, only two (5%) gave a history of sexual abuse. 43 (23%) of the men described disturbance of their sleep as their only psychological symptom. Of these, five (13%) had a history of sexual abuse. Two (1%) men were anxious, but had no other psychological symptoms. 65 (35%) of the men said that they did not have any psychological symptoms. Of these, ten (26%) gave a history of sexual abuse.

Sexual abuse in detention starts with forced nudity, which many of the Sri Lankan detainees described. This is usually associated with verbal sexual threats and mocking, which adds to the humiliation and degradation of being tortured. In 37 (20%) of the men in this study, this psychological sexual abuse was followed by physical abuse, and 5% were raped by or at the instigation of their captors.

There is some awareness of sexual assault in detention in Sri Lanka in the general population, and for those to whom this happened, it was a form of physical assault used in the course of interrogation. Rape of men in detention has never been discussed in the press, so those who had been raped would not have been prepared. Most said they had been taken out individually by the soldiers on guard and raped. Most were not able to describe the detail of the rape, because they did not have the language to explain what happened. They felt that they had been picked because they were young. Most were telling of the experience for the first time in their interview at the Medical Foundation. Most of these men had not told the authorities, particularly because they were too ashamed. Shame is a very real deterrent to seeking all forms of help for both male and female victims of rape.

Other difficulties for male rape victims are caused by common myths about male rape, for example, the belief

Equity, post-conflict, and human rights

A meeting in Ottawa, Canada earlier this year—A symposium on post conflict health and health systems: issues and challenges—brought together researchers, non-governmental organisations, and policy makers concerned with the challenges facing countries emerging from major periods of conflict. Those represented included Rwanda, Bosnia, Kosovo, East Timor, Mozambique, Angola, and Somaliland.

Among the key issues debated was how equity should be addressed in "post-conflict" settings. Inequitable distribution of development resources, services, and economic and political power, are potent contributors to intranational

conflict. Following conflicts, opportunities to rethink and redesign health systems may be present. Reaching agreement about the values underlying the system, including the extent to which equity will be promoted, is crucial.

Failure to recognise the need to incorporate such values may reinforce differences between communities and their access to resources and services, so investment in identifying good practice assessment tools and intervention strategies is required.

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Health and human rights

Health-care ethics in Zimbabwe

The current situation in Zimbabwe is not conducive to ethical conduct within the health sector. In a country on the brink of high profile presidential elections (March 9–10), with a recent history of violent electioneering, Zimbabweans again fear widespread unrest with serious consequences (see *Lancet* 2002; 359: 455).

Health professionals may encounter human rights abuses such as torture and other politically motivated violence.¹ As leaders and easily identifiable representatives of the educated middle class, health professionals are in a position to exert a beneficial influence on human rights issues; but they may also again become the focus of repressive policies. During the run-up to parliamentary elections in Zimbabwe in 2000, party political violence spread to small rural district hospitals and health centres. There were instances of nurses being physically assaulted by party political thugs. Rapes were reported.¹ Staff encountered demands to not treat or admit victims of political violence, usually after or around election rallies. Their choice was between complying with the demands, thus acquiescing to discrimination and so not treating often seriously injured members of the local community, or ignoring the personal risks and facing harassment and probably personal injury in order to con-

tinue normal medical duties. Understandably, a number of hospitals closed temporarily when staff did not report for duty. Various hospitals in other areas also closed briefly when staff stayed away for fear of possible political activities. Because of these closures, it is likely that many innocent people did not receive treatment and even died. In light of these events and more recent violence, scarce Zimbabwean and expatriate doctors have fled many district and mission hospitals, in a number of cases leaving the country altogether.

Government authorities and agencies have so far shown little interest in protecting health staff; indeed, the violence was traced to government agents on several occasions. Concerned professional organisations, like the Zimbabwe Medical Association, or the Zimbabwe Nurses Association, felt they had no realistic avenues of appeal in circumstances in which the rule of law was disregarded by the very agencies of enforcement. When a tenuous hold on legitimacy and power motivate a government to sponsor or tolerate human rights abuses, and health professionals suffer intimidation that hinders them from fulfilling their professional obligations, there is a case for intervention from the international community.

There are also reports that a promi-

nent medical practitioner has been engaged in state-sponsored violence (in the form of torture) in his own surgery.¹ The professional body of the medical community (the Zimbabwe Medical Association), however, has been too afraid to investigate, sensing powerful pressure from within its own organisation and the government. Because many members were critical of the decision not to investigate allegations, international support should have been rallied from groups such as the World Medical Association.

Fletcher Dulini was an opposition Member of Parliament who was wrongfully arrested and mistreated by a prison doctor. According to UK press reports:¹ "In a case that could gravely embarrass the regime of President Robert Mugabe, a leading member of the Zimbabwean opposition is suing a prison doctor who, he claims, prescribed medicine that would have blinded him. He also accuses the doctor of falsifying his diabetic record in a way that nearly cost him his life". Once again, it is highly unlikely that the medical association or the Health Professions Council (the professional regulatory body in Zimbabwe) will be willing or able to investigate the physician, for fear of reprisal.

Should the international medical community be concerned with the plight of colleagues in a country such

Torture and organised violence in Zimbabwe

There has been a sharp rise in the number of reported human rights abuses in Zimbabwe in the run up to this month's election, involving both torture and organised violence (figure). Data from a Physicians For Human Rights' delegation to Zimbabwe this year¹ show that between July and November, 2001, the average number of selected politically-motivated human rights violations each month was: five killings; 548 physical assaults; 35 detention/abductions; 805 threats of assault; 73 death threats; 360 property offences; and more than 4000 displacements. 92% of the incidents were reportedly perpetrated by organisations affiliated to the government. According to Hans Draminsky Petersen, who led the investigation, "We are absolutely convinced that severe human rights violations are taking place in Zimbabwe on a large scale at the moment... and we foresee a sharp increase in violence after the election". He expressed concern about the politicisation of health care in Zimbabwe and the harassment of organisations offering treatment to victims of political violence. "The medical profession has a particular responsibility... because doctors should be involved in the documentation of human rights abuses", he added.

1 Physicians for Human Rights. Zimbabwe 2002. The presidential election: 44 days to go. Denmark: PHR, 2002 (www.zimnews.com).



A 28-year-old Movement for Democratic Change supporter who was beaten by members of ZANU-PF with wires and sticks.

as Zimbabwe and be willing to act in the interests of solidarity, human rights, and peace? International professional groups should take up human rights issues at their global meetings, draw up resolutions, and use them to advocate for the rule of law in political arenas. Discussion at a WHO congress will carry more weight than complaints from potentially vulnerable national groups, especially in Zimbabwe, where there is a real risk of retaliation at home.

Academic bodies in developed countries with bioethics expertise should use their knowledge and skills to collaborate with centres or individuals in developing countries. In this way, capacity to educate health professionals within Zimbabwe in ethical and legal issues will be enhanced. Non-governmental organisations and other philanthropic groups should support national groups seeking outside support. Without this help, the Zimbabwean medical community

remain powerless in the face of ongoing human rights abuses.

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The author is a practising physician in Zimbabwe; however, as a result of the Zimbabwean Public Order and Security Bill, which became law on Jan 23, 2002, the author's name cannot be disclosed.

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Detention of asylum seekers in Australia

Detention is the most draconian punishment known to most liberal democratic societies. To incarcerate a person for an indefinite period when they have committed no crime is difficult to justify under any circumstances. Australia places many asylum seekers, most of whom have suffered past trauma, including torture, in open-ended terms of detention. Terms of 4 years or more are not uncommon. Children are not exempt from such treatment, whether or not accompanied by a family member. The health effects of detention have been previously documented (see *Lancet* 2001; 357: 1436-37). In addition, recent reports¹ indicate that compromises are being made in the provision of ethical health care offered by the private company Australasian Correctional Management (ACM), which is responsible for the running of the detention centres in Australia on behalf of the federal government.

There have been continuing acts of self-injury, hunger strikes, and attempted suicide in Australia's six detention centres and similar tales in the newly established Australian-funded centres in Pacific countries of Papua New Guinea and Nauru. On more than one occasion in recent years, asylum seekers have sewn their lips together to draw attention to the hopelessness of their situation. In August, 2000, ACM used tear gas, and for the first time in Australian history, water cannons to quell a riot in one of the centres.¹

A recent edition of the *Medical Journal of Australia* featured discussion on the health of asylum seekers. Of note was the impact of detention itself, compounding the psychological effects of earlier experience under inhumane regimes.² Detainees may be called by number not name, and are subject to line-ups, head counts, and room searches, often at night. Asylum seekers may be placed in solitary con-

finement. Detainees commonly lack meaningful activities. These conditions, characteristic of imprisonment, are hard to justify. Of particular concern are the effects on children. As A Sultan and K O'Sullivan note³ "A wide range of psychological disturbances are commonly observed among children... At the most severe end of the spectrum, a number of children have displayed profound symptoms of psychological distress, including mutism, stereotypic behaviours, and refusal to eat or drink."

ACM is responsible for the provision of health care to detainees. Nurses work in the centres and general practitioners, who do not necessarily have relevant experience (see *Lancet* 2001; 359: 683) are commonly contracted and seen by appointment. Consultations sometimes occur in the presence of guards. Access to medical care at times other than the contracted periods must be negotiated through staff. If official escorts are unavailable, appointments may be cancelled. Should a detainee require treatment outside a centre or admission to hospital, they may be handcuffed or otherwise restrained and accompanied by one or more guards. The Australian Medical Association has asserted that detainees are often deprived of basic medical care, particularly emergency care. It has argued that the government should provide temporary access to Australia's universal subsidised system of health care.

The Royal Australian and New Zealand College of Psychiatrists has been outspoken in raising the ethical concerns for medical practitioners working in the centres. Without calling for a ban on medical practitioners working for ACM, the college has stated that medical professionals need to seriously consider the ethical implications of accepting such positions given the inadequacy of health serv-

ices available in the centres. Louise Newman, the Chair of the Faculty of Child and Adolescent Psychiatry told *The Lancet* "Medical practitioners face the dilemma of an intrinsic conflict between the desire to provide appropriate care, and the compromising of this by supporting a pathological system. This is similar to the issues that confronted doctors in Soviet Russia or Nazi Germany."

An incomplete version of the contract between ACM and the federal government for the running of immigration detention centres is publicly available (www.immi.gov.au/illegals/acs.htm). Medical officers are to monitor solitary confinement, and chemical restraints may be used only under medical or nursing supervision. In at least one instance, however, a general practitioner gave authority to an accompanying nurse to apply chemical restraint with haloperidol to avoid difficult behaviour by a family being forcibly deported.

The ACM contract for health-care professionals working at the centres states that the care needs of detainees are to be regularly monitored and they are to be provided with necessary care and reasonable dental treatment. Expectant mothers are to have access to antenatal and postnatal services. There is now substantial evidence to suggest that these contractual obligations have not been met. Yet it is difficult to ascertain what action is being taken by the government on these issues.

Australia must remain true to its traditions of welcoming people who have fled there fearing persecution in their original homeland. Despite mounting criticism, the Australian government continues to assert that it is not in breach of its international obligations to asylum seekers. But what of health-care personnel in their provision of care? In 1982 the UN General Assembly came to the

decision that "Health personnel, particularly physicians, charged with the medical care of prisoners and detainees have a duty to provide them with protection of their physical and mental health and treatment of disease of the same quality and standard as is afforded to those who are not

imprisoned or detained". This standard is not being uniformly upheld.

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A body of evidence: torture among asylum seekers to the West

It is a depressing fact that despite universal condemnation of the use of torture, it is still practised systematically throughout more than half the world. Indeed, the last worldwide torture survey by Amnesty International (www.stoptorture.org) reports that cases have dramatically increased in recent years; most individuals, according to the survey, are women and children.

Victims of torture are often faced with no option but to flee their homes; some individuals will brave long and dangerous journeys in order to reach western shores to claim political asylum. All medical practitioners therefore need to be aware of the consequences of torture when they see an asylum seeker or a refugee for the first time. There may be obvious signs of physical torture, but most will be of mixed physical and psychological origin.¹

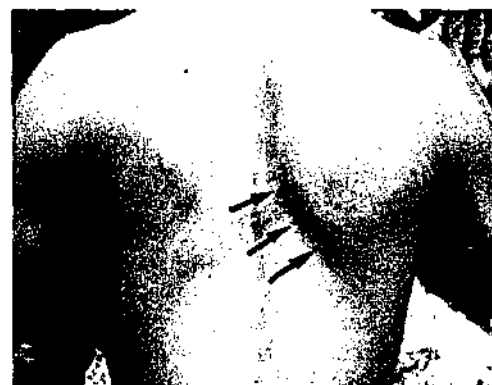
Michael Peel from the Medical Foundation for the Care of Victims of Torture (London, UK), says that in excess of 5000 individuals each year are referred to his centre, the vast majority of whom will have had some degree of torture in their country of origin. "In most of the countries we see people from, the torture is relatively unsophisticated: punching, kicking, beating with batons, and other objects. Cigarette burns are surprisingly common, and electrical devices are used in a number of countries." Although in many African countries, particularly in West Africa, there is torture with impunity, Peel told *The Lancet* "in countries such as Turkey and India the authorities are careful not to leave scars . . . in Sri Lanka, for instance, the army uses a technique in which a plastic bag containing a small amount of petrol is wrapped around the victim's head—the smell of the petrol partially asphyxiating the victim, and making them feel sick and faint. A similar technique is used in

Zimbabwe, but foul water is used in place of petrol".

Peel stresses that most medical concerns of asylum seekers and victims of torture are the same as anyone else's, and that ongoing care and support does not have to be provided by specialists. However, he adds "you can't do a proper assessment without a good quality interpreter. Taking a thorough testimony can be therapeutic, but it needs to be done in an encouraging environment and needs to have time dedicated to it".



Left: Teeth have fallen out following direct trauma and electric-shock torture. **Right:** "Wing" scapula after prolonged suspension—a common form of torture, causing extreme pain but leaving little visible evidence of injury



A recent publication from Physicians for Human Rights² notes that medical practitioners are often reluctant to raise the question of torture among refugees and asylum seekers who present to the surgery, but that documenting this information is often crucial in enabling adjudicators to make accurate decisions on asylum claims. As a practical guide to issues relevant to torture in this group, the book offers advice for practitioners on assessing psychological and physical evidence of torture, and includes an overview of political asylum law and procedure in the USA. It is important to note, say the authors, that the absence of obvious physical evidence should not be construed to suggest that torture did not occur. Although acute lesions may be characteristic of the alleged injuries, most lesions heal within about 6 weeks of torture leaving no scars or

Asylum seekers who have previously been tortured are of increasing concern to many medical professionals in countries like the USA, Australia, and the UK in light of a growing and worrying trend to detain asylum seekers in prison-like conditions on arrival, often for uncertain time-periods. A recent study of Tamil refugees³ found that among those who had been tortured there were statistically significant higher scores for diagnosis of post-traumatic stress disorder than other war trauma survivors; mental health concerns that are certainly exacerbated by prolonged periods of detention. According to lead investigator, Derrick Silove, "detention poses a profound crisis not only for the mental health of those detained, but for any claims that the world's developed nations may have to providing leadership in the human rights field.

Long-term detention under harsh, prison-like conditions is the antithesis of the conditions of support and stability that trauma survivors need in order to achieve psychosocial stability."

Sally Hargreaves
C/o The Lancet

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DNA and immigration: the ethical ramifications

Although family reunification accounts for the bulk of legal immigration, global economic slow-downs have caused governments to narrow the range of people that qualify for family reunification. At the same time, governments are requiring more extensive documentation to prove applicants' biological relationships to their sponsors. Since western style identity documentation is uncommon in numerous developing countries, many immigrant-receiving nations, including Canada, Australia, the USA, Finland, Denmark, Sweden, Italy, the UK, and New Zealand, have turned to DNA technology to provide proof of family relationships. The number of individuals who undergo DNA testing fluctuates from a small number of cases each year in some countries, to more than a thousand in one major immigrant receiving country.

Family reunification is vital to the welfare of immigrants. Experience has shown that family units have a better chance of successfully integrating into a new country. Unwanted separation from close family members creates an emotional burden for everyone involved, and children separated from their parents or customary caregivers are particularly vulnerable to long-term physical, intellectual, and psychological problems.¹ Separated refugee or displaced children are at an especially high risk for abusive situations such as sexual violence and exploitation. Although DNA testing can assist immigrants and refugees by facilitating family reunification in the absence of required documentation, there exist a myriad of ethical concerns that require due consideration.

First, families are not always biologically related. In western societies, babies born within the context of a relationship are automatically accepted as the children of that relationship. However these same countries require a positive DNA result in order to make determinations with respect to family reunification. Not surprisingly, DNA test results can be a

shock to some families that receive them. In one case, for example, a child from Kenya was proven not to be the biological offspring of either his father or his mother after DNA testing. Apparently he was reclaimed mistakenly by his mother after several years' separation as a result of civil war.

Further, there is no universally recognised definition of family. In many cultures "family" incorporates both a wider range of biological relatives and members that are related socially rather than biologically. Indeed, 58% of Somalis given DNA testing by Danish authorities between January, 1997, and September, 1998, received a negative result. In response to these findings, Somali community leaders argued that "the concept of family is very different in [Somali] culture, and many Somalis are not aware of the Danish concept of who is a family member and thereby entitled to family reunification".²

DNA testing can disrupt the family unit, particularly affecting the welfare of the children involved (panel). Requests for DNA testing can also be discriminatory as certain ethnic groups are asked to submit to DNA testing more often than are others. Concerns have been raised that officials appear to more readily reject documents provided by people from poorer countries. In fact, the Canadian Council for Refugees claims that applicants at some Canadian visa posts (particularly those in Bangladesh and Africa) are often asked to undergo DNA testing.

Not everyone is able to provide DNA test results on demand. For one, the tests are extremely expensive and many applicants cannot afford to pay. Moreover, there may be religious constraints preventing applicants from agreeing to submit to DNA testing. In one Canadian case, the defendant, a refugee from the Democratic Republic of Congo, refused a request for DNA testing because it contravened his religious beliefs as a Jehovah's Witness.

DNA technology has the potential to be a useful tool in making decisions

Case study

In January 2002, the appeal division of the Canadian Immigration and Refugee Board rejected a Somali father's petition to be reunited with his 14-year-old son. After having immigrated to Canada, the man applied 3 years previously to be reunified with his three children, born during his marriage to his now deceased first wife. He was told that there was insufficient evidence to establish his parentage and he was invited to submit DNA samples. The tests indicated that the youngest child was not the man's biological son. As a result, the two older children are now living in Canada with their father whereas the youngest remains in Nairobi, Kenya. The father's representative is currently applying for judicial review of the Board's decision.

about family reunification in cases that lack documentary evidence to establish a relationship. However, for DNA testing to help rather than hinder the family reunification process, it is essential that the proper safeguards be in place. Because countries make their own determinations regarding family reunification, strict national guidelines are essential to ensure that it is used in an even-handed and non-discriminatory manner. Above all, DNA testing should be reserved as an absolute last resort when no other evidence is available and the applicant would otherwise have to be rejected. Immigration authorities need to be aware of the intrusiveness of the test and its potential to disrupt a family unit when deciding whether to recommend biological testing. If testing is required, it is imperative that adequate counselling be provided to deal with the repercussions of the results. Due consideration should also be given to the high cost of DNA tests and the fact that they delay the reunification process.

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MELBOURNE

"Inside" Australia's Woomera detention centre

On Feb 6, the Australian Human Rights and Equal Opportunity Commission announced that the Woomera Immigration Reception and Processing Centre is in breach of several articles of the Convention on the Rights of the Child, to which Australia is a signatory. Woomera, in South Australia, is the newest of three national processing centres, which are mainly used to hold unauthorised asylum seekers who arrive by boat. Another three detention centres house people in breach of visa conditions, and a further four centres are planned.

In January this year, the number of people incarcerated at the Woomera centre fell to around 650 asylum seekers from a peak of around 1400 late last year. Conditions are now less crowded, but detainees still face harsh conditions. Woomera is located in Australia's isolated desert heart, where temperatures reach up to 50°C. Independent observers have great difficulty getting inside Woomera. However, information we have gathered during interviews with ex-detainees and centre staff paints a picture of a grim and punitive environment.

Staff and ex-detainees we have interviewed describe the compound as U-shaped. Detainees are assigned to sections according to the stage of processing of their immigration application. People from different sections cannot easily communicate with each other except by shouting. A grassed administration complex sits in the centre of the compound, separated from the asylum seekers' quarters by a double razor-wire fence and outside the perimeter fence, two water cannons are ready for use.

Many families live in portable units. Air conditioning is often broken and sometimes these units house two families separated by only a curtain. Others live in very small rooms or dormitories. Personal belongings, including photographs, are taken from detainees when they arrive. Children don't have enough room to crawl or play inside, and the climate is too extreme for outside play.

According to the staff and ex-detainees we have spoken to, four musters are held every 24 h, sometimes at night—staff shine torches into peoples' faces to identify them. Detainees are identified by number and have reported feeling dehumanised by this process.

Housing units have no running water, and the toilet block can be up to 500 m away. Because of the distance, children have been known to wait until they are incontinent. Visiting specialist professionals with limited access have noticed mattresses left drying in the sun. When the camp was set up in November, 1999, water for washing and drinking

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Welcome to Woomera

was available only in the toilet blocks. Water ran hot because the pipes were exposed to the sun. People tried to run the water long enough for it to become cool, but were reprimanded for being wasteful. Eventually, detainees were given small tanks for storing drinking water.

Meals in the centre are provided in an area some distance from the accommodation. Food consists largely of rice, vegetables, and meat thought unpalatable by detainees because it is badly cooked. Furthermore, despite official assurances, the Muslim asylum seekers are not convinced that the meat is halal. Some of the women help with cleaning the kitchen and chopping food. Detainees volunteer but are not allowed to help with the cooking. Because many children do not like the food, parents supplement their diets with crisps and sweets if they can afford them, and some children are reported to have lost weight.

Education is available only for children aged 12 years and younger, several older children receive almost no schooling. Teaching was provided in one portable unit, 4 days per week for 2 h, by detainees with teaching experience or some English language. In the past week, there has been some improvement, with some children being bussed to local church buildings for 3 h schooling per day.

There are few recreational facilities for children. Only one swing was

observed for about 50 children, and fights erupt. Families face difficulties getting their children appropriate clothes that fit—they are given what is available or can place orders that can take from 6 to 9 months to be delivered.

Mothers do not get routine maternal and child health support for breastfeeding or weaning. Nor are weaning foods provided that are appropriate for the age of the children. Each week, families are given 2 L of cow's milk, which some mothers feed to infants younger than 12 months.

To obtain disposable nappies, detainees have to submit a form to designated staff at certain, set times. Because of this difficulty, many mothers make nappies from old sheets or other material. Changing nappies is hindered by the lack of running water.

Women also have to complete a form including the date and personal details when they need sanitary towels. They are supplied with ten pads and face possible questioning by a staff member, who is not always a woman, if more are needed.

Health care is provided in an area separated from accommodation by a wire fence. Detainees are discouraged from seeking health care outside working hours, often have to wait in strong sun, and are introduced by number. Medical staff at the centre are not trained in the treatment of disorders that are common in the home countries of detainees, and have no cross-cultural training. Dental care is not provided routinely to the asylum seekers and consists mainly of extractions—restorative care is almost non-existent.

These conditions have had an enormous effect on the emotional and physical wellbeing of detained families. Parents, frustrated and fed up with trying to care for their families in cramped, oppressive conditions, as well as bearing the uncertainty of their immigration status, find it very difficult to remain positive. Many children are unhappy, some cry a lot, and others, craving attention, are aggressive, irrational, and disobedient.

One asylum seeker who had experienced both detention and imprisonment in Australia was quite clear—he preferred prison.

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HANDS-ON HEALTH PROMOTION

Edited by
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Chapter 4

Public health, health promotion, and the law

Bebe Loff

Why health promotion practitioners should know about the law

Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they can exercise their authority. The law is a tool in public health work, which is used to influence norms for healthy behaviour, identify and respond to threats, and set and enforce health and safety standards. The most important social debates about health take place in legal fora—legislatures, courts and administrative agencies—and the law's language of rights, duties, and justice. It is no exaggeration to say that 'the field of public health ... could not long exist in the manner in which we know it today except for its sound legal basis' (Gostin 2000, p. 309).

Public health in many countries is highly regulated and the breadth of subject matter dealt with is enormous, indeed far too large to be dealt with comprehensively in a short chapter. Laws governing public health and health promotion may be draconian, enabling the detention of individuals suspected of harbouring an infectious diseases, just as they may be an ordinary and unremarkable aspect of life governing matters such as the orderly disposal of garbage. Public health law is primarily law made by parliaments, not courts. These laws may regulate matters such as: quarantine; acquisition of property; compulsory bodily examinations, illicit drugs, alcohol and tobacco; privacy; food standards, nuisance; the environment; injury prevention; occupational health and safety; radiation exposure; sewerage; and vermin control.

Understanding the context from which contemporary public health laws emerge may enable the status quo to be articulately challenged if necessary. To operate successfully as a practitioner and/or as an advocate for change in public health is difficult without having at least some sense of the background, content, and the administration of laws affecting public health. Historically,

public health law has been distinguishable from other areas of law in that the interests of society (as understood by the law-maker) have prevailed unquestionably over the interests of the individual.

Many bodies are involved in enforcing these laws. They include national, provincial, and local governments and agencies of government, such as the police, the courts, schools, and health care organisations. The prescription of certain responsibilities to one group, such as the police, as opposed to another, say government health officers, says something about how a society regards a task or behaviour.

This chapter will briefly discuss the process of law making, different ways of conceptualising public health law, infectious diseases law as a specific example, the law in general as it impacts upon public health, the law in the design and implementation of public health programs, and health and human rights. The aim is to provide you with a greater understanding of how public health law may relate to your work, and assist you in accessing people who can provide further advice in different areas of these laws.

The process of law making

First a few short words on the making of law. In the domestic (individual country) context, parliaments, courts, and the executive arms of government may make laws. In a well functioning democracy, civil society will be enabled to make a contribution to the direction and content of the law. Thus a law reform process carried out by government ought to be a reasonably lengthy process in which individuals and communities are provided with comprehensible information, consulted, and responses included in government decision making. Consultation processes about law may be one mechanism by which to educate the community, not only about the content of the law and options for change, but also about the area of public health in question.

The reality is usually otherwise. The political process often demands a timetable that serves the priorities of the day as opposed to a proper examination of the adequacy of law. The time and resources required to undertake a true consultation are often not present. In many countries officers working in the executive arm of government, who may be responsible for carrying out a law reform project, may be insufficiently resourced, themselves lacking basic materials and equipment. In all jurisdictions when a new law is passed by parliament it will often have gaps or errors and need to be returned to parliament for amendment.

Jurisdictions may be civil (for example France, the Netherlands, and Louisiana alone within the United States) or common law (for example Australia and Great Britain) in character. Essentially, in civil law jurisdictions the law is codified, that is, the laws are compiled into a collection intended to be easily accessible to the public, not determined, as in common law jurisdictions, by judges. However, although the judiciary are bound to enforce codes as developed by parliament, considerable room nonetheless exists for the exercise of discretion and

creativity. In common law countries, in addition to the enforcement of statutes, the courts follow precedents established by earlier decisions of superior courts. Of course this is an oversimplified account; however any further discussion is beyond the scope of this chapter.

Courts make an impact on the law when deciding the cases that come before them. Their impact is limited by the facts of the individual cases and the lack of ability to deal with any issue comprehensively. Nevertheless, decisions of the courts may determine crucial issues, such as whether and how a service like abortion is to be available, or how information is to be made accessible, or the proper role of government according to law. The capacity of courts to impose penalties or award damages may be exercised in the furtherance of public health objectives.

As some countries are arguably becoming more litigious, the scope for court involvement in public health will grow. This may or may not be a good thing. Public policy is not always best made in courts that are bound to deal with the facts arising out of cases that will come before them in an arbitrary fashion. Nevertheless, courts have a significant and crucial contribution to make, particularly when redressing wrongs committed against individuals or balancing the powers exercised by government.

Different ways of conceptualising public health law

Laws exemplify contemporary social, cultural and political trends in both their style and content. The citizen as consumer or customer has been a dominant theme of the latter part of the twentieth century and this has been reflected in law. Governments have tended to take a deregulatory approach, seeking stronger justification for intervention in the marketplace. This has meant that much of what was previously thought to be a responsibility of government has been privatised and been made subject to contract.

Traditionally public health law has been thought of simplistically as being a subset of the body of law administered by ministries of health. The law is developed according to what the government agrees are key health issues to be addressed; and legislation may appear as a mixed bag of responses to particular diseases, such as typhoid or syphilis, or issues relevant to health, such as waste disposal or tobacco, without clear objectives or a sense of structure.

In trying to create a unified conceptual approach, some have suggested that public health might be seen as a matter of risk management. The law may be drafted in general terms rather than addressing specific health topics. It might include, for example, the functions of a health ministry and the framework of the responses to be taken to address a public health risk of any sort. The law may require that a public health risk be identified and assessed, that the risk be evaluated according to its social and economic costs, including personal costs to

individuals, and the range of responses that might be adopted. Some additional detailed attention may be given to issues such as privacy and access to information. Specific details to give such framework legislation structure will often be left to subordinate legislation developed by the executive arm of government. It is clear that assessments of risk and of the balance to be struck between the individual and the community will be value laden.

Gostin (2000, pp. 86–7) provides a table in which he systematically evaluates public health activities according to the public benefits they produce and the private interests and rights that may be affected. This type of exercise is most useful when attempting to identify what the law ought to address in order to strike the right balance between community and individual interests.

Gostin, Burris and Lazzarini (1999, pp. 59–128) have devised a useful three-part framework describing public health and the legal responses to it, none being exclusive.

- First they describe the *microbial* model of public health. Disease here is a result of a microbial infection or exposure to toxic substances. The legal response to this classification may be the identification of infected people by testing or screening and reporting to a central authority, ensuring they are treated or are unable to infect others, and conducting epidemiological surveillance. The enforcement of these measures may be controversial.
- Their second model is a *behavioural* model. This assumes that human behaviour can contribute to disease. Here lifestyle may be the issue, or behaviours that may lead to disease or injury. The state may intervene to ensure that seatbelts are worn, or provide needle exchange services. Dependent upon the action taken, the state may be seen to be too interventionist or not sufficiently so. The same legislative response might be seen to be approving of illicit behaviour on the one hand or causing increased stigmatisation on the other. An example of this might be the provision of a methadone program in a coercive environment.
- The third model is an *ecological* model, examining social institutions and conditions. This may include how society produces and distributes wealth, provides access to education, or subsidises industry creating environmental damage. Many legal avenues may be used to underpin social institutions such as taxation law, laws creating industry subsidies, environment protection laws, laws forming the structure of our educational bodies, and anti discrimination laws, to name but a few. These laws are not considered to be health law, though there is little doubt of their impact on health.

Infectious diseases law

It is undoubtedly the area of infectious diseases law that raises some of the more controversial issues. These include immunisation, disease reporting to government, quarantine, legislative authority to breach confidentiality, and powers to restrict or detain individuals. Fear of the theoretical risk posed by a person

infected with an infectious disease has often led to responses that are unjustifiable if evidence of the real risk posed was accurately assessed. In many communities leprosy was the foremost instance in which the perceived interests of the community outweighed those of the individual. The infected person was deprived of all ordinary entitlements of citizenship and made to live outside city bounds with other lepers. Today it is the person living with HIV or AIDS who, in some communities, sits in this position.

Immunisation, when imposed by government as a compulsory measure, is often cited as an example of the tension between those wishing to protect the public health and those who believe that society is not justified in imposing such measures upon its members without their voluntary participation. This has been true since the earliest legislation was introduced to support the work of public vaccinators. It should however be noted that, during the nineteenth century, disease was undoubtedly spread through the process of immunisation. For example William Tebb argued in 1884:

It is well-known that Vaccination was made compulsory by Parliament in England, at the instance of Lord Lyttelton, through the activity and persistency of Dr. Seaton, Secretary to an obscure association of a very few medical men, calling themselves the Epidemiological Society, who issued a report on the state of small-pox and Vaccination in England and Wales, and other countries, dated 26th March, 1853, in which no mention whatever is made of the failures and mischiefs arising from the practice recorded by any of these early writers ...

And this is the 'perfectly efficient prophylactic' which Parliament, relying upon the anonymous authors of this report, forces upon the people of the United Kingdom, under pains and penalties!

Between 1901 and 1930 New York City officials routinely deployed police officers and nurses or physicians to the homes of those suspected of carrying disease, and force, or the threat of force, was commonly used to overcome vaccine refusers. In some cases, police officers pinned the arm of those who refused while a city nurse jabbed it with a vaccination needle (Garrett 2000, p. 299).

Much of the law was about confining individual rights in the interest of the greater good. Because, during the early part of the twentieth century, bacteriology-based public health was perceived as extraordinarily powerful and the background of disease was obviously grim and urgent, both public health leaders and the courts tended to tip the balance in public health far in the direction of community needs (Garrett 2000, p. 299). Historically, though, repressive action to limit the spread of disease often did not achieve its purpose. However, governments felt compelled to take action in response to apprehended threats to health and social stability.

In our own time, China threatened to execute or jail for life anyone who disobeyed SARS quarantine orders or intentionally spread the virus. The penalty for officials found guilty of negligently allowing the disease to spread is imprisonment for three years, and those using violence to hinder aid workers face similar consequences (BBC World News, 2004). Indeed a man in northern China was sentenced to death for killing the head of the local SARS prevention team following a prohibition on people entering SARS affected regions. Police staffed checkpoints in China and arrested patients suspected of having SARS who had not stayed in quarantine (News 24, Com, cited in Loff & Black 2003). Extreme reactions were not confined to China.

In Canada, members of the Immigration and Refugee Board wore masks to hearings of cases brought by Chinese claimants ... In Hong Kong, authorities used a police electronic tracking system used in criminal investigations for tracing contacts and monitoring compliance with quarantine. (Loff & Black 2003)

For those who might have instigated policing for public health purposes there were often unanticipated outcomes. For example, analysis of past incidences of epidemics has demonstrated that, although social and political upheavals did take place during epidemics, they were not always caused by the epidemics. They were rather responses to the imposition of severe controls upon human conduct and repressive policing, as well as the failure of governments to effectively communicate their purpose (Ranger & Slack 1992).

Ultimately it is the individual identified as the source of risk who is constrained, behaviourally and physically, in the interests of the community. Rights might not merely be attenuated, as might be the outcome of a conviction for a criminal offence, but may be totally denied. Rarely, even now in progressive jurisdictions, will individuals who are perceived to be the source of risk be accorded even procedural justice (in brief, the right to be heard before an impartial tribunal, with sufficient notice of the accusations made), fundamental in other areas of law, let alone substantive rights (such as the right to privacy). And it is primarily the marginalised, impoverished, and possibly intellectually disabled or mentally ill person that is the focus of society's attention.

The law in general as it impacts upon public health

As should now be clear, many areas of law may make a contribution to public health. Clearly the contribution of the criminal law should not be overlooked. Laws concerning abortion, drunk and culpable driving, assault, and murder pertain to public health. The criminal law has been used (often inappropriately) to respond to HIV/AIDS. It is the criminal law that makes drug use illicit. Coroners' courts, whose role is to inquire into the cause of death from criminal or

other causes, have often made recommendations for system changes. Recommendations might have an impact on, for example, the distribution of a faulty product, road traffic safety, or hospital procedures.

Other areas of law, such as laws governing access to information, anti discrimination law, intellectual property law, or laws dealing with the infrastructure of institutions, can all impact upon public health because they can directly or indirectly affect how people are treated and perceived, how services are rendered, and the availability of goods.

As noted earlier, the courts can have an impact in defining standards. Individual or class actions may have major ramifications for a great number of people. In some countries, litigation surrounding tobacco-related diseases is an example of this. There are many other examples. The failure to diagnose positive screens for cervical cancer has been brought before the courts and has resulted in further formal government inquiry. Actions might be brought with respect to defective products causing harm to health. Public health administrators may be brought before the courts under administrative or constitutional law.

International law and the work of international agencies such as the World Trade Organization and the World Bank can have significant local impact. Multilateral and bilateral agreements, to which a country is a party, relating ostensibly to matters unconnected with health, may ultimately impact upon health. National laws of powerful countries such as the United States can impact upon decision making in other countries. For example, the powers of the United States Trade Representative to blacklist a country, and exert pressure upon it, may determine what drugs that country will be able to access or whether its goods will be allowed into the profitable US market (Consumer Project on Technology website below).

Each of these matters could be (and is) the subject of texts. The purpose here is simply to alert the reader to some of the many areas of law that might impact upon a particular concern.

The law in the design and implementation of public health programs

Given the extent of what might properly be included within the realm of public health, it is impossible to give a general picture of which law might apply to what project. Suffice to say that it is likely that law will often be a consideration, and any public health practitioner should seek advice about the nature of any relevant law and its application. Negotiation between many areas of government administration may be required to properly address a public health concern. Only one example will be provided here, that of infectious disease.

Laws that might be relevant to a public health practitioner working in the area of infectious disease might include:

- domestic anti discrimination law, including laws prohibiting discrimination on the grounds of sex, impairment, occupation, religious or cultural belief, or sexuality;
- international human rights law;
- criminal law, such as laws dealing with assault, manslaughter, murder, drug use, prostitution, and homosexuality;
- employment law;
- immigration law;
- intellectual property law;
- world trade law;
- laws governing the conduct of research;
- censorship laws; and
- laws governing the distribution of pharmaceuticals.

There are other areas of law that could be added to this list. However, this should demonstrate the centrality of law and the need for awareness of its breadth and content in both a clinical setting and in political advocacy.

As is the case in any professional discipline, lawyers have different areas of expertise. For example, it is unlikely that a lawyer specialising in criminal law will have much to say about intellectual property. It might require some searching before a legal practitioner with the relevant skills is found to assist in a specific case or to provide general information. Generally speaking, it is likely that, once approached, a lawyer without the appropriate expertise will refer to a lawyer practising in the required area.

Health and human rights

Impartiality, non-discrimination, a fair hearing—principles well understood in the law generally—are often not present in public health law and practice. Do these and other human rights standards and norms have something positive to contribute to public health policies and programs or are they simply a hindrance? It is sometimes assumed that a human rights approach demands that the interests of the individual always take precedence over those of the community or that these interests are fundamentally in opposition. This is not correct.

Lately it has been asserted that these two approaches are complementary and in synchrony. Although the advocacy around women's health and indigenous health clearly produced rights-based debate, it was the advent of HIV/AIDS that generated a movement for 'health and human rights'. In the context of HIV/AIDS it was asserted that, when human rights are respected, vulnerability to infection is reduced. In tracing the development of this thought, it has been noted that the response to HIV/AIDS developed in four phases (Mann & Tarantola 1997, pp. 6–8):

- 1 a danger to be alerted about;

- 2 a problem of individual behaviour;
- 3 a societally contextualised behavioural issue; and finally
- 4 a human rights-linked challenge.

The fulfilment of rights may have much to contribute to improving health. Rights to, for example, education, information, and accommodation, and to the benefits derived from scientific progress may appear obvious in their contribution to public health. However, as should now be apparent, a transparent and accountable government and functioning judicial system are also essential to the promotion of public health. This has been recognised in a 'General Comment' (an authoritative interpretation) on the right to the highest attainable standard of health produced by a treaty body of the United Nations—the Committee on Economic Social and Cultural Rights (CESCR 2000).

The General Comment further highlights principles of 'availability, acceptability, accessibility, and quality':

These terms have concrete implications: availability—health care must be offered to the extent possible within available resources, and benchmarks need to be set to guarantee that this goal is reached progressively; accessibility—health facilities, goods, and services must be attainable for everyone without discrimination on the basis of such factors as socioeconomic status, community, or disability; and finally, health care must be the highest possible quality and acceptable, culturally and otherwise, to all groups (Gruskin & Loff 2002, p. 1880, reprinted with permission from Elsevier.)

It is only in exceptional circumstances that one should seek to limit rights. Should a question arise about the restriction of a human right, such as the right to freedom of movement, governments are required to consider the 'Siracusa principles' adopted by the UN Economic and Social Council (ECOSOC) in 1985. The principles require that the proposed restriction be provided for and implemented in accordance with the law. The restriction must be directed towards a legitimate objective of general interest, such as preventing transmission of tuberculosis, and must be strictly necessary to achieve the objective in question. It must be the least intrusive and restrictive means available to reach this objective. Finally, the restriction cannot be unreasonable or discriminatory in its application. Clearly, responding to these criteria requires sound evidence. When this process is followed, limitations to human rights will be justifiable.

Human rights standards and norms may also be used to evaluate public health policies and programs. For example, sensitivity to underlying discrimination in a community against a certain ethnic group might suggest that, when a program is assessed, particular attention is paid to the impact of the program on this group.

Debates grounded in health may also have an impact on the interpretation of rights. In the 1992 case of *Toonen v Australia* before the Human Rights

Committee of the United Nations, Nicholas Toonen, a Tasmanian gay rights activist, sought to challenge Tasmanian laws making it an offence to have 'unnatural sexual intercourse', or 'intercourse against nature', or 'indecent practice between male persons'. The laws had not been enforced for a decade. Toonen asserted that those laws constituted an arbitrary interference with privacy, contrary to article 17 of the International Covenant on Civil and Political Rights. The Tasmanian government claimed that the laws were not arbitrary but were motivated by a concern to protect public health. In response, the Committee noted that:

... the criminalization of homosexual practices cannot be considered a reasonable means or a proportionate measure to achieve the aim of preventing the spread of HIV ... Secondly the Committee notes that no link has been shown between the continued criminalization of homosexual activity and the effective control of the spread of the HIV/AIDS virus.

These laws could not be justified by appealing to a public health risk exception. The Committee required there to be a degree of reasonableness and proportionality, but offered no further insight into what might satisfy these requirements.

Consideration of the implications of health policies and programs for human rights has enabled those working in public health to bring a new focus to their activities, placing health in a rights framework and examining *how both rights and health outcomes may be maximised instead of how health might be bettered at the expense of rights.*

For simplicity the Universal Declaration of Human Rights has been utilised as the fundamental tool, creating a framework within which to consider public health policies and programs, but obviously there is a wealth of international and domestic law that might be relied upon. In a similar manner, legal systems may benefit from a critique from the perspective of public health.

Conclusion

For a health promotion practitioner to operate with a full armoury, he or she must develop a sense of when law is an issue, why it is an issue, and what to do about it. An understanding of human rights will bring further richness to debates in public health and health promotion. To truly derive the most benefit from law for the purposes of public health or to challenge its drawbacks, an interdisciplinary approach involving lawyers with knowledge in the area is essential. The complexity, breadth, and range of issues that might arise in public health and health promotion make it imperative that assistance be sought to maximise the positive impact of law on public health.

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Useful websites

- Consumer Project on Technology, Country disputes involving intellectual property and health care: <<http://www.cptech.org/ip/health/country/>>.
- Francois Xavier Bagnoud Center for Health and Human Rights: <<http://www.hsph.harvard.edu/fxbcenter/>>.
- UNAIDS: <http://www.unaids.org/en/in+focus/hiv_aids_human_rights.asp>.
- United Nations Office of the High Commissioner for Human Rights: <<http://www.unhcr.ch>>.
- World Health Organization: <<http://www.who.int/hht/en/>>.

HUMAN RIGHTS IN AUSTRALIAN LAW

Principles, Practice and Potential

Editor

David Kinley

Foreword

The Hon Justice Michael Kirby AC CMG

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HEALTH LAW AND HUMAN RIGHTS

Ian Freckelton and Bebe Loff

INTRODUCTION

Health rights postulate values that mediate the boundaries between patients and health care practitioners. The assertion of such rights necessarily embraces the contention that fundamental principles of human rights – entitlement to dignity, non-discrimination, confidentiality and equitable distribution of resources – are relevant to the provision of health care and to the allocation of priority in the distribution of limited health resources.¹ It can legitimately be said that a collection of human rights, such as respect for autonomy, consent, truth-telling, confidentiality, personhood and persons, human dignity and justice permeates almost all scenarios that involve the intervention of health laws into the relationship between health professionals and their patients.² However, it has been pointed out by a number of commentators, including Kennedy and Grubb, that legal obligations in relation to provision of health care services for a long time have not been sufficiently emphasised and recognised.³ The only partial exception to this proposition lies in the series of cases, in especially England and New Zealand, which have dealt with the circumstances in which life support for those in a permanent vegetative state or suffering from Guillain-Barré Syndrome should be able to be terminated. These decisions have tended to articulate relevant principles in a more organised and human rights-oriented manner than has occurred elsewhere in the course of medico-legal judgments. They have stressed matters such as the dignity of the patient and

1 Leary, V. "The Right to Health in International Human Rights Law" (1995) 1 *Health and Human Rights* 25 at 27.

2 Kennedy, I and Grubb, A, *Medical Law. Text and Materials* (Butterworths, London, 2nd ed, 1994), p 4; see also Kennedy, I, "Patients, Doctors and Human Rights" in Blackburn, R and Taylor, J (eds), *Human Rights for the 1990s: Legal, Political and Ethical Issues* (Mansell Publishing, London, 1991), p 84.

3 *Ibid.* p 52.

the inutility of the provision of futile treatment. They have also taken account of the impact of continuing ineffective treatment upon patients' relatives.⁴

Otto has usefully argued that:

Perhaps the most important outcome of conceiving health as a human right is that it makes human rights principles applicable to health standards and practices. A human rights framework provides new tools for challenging and reimagining the utilitarian and technical approaches to health that have been preferred by WHO and the conservative professional medical community.⁵

While there is merit in principle for the analysis of health law in terms of human rights, such a vehicle for analysis historically has been subject to real limitations. In the context of medico-legal litigation initiated in Australia, it has been comparatively rare for principles of international law and even the instruments to which Australia is a signatory to impact upon the rulings of courts and tribunals. Moreover, the complex and competing principles which are relevant to health law decisions in the forensic arena for the most part have been ill-articulated and frequently not the subject of clear delineation in reported decisions. However, a number of charters of health rights and responsibilities on the part especially of government have started to enter Australian law. This has been part of the movement toward involvement of consumers in the formulation of health policy and of the creation of health complaints mechanisms. While the justiciability of such statements of rights remains to be finally determined by the courts, in principle, such charters may enable creative actions to enforce provision not only of services but services of the standard mandated within the charters.

Applying the broad approach of Kennedy and Grubb, whereby the notion of health rights is construed liberally, this chapter examines a range of areas of medical practice in which rights could be thought to arise for patients, and may be susceptible of enforcement via legal means. Given space limitations, it deals with a series of important issues that have come before the courts but does not address controversies relating to euthanasia and abortion in any detail. While these areas were highly controversial in Australia in 1997 and 1998, the law is clear in relation to the illegality of deliberately assisting another person to kill themselves and in

4 See, in particular, the analysis of fundamental principles by the House of Lords in *Airedale NHS Trust v Bland* [1993] 2 WLR 316, in terms of sanctity of life and discussion of art 2 of the *European Convention for the Protection of Human Rights and Fundamental Freedoms* and art 6 of the *International Covenant of Civil and Political Rights* (ICCPR); the principle of self-determination; respect for the dignity of the patient; the operation of the doctrine of necessity; and the notion of the benefit able to be derived from the provision of medical treatment. See further Freckleton, I. "Withdrawal of Life Support: the Persistent Vegetative State Conundrum" (1993) 1 *Journal of Law and Medicine* 35; Kerridge, I. Mitchell, K and McPhee, J. "Defining Medical Futility in Ethics, Law and Clinical Practice: An Exercise in Futility?" (1997) 4 *Journal of Law and Medicine* 235; Gillett, G. Goddard, L and Webb, M. "The Case of Mr L: A Legal and Ethical Response to the Court-Sanctioned Withdrawal of Life-Support" (1995) 3 *Journal of Law and Medicine* 49; Peart, N and Gillett, G. "Re G. A Life Worth Living?" (1998) 5 *Journal of Law and Medicine* 239; McLean, S. "Letting Die or Assisting Death: How Should the Law Respond to the Patient in a Persistent Vegetative State?" in Petersen, K (ed), *Intersections: Women on Law, Medicine and Technology* (Dartmouth, Aldershot, 1997).

5 Otto, D. "Linking Health and Human Rights: A Critical Legal Perspective" (1995) 1(3) *Health and Human Rights* 273 at 276.

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relation to the unlawfulness of committing homicide, even if the victim consents.⁶ In relation to abortion, important debates in Western Australia resulted in the *Acts Amendment (Abortion) Act 1998 (WA)*, which provides that abortion is now available for adult women who consent to the procedure. However, elsewhere in Australia the common law remains as uncertain as it did in the 1960s.⁷

The chapter examines the role of public law in the context of the regulation and protection of people's rights, and the contribution made by international human rights instruments and local guidelines implementing obligations created by Australia's becoming signatory to such instruments to Australian citizens' rights to the provision of health care. It analyses an aspect of the *Toonen* decision⁸ in which the Human Rights Committee accepted and applied arguments relating to Australian domestic law, including health law, framed in terms of international human rights law. Then it examines a range of important areas of Australian medical law, where individual patients have asserted their need for redress or assistance from courts, including consent to treatment, sterilisation, reproductive rights and the entitlement of patients to gain access to their medical records. The chapter concludes with an analysis of the significant "legal" steps forward in relation to the rights of the mentally ill to be accorded due process but highlights the fact that the clampdown on available resources and the emphasis on deinstitutionalisation have resulted in many patients who need treatment failing to receive what is required for them to return to reasonable health. However, it suggests means by which those with mental illnesses may be able to use legislative responses to Australia's international obligations to enforce their rights to particular kinds of health service provision. Wherever possible, the chapter examines rights issues in terms of patients' "rights" to "self-determination", information about risks, freedom to reproduce, rights to dignity and rights to information held about them.

PUBLIC HEALTH AND HUMAN RIGHTS

The discipline of public health focuses upon the health of populations rather than clinical treatment of individuals. It is a given to public health practitioners that a critical determinant of health status is socio-economic status.⁹ However, because there seems to be no workable alternative, health policy and programmes continue to operate within a biomedical framework. This model tends to promote consideration of illness in individuals and a response to a series of individual problems, rather than focusing upon systemic factors of causation. Mann, who has been a leader in the development of thinking in the area of health and human rights, has argued that the difficulty for public health in

6 See, in particular, the discussion by Mendelson, D, "The Northern Territory's Euthanasia Legislation in Historical Perspective" (1995) 3 *Journal of Law and Medicine* 136.

7 See, for example, Stuhmcke, A, "The Legal Regulation of Fetal Tissue Transplantation" (1996) 4 *Journal of Law and Medicine* 131; Eburn, M, "The Status of the Living Fetus" (1997) 4 *Journal of Law and Medicine* 373.

8 *Toonen v Australia*, Human Rights Committee, CCPR/C/50/D/ 488/1992; views of the Committee adopted on 31 March 1994, delivered on 4 April 1994.

9 See, for instance, Reynolds, C, *Public Health Law in Australia* (Federation Press, Sydney, 1995).

addressing the indisputably predominant social determinants of health status is exacerbated by the lack of a coherent conceptual framework for analysing societal factors that are relevant to health; the social class approach, while useful is clearly insufficient. Public health action based on social class is simply accusatory and it raises, but cannot answer, the question: "what must be done?"¹⁰

In this sense, "poverty" as a root cause of ill health (though clearly not the only cause) is both evident and paralysing to further thought and action. Also, without a consistent approach or vocabulary, we cannot identify the societal factors common to different health problems (cancer, heart disease, injuries, infectious diseases) and to different countries. Finally since the way in which a problem is defined determines in part what is done about it, it is significant that the prevailing public health paradigm is unclear about the nature and direction of societal change that is needed to promote health.

This school of thought argues that health policies and programmes may be enhanced by placing them in a human rights framework. Instead of imagining the unwell person as *the other*, as commonly happens in the context of infectious disease, the aim is to maximise the individual's human rights in so far as this is consistent with good science. A good example of this approach is the Australian National Strategy on HIV.¹¹ The legal component of this Strategy promoted the protection of privacy, informed consent, graded coercive powers ranging from minor restrictions to detention and rights of review and appeal when restrictions are imposed. Harm minimisation approaches in the context of drug usage have also been informed by consideration of human rights. The creation of laws supporting needle exchange schemes is also, in part, a recognition of a right to health. Similar comments could be made about the supply of condoms in prisons.

Comparatively rarely under current Australian law have individual litigants been able to utilise international human rights instruments to enable them to assert their own rights. An exception is to be seen in *Toonen v Australia*¹² where health policy issues were the subject of attempts at lobby-induced change at the behest of two men who asserted health rights to practice their sexuality as they wished. In December 1991 the United Nations Human Rights Committee, received a petition from Nicholas Toonen, an activist for homosexual rights in Tasmania. He sought to challenge ss 122(a) and (c) and 123 of the Tasmanian *Criminal Code* that criminalised sexual contact between gay men in private on the basis of their functioning in a discriminatory way. Ultimately the decision of the Human Rights Committee was based upon the right to privacy under art 17 of the ICCPR and what it characterised as an arbitrary infringement of this right.

However, in the course of argument before the Committee health issues were raised both in favour of and against the criminalisation of homosexual activity. Amongst the arguments proffered, Tasmania stated that, although laws criminalising homosexual activity might constitute an arbitrary interference with privacy, they

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10 Mann, J. "Health and Human Rights" (1996) 312 *British Medical Journal* 924.

11 See for example Watchirs, H "HIV/AIDS and the Law: The Need for Reform in Australia" (1993) 1 *Journal of Law and Medicine* 9.

12 Above, n 8; see further, Joseph, S "Gay Rights under the ICCPR - Commentary on *Toonen v Australia*" (1994) 13 *University of Tasmania Law Review* 393; and Ch 14 by Eastman and Ronalds in this volume.

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should be retained in order to protect public health and prevent the spread of HIV/AIDS in that jurisdiction. This argument was opposed by the federal government which contended before the Committee that such laws impede public health programmes by driving people underground. Further, it pointed out that the position of the Tasmanian government ran counter to the National HIV/AIDS Strategy.

The Committee found that criminalisation of homosexual activity was not a "reasonable means or proportionate measure" to prevent or limit the spread of HIV.¹³ The Committee noted further that there was no evidence which demonstrated that criminalising homosexuality was effective in limiting the spread of HIV. The Committee did not accept the argument that this matter was a moral concern and thus a domestic matter. The *Toonen* decision highlights an opportunity, albeit a comparatively rare one, for health rights arguments to be invoked under the framework of the ICCPR to facilitate the achievement of health, in the broad sense of the concept, by individuals otherwise deleteriously affected by legislative impediments to their health.

Not surprisingly, though, individual case decisions on occasions have achieved the opposite result. The interpretation by the courts of important public health initiatives is not always consistent with the effective provision of needed services. For instance, in *Atyeo v Aboriginal Lands Trust*¹⁴ Templeman J of the Western Australian Supreme Court found public health legislation relating to the provision of adequate sewerage facilities and sanitation not to be binding upon the Crown for the advantage of Aborigines. Section 99 of the *Health Act* 1911 (WA) prohibits a person from erecting, rebuilding, maintaining or using any house without providing it with sanitary conveniences and with bathroom, laundry and cooking facilities in accordance with the by-laws of the local authority. It allows a local authority to require a landlord to provide and install apparatus for the treatment of sewerage. The plaintiff, who was the Principal Environmental Health Officer for a shire in Western Australia sought a declaration that the Aboriginal Lands Trust was bound to comply with such a notice "because of his concern about the lack of toilet and ablution facilities" at an Aboriginal reserve. Templeman J found that the purpose of the legislation in preventing disease was not determinative and that the Crown, and therefore the Trust, was not bound by it. Thus, the purpose of the public health legislation was thwarted. The case was ultimately decided on the basis of the black letter issue of whether certain kinds of legislation should be taken to bind the Crown, but its resolution, and the manner of its resolution, in which health rights issues ended up becoming secondary considerations, have important, if depressing, ramifications.

In addition, some developments in the area of public health law are inconsistent with a rights based approach such as proposals for the criminalisation of the intentional spread of serious disease with a maximum penalty of life imprisonment. The risk thereby created is that fewer HIV positive persons will submit to testing and so more people will be put at risk of the transmission of the disease.¹⁵ However, the health and human rights framework is gaining support amongst the

13 Above, n 8, paras 8.4-5.

14 (1996) 93 LGERA 57.

15 In relation to regulation of the passage of HIV to women see S Hardy, "Regulating the Conduct of HIV-positive Women" (1998) 6 *Journal of Law and Medicine* (forthcoming).

international community.¹⁶ It may be that the move toward the development of a "therapeutic jurisprudence", which explores ways in which, consistent with the principles of justice, the knowledge, theories and insights of the health and related disciplines can help shape the development of the law,¹⁷ has the potential to facilitate the evolution of health law in a direction which is consistent with an integrated rights framework. By its focus upon the development of law in a way which promotes health, such a jurisprudence carries the promise of influencing law-making by legislatures as well as the interpretation of laws in cases such as *Atyeo* to the advantage of those whose health such legislation is designed to enhance.

INTERNATIONAL LAW AND THE RIGHT TO HEALTH

In international law there are many references to the "right to health" but few to specific rights in relation to particular kinds of treatment, to what constitutes "adequate treatment", or to the remedies available for persons adversely affected by the treatment that they do receive. A right to health is not only located in the *Universal Declaration of Human Rights* (UDHR) and the *International Covenant on Economic Social and Cultural Rights* (ICESCR). References to a right to health may be found in the preamble to the Constitution of the World Health Organisation (WHO), art 24(1) of the *Convention on the Rights to the Child* (CROC), art 5(e)(iv) of the *Convention on the Elimination of All Forms of Racial Discrimination* (CERD) and art 11(1)(f) of the *Convention on the Elimination of All Forms of Discrimination Against Women* (CEDAW).

The basic reference, art 12 of the ICESCR, provides that:

- (1) The State Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
- (2) The steps to be taken by the State Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

This right is limited in the help which it extends for the framing of health legislation. For a start, the meaning of the article is not all that clear, although there has been an

16 See, for example, the *International Guidelines on HIV/AIDS and Human Rights* published by the United Nations (New York and Geneva, 1998) and the UNAIDS Guide to the United Nations Human Rights Machinery for AIDS Service Organisations, People Living with HIV/AIDS, and Others Working in the Area of HIV/AIDS and Human Rights (UNAIDS, 1997).

17 See, for example, Magner, ES, "Therapeutic Jurisprudence: A New American (?) School of Thought" (1998) 5(2) *Psychiatry, Psychology and Law* (forthcoming); Wintick, B, "The Jurisprudence of Therapeutic Jurisprudence" in Wexler, DB and Winick, BJ (eds), *Law in a Therapeutic Key. Developments in Therapeutic Jurisprudence* (Carolina Academic Press, Durham, Nth Carolina, 1996).

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ongoing, albeit not very successful, international process aimed at its clarification. The Committee created to monitor the implementation of the Covenant sought to issue a General Comment on Article 12 to provide a better standard against which to measure States' compliance. International health experts debating the possible content of such a General Comment struggled with the knowledge that health status is generally determined by social and economic factors. They concluded:

By over-emphasising the correlations between health and other factors, the impression may appear that any health specific effort is doomed to fail in the absence of general socio economic reforms. A next step would be that the State may feel justified to suspend its health promotion and health care programs until better times come. Given the fact that the "healthy and wealthy" hardly ever depend on State interventions in the field of health, the implications of such a State withdrawal would disproportionately affect the poor and vulnerable groups in society. The consequence of such a decision would be that the gap between rich and poor and between healthy and less fortunate would dramatically increase.¹⁸

The right to health has been the subject of considerable controversy concerning whether it is a meaningful or enforceable right.¹⁹ It has been suggested that if health is defined as "a state of complete physical, mental and social well-being" then it must be extremely difficult to implement and unlikely to be justiciable.²⁰ Defining human well-being is far from a straightforward exercise and it has been observed that public health and human rights have actually been used at times as powerful tools for maintaining the status quo and reinforcing hierarchies of power based on race, gender and class.²¹

However, Gostin and Lazzarini have suggested that the right to health may be defined as "the duty of the state, within the limits of its available resources, to ensure the conditions necessary for the health of individuals and populations".²² This definition only requires the state to act within its capabilities to achieve as good a standard of health as it can and recognises that while government may do a great deal to improve population health there are also many factors beyond the power of the state.²³

Two important recent cases – in South Africa and New Zealand – have tested the right of patients to treatment.²⁴ It is significant that both did so by using the mechanism of arguing that entrenched objectives of the provision of health care had not been met. It will be argued below that this is a mechanism likely to be more frequently availed of by litigants in the future, advocacy services and legal aid resources permitting.

18 See Hendriks, A "The Right to Health" (1994) 1(2) *European Journal of Health Law* 187 at 195.
19 See, for instance, Bell, S. "Rationing the Right to Health" (1998) 6(1) *Journal of Law and Medicine* 83.
20 Gostin, LO and Lazzarini, Z, "Human Rights and Public Health in the AIDS Pandemic" (Oxford University Press, Oxford, 1997), pp 28-29.
21 See, for example, Freedman, L, "Reflections on Emerging Frameworks of Health and Human Rights" (1995) 1(4) *Health and Human Rights* 3 15.
22 Gostin and Lazzarini, above, n 20, p 29.
23 However, note that the term employed in art 12 of the ICESCR is for the "highest attainable standard" of health to be striven for by the state.
24 For a useful discussion, see Bell, above, n 19.

In *Soobramoney v Minister of Health (Kwazulu-Natal)*,²⁵ a patient with renal failure sought to be reinstated on dialysis treatment by reliance on a provision in the South African Constitution which provided that all citizens had the right to health care services, subject to the availability of necessary resources, and that no-one could be refused emergency treatment. The court, while it conceded that the preservation of human life was of paramount importance, held that treatment for end-stage renal failure did not constitute emergency treatment and that acceptance of the patient's argument would have the effect of undermining the values which the provision in the constitution sought to protect by an unwarranted conflation of emergency and non-emergency treatment.

Similarly, in New Zealand a number of decisions in the courts were generated by the refusal of access by the Northland Regional Health Authority to an end-stage renal failure programme for an elderly man with renal failure. The patient initially challenged the decision on the ground that the Authority was not fulfilling the duty it owed him under the *Health and Disability Services Act 1993* (NZ), maintaining that the Authority was in breach of its obligation to provide the best health care and support to those needing health services and had failed its obligation to exhibit a sense of social responsibility and to provide its services in accordance with the ethical standards to be expected to providers of health and disability services. Thus the claim was one of treatment based upon application of the values statutorily mandated of health care providers. However, Salmon J of the New Zealand High Court applied the reasoning of Lord Donaldson MR in *Re J (A Minor)*,²⁶ holding that the obligations spelled out in the legislation were not absolute but subject to the exercise of clinical judgment. Balcombe J went even further, emphasising "the absolute undesirability of the court making an order which may have the effect of compelling a doctor or health authority to make available scarce resources ... without knowing whether or not there are other patients to whom these resources might more advantageously be devoted". The court declined to interfere with the Authority's decision, holding that the clinicians had relied properly on the Authority's guidelines in relation to the allocation of resources in a principled manner and without any reviewable administrative deficiency. The Court of Appeal upheld the High Court's decision.²⁷

As already noted, of greater assistance in conceptualising health in terms of rights are the notions of rights to life, liberty and security of the person; the right to be free of arbitrary interference with one's privacy; the right to benefit from scientific advances; the right to seek, receive and impart information and ideas; and the right to found a family. Merely the enunciation of such a series of rights illustrates the indivisibility and interdependency of fundamental human entitlements. In this regard Leary has noted that a consequence of "embracing a human rights paradigm is the assumption that universal health standards, which are legally cognisable and enforceable, can be identified. That is, health is constructed as a legal entitlement rather than a privilege, commodity or result of altruism".²⁸

25 CCT 32/97, 27 November 1997.

26 [1992] 3 WLR 507.

27 *Shortland v Northland Health* (unreported, CA NZ, 10 November 1997, CA 230/97).

28 Ibid at 276.

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Nevertheless, it must be conceded that the statements of rights to health which emanate from international documents are frequently not immediately helpful in arguing cases locally. In areas where well-established precedent exists, such as in the area of medical malpractice, it is unlikely that submissions constructed in a rights framework will be accepted by an Australian court. Greater scope exists where the boundaries of current law are challenged and international human rights law may then become a useful resource. In addition, increasing scope exists for human rights discourse and analysis to influence the development of new statutory regulation of health care processes.

AUSTRALIAN MEDICAL LAW

There is no specific right to "treatment" or to "good treatment" in Australia. However, the common law has entitled persons to sue if they have been harmed in the course of treatment. The law that has built up around medical malpractice, largely framed in terms of the law of tort (negligence, nuisance, and trespass to the person) goes some way toward enabling litigants to assert rights in respect of their bodies. The notion of a person's right to autonomy of decision-making and thus the right to make decisions about accepting or refusing medical treatment on the basis of adequate information to make such decisions are central.

In the following discussion we concur with other writers in locating their deliberations concerning autonomy and consent in the right of the patient to security of the person.²⁹ Gostin and Lazzarini, for instance, suggest that to realise the right to personal security:

Individuals must remain free to voluntarily accept or refuse physical intrusions, even when the purpose is benign. The doctrine of voluntary consent to medical testing, treatment, or research, which much of the international community endorses, may be seen as arising from the right to security of the person.³⁰

Only when competent persons make uncoerced choices, based on full information, can they truly exercise their right to security of the person. Security of the person, then, requires "information, competency, and a voluntary assent to intervention absent undue influence, duress, or coercion".³¹ Other options for classification of rights within the provision of health care are the right to self-determination or remotely, the right to privacy, but in terms of Australian jurisprudence the right of a person not to be the subject of medical intervention, save in certain circumstances, can most usefully be termed not as a function of decision-making but as a right to bodily integrity, save when that is waived by the person's own decision.

29 ICCPR art 17. Privacy is central in medical law and the right to privacy as understood in international law is relevant to this element. However, it is distinct from consent. Self-determination as a principle may apply both to populations and, especially in the medical law context, to individuals. For a useful discussion, see Jones, M and Marks, LA, "Female and Disabled: A Human Rights Perspective on Demand Medicine" in Petersen, above, n 4.

30 Gostin and Lazzarini, above, n 20, pp 14-15.

31 Ibid, p 15.

Consent to treatment

The most significant Australian case in relation to patients' rights to sound treatment and to decide upon medical treatment is the High Court decision of *Rogers v Whitaker*.³² The defendant ophthalmic surgeon, Rogers, conducted surgery on the injured and sightless right eye of the plaintiff, Mrs Whitaker. This resulted in a condition known as sympathetic ophthalmia and consequential loss of sight in the respondent's left eye, leaving her almost totally blind. Evidence was given that the chance of this occurring was one in approximately 14,000 cases and that the condition did not always result in loss of vision.

The ground upon which the case was argued was that the surgeon had been negligent in failing to warn his patient of the risk of sympathetic ophthalmia. The trial judge concluded that such a warning was necessary in light of the respondent's desire for this information, she having particularly expressed concern about the conduct of the operation and her capacity to continue to enjoy vision.

The traditional view applied by the English courts was that derived from the case of *Bolam v Friern Hospital Management Committee*.³³ This was relied upon by the surgeon when he suggested that the standard of care required of him was no more than that of the ordinary skilled person exercising and professing to have a special skill. In this instance there was a body of reputable medical practitioners who would not have warned the patient of the risk of sympathetic ophthalmia, so it was said that the surgeon had behaved in accordance with the standard required.

This test had been applied by the English courts to diagnosis, treatment and the provision of information. Such a test is professionally-oriented, rather than oriented toward the wishes and needs of the patient. In *Sidaway v Bethlem Royal Hospital Governors*,³⁴ Lord Scarman, in a dissenting judgment, stated that it was a matter of law whether or not a doctor has provided a patient with sufficient information. The relevant standard, he held, was not a matter able to be determined solely by reference to current accepted practice. In arriving at this position, Lord Scarman referred to the Canadian decision of *Reibl v Hughes*³⁵ and, in doing so, recognised that the significant determining factor in the information to be imparted was individual autonomy, that is the patient's right to decide what will happen with respect to medical treatment.

In *Rogers v Whitaker*³⁶ the majority in the High Court held that:

32 (1992) 175 CLR 479.

33 [1957] 1 WLR 582.

34 [1985] 1 All ER 643.

35 (1980) 114 DLR (3d) 1.

36 See also the discussion in *Anasson v Kozial* (unreported, SC ACT, 20 December 1996) at 13, where Miles CJ commented that, "it might be observed that it seems that the *Bolam* principle is not as rigid as Australian lawyers have sought to express it in order to reject it. With respect to their Lordships, they might have been surprised to learn that they had delegated the duty of the courts to the medical profession (*F v R* (1983) 33 SASR at 193), let alone handed over their responsibilities to a section of the community with an interest in the outcome (*Reibl v Hughes* (1980) 114 DLR at 13). Some might regard *Bolam* as a case decided on its facts. It was not considered important enough to be published in the authorised reports".

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37 (1992) 175 CLR

38 Ibid at 490.

39 Ibid at 490.

40 *Breen v Williams*

41 Note though that *Whitaker* had not that it is for the been observed.

[I]n the field of non-disclosure of risk and the provision of advice and information, the Bolam principle has been discarded and instead the Courts have adopted ... the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the "paramount consideration that a person is entitled to make decisions about his own life".³⁷

They resisted characterising the obligations of the medical practitioner as a matter of "the patient's right of self-determination", seeing this as pertinent to cases where there may be doubt as to whether a person has agreed to a treatment or procedure generally. They suggested that concepts like self determination or informed consent were applicable to actions in trespass or battery, but not in negligence. However, the effect of the decision is to forge a connection between a patient's right to self-determination in terms of consent or refusal to treatment, a self-determination founded in the provision of information which enables the making of a considered decision about medical intervention.

While the court dealt with the case as one located within the framework of negligence law, the requirement imposed upon medical practitioners by the decision is broadly consistent with a rights framework and the right to security of the person in particular. The court held that:

The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.³⁸

The decision needs to be seen within context. It has not ushered into Australia the doctrine of the oft-used and somewhat amorphous phrase "informed consent". In fact, the court observed that there was nothing to be gained by reiterating expressions used in United States authorities such as "the patient's right of self-determination" or even "informed consent",³⁹ pointing out that the term "is apt to mislead as it suggests a test of the validity of the patient's consent and that, moreover, consent is relevant to actions framed in trespass, not in negligence".⁴⁰

The decision has been responsible for a major shift away from an environment of medical paternalism toward a recognition of patient autonomy in that the patient's views and desires are now preferred to what the doctor might paternalistically and without proper consultation consider to be in the patient's best interests.⁴¹ However, the High Court decision has left many questions unresolved in relation to doctor-patient interaction. Included among the uncertain factors in the aftermath of *Rogers*

37 (1992) 173 CLR 479 at 487.

38 *Ibid* at 490.

39 *Ibid* at 490.

40 *Breen v Williams* (1996) 138 ALR 259 at 298 per Gummow J.

41 Note though the comment of Dawson and Toohey JJ in *Breen v Williams* at 276 that *Rogers v Whitaker* had nothing to say about medical paternalism save, perhaps, to the extent that it decides that it is for the court, not medical opinion, to determine whether the required standard of care has been observed.

v Whitaker is the variable of the extent to which a doctor must take steps to acquaint him or herself with the personal circumstances of a patient so as to provide information responsive to idiosyncratic aspects of the patient's circumstances and wishes. Another fundamental question, that has troubled medical practitioners, is the extent to which remote risks, but of a kind which would prompt anxiety in patients, need to be drawn to their attention. If risks as remote as one in 14,000 need to be the subject of warning, where does the obligation cease? And how can it be discharged – for instance, by the provision of written information or video tapes descriptive of the procedure.

To what extent does communication through such media need to be supplemented by one-to-one doctor-patient interaction?

The difficulties inherent in the case of *Chappel v Hart*⁴² are illustrative of the uncertainties that exist in relation to the entitlements of patients in the post-*Rogers v Whitaker* era. The plaintiff sued her ear, nose and throat surgeon for failing to warn her of the dangers of a procedure which he advised her to undergo. She expressed concern about side-effects but was not advised of a significant complication of the operation that was ultimately undertaken. Notwithstanding the surgeon's exercise of due care and skill, her oesophagus was perforated and she developed an infection which damaged her laryngeal nerve, resulting in paralysis of her right vocal chord. The difficult aspect of the case was that she would have undertaken the operation even if properly advised of the risks. No negligence in the conduct of the procedure was asserted.

The New South Wales Court of Appeal found that had the patient been advised of the risks, she would have postponed the operation and had a more experienced surgeon carry it out. However, the evidence was equivocal about whether this would have reduced in any way the risks of the complications which ultimately afflicted the patient.⁴³ Mahoney JA, with whom Handley JA agreed, framed the duty to advise thus:

The doctor is responsible for the damage by reason of the failure to warn of the existence of the possibility of damage only when, in the circumstances, he has a duty to give a warning of it. ... [W]here, as here, it is accepted that there was a duty to warn, then the failure to warn may properly be held to be the cause of the damage when the risk eventuates.⁴⁴

Thus, the right to bodily integrity was very generously construed by the court and the burden placed squarely upon the medical practitioner's shoulders to ensure that adequate information was provided to the patient, the penalty for failure to do so being liability for any damage thereafter ensuing from the procedure undertaken by the patient in the absence of such information.

42 Unreported, CA NSW, 24 December 1996. See further Freckelton, I "Medical Malpractice Litigation" in Freckelton, I and Petersen, K (ed), *Controversies in Health Law* (Federation Press, Sydney, 1998) (forthcoming).

43 For a discussion of the case, see Mendelson, D, "The Breach of the Medical Duty to Warn and Causation" (1998) 5(4) *Journal of Law and Medicine* 312.

44 At the time of writing, an appeal had been argued before the High Court and the decision was reserved.

Sterilisation

If human rights are to be the most vulnerable in the human rights approach, *Health and Community* is an application for the deafness, epilepsy, "order authorising the The hysterectomy v psychological and b stabilise the hom behavioural respons these procedures.

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45 (1992) 175 C Ch 8 by Behr

46 Ibid at 249.

Sterilisation

If human rights are to have any role in medical law, it should be in the protection of the most vulnerable in our community. A case that demonstrates the influence of a human rights approach to a difficult health care issue is *Secretary, Department of Health and Community Services v JWB and SMB (Marion's Case)*,⁴⁵ which involved an application for the sterilisation of a young intellectually disabled girl with severe deafness, epilepsy, "behavioural problems" and an ataxic gait. Her parents sought an order authorising the performance of a hysterectomy and a bilateral oophorectomy. The hysterectomy was sought to prevent pregnancy and menstruation and their psychological and behavioural consequences. The oophorectomy was proposed to stabilise the hormone fluxes, helping to eliminate consequential stress and behavioural responses. The term "sterilisation" was used as a shorthand reference to these procedures.

The issue before the High Court was whether such a sterilisation could be performed, and if so whether it could be done with the provision of parental consent or only in accordance with an order of the Family Court. Basic human rights, the concept of "best interests of the child" and the ability to distinguish therapeutic from non-therapeutic treatments or procedures were discussed in the course of the decision-making process by the Family Court and then, on appeal, by the High Court. The High Court addressed the power of parents to consent to medical treatment on behalf of a child, the capacity of a child to consent and the specific issue of sterilisation. The decision of the majority, comprising Mason CJ and Dawson, Toohey and Gaudron JJ, was that except where sterilisation is an incidental result of surgery performed to cure a disease or to correct a malfunction, the decision to sterilise a minor falls outside the ordinary scope of parental powers and thus the powers and duties of a guardian. They found that the task of the Family Court when approached in its *parens patriae* jurisdiction to authorise the sterilisation of a child is to determine what is in the child's "best interests". They remitted the task of formulating guidelines for determining what is in such a child's best interests to the Family Court.

The majority summarised the reasons given in previous cases for considering the authorisation of sterilisation to be beyond parental power: "first, the concept of a fundamental right to procreate; secondly, in some cases, a similarly fundamental right to bodily inviolability or its equivalent; thirdly, the gravity of the procedure and its ethical, social and personal consequences".⁴⁶ They found court authorisation to be a necessary safeguard for sterilisation which is not the "by-product of surgery appropriately carried out to treat some malfunction or disease". Sterilisation was characterised as irreversible surgery carrying a significant risk of error which in turn could bring grave social and psychological consequences. Children with an intellectual disability were recognised as falling into a particularly vulnerable category of the community.

45 (1992) 175 CLR 218. For discussion of this case in the context of family law and human rights, see Ch 8 by Behrens and Tahmindjis in this volume.

46 Ibid at 249.

The majority endorsed the well-known formulation of the principle of inviolability articulated by Cardozo J in *Schloendorff v Society of New York Hospital*.⁴⁷ "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault."

The majority judges in the High Court based their conclusion upon what they termed "a fundamental right to personal inviolability existing in the common law", a right which they said underscored the principles of assault, both criminal and civil, as well as upon the practical exigencies accompanying this kind of decision. They emphasised, though, that their conclusion did not "rely on a finding which underpins many of the judgments discussed; namely, that there exists in common law a fundamental right to reproduce which is independent of the right to personal inviolability".⁴⁸

The High Court's decision in *Marion's Case* is the most prominent example of a judicial decision in Australia which has canvassed in detail and with sophistication the conflicting human rights issues in a medical law context. However, the decision also included powerful dissents by Brennan, Deane and Wilson JJ.

The Human Rights and Equal Opportunity Commission was permitted standing to appear before the High Court.⁴⁹ It argued that an invasive surgical procedure such as a sterilisation of a young woman who is unable to provide her own consent should only be undertaken with the authorisation of a court. It successfully contended that this requirement is consistent with the exercise of the *parens patriae* or statutory welfare jurisdiction of the Family Court and "as such is sufficient safeguard of the rights of the mentally retarded and disabled persons recognised in the international Conventions and Declarations incorporated in schedules to the *Human Rights and Equal Opportunity Commission Act*".⁵⁰

Brennan J, in dissent, though, rejected the Commission's approach. He sought to identify the "basic principles of our legal system" since there were no cases of binding authority. He looked to what in the law governs physical integrity and noted that:

Blackstone declared the right to personal security to be an absolute, or individual, right vested in each person by "the immutable laws of nature".⁵¹ Blackstone's reason for the rule which forbids any form of molestation, namely, that "every man's person [is] sacred", points to the value which underlines and informs the law: each person has a unique dignity which the law respects and which it will protect.⁵²

He pointed out that "human dignity"⁵³ is a value common to Australian municipal law and to international instruments relating to human rights:

47 105 NE 92 (NY 1914), referred to at 234. *Schloendorff* was determined independently of the United States Bill of Rights considerations.

48 Ibid at 253-54.

49 See Ch 14 by Eastman and Ronalds in this volume.

50 (1992) 175 CLR 218 at 231.

51 Ibid (*Blackstone's Commentaries on the Laws of England*, vol 1, pp 124, 129, vol 3, p 119).

52 Ibid at 266.

53 Ibid, "[t]he inherent dignity of all members of the human family is commonly proclaimed in the preambles to international instruments relating to human rights": at 266.

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54 Ibid at 266.

55 Ibid at 269.

56 Ibid at 276.

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58 *Re Marion (No 2)* (1991) 175 CLR 218 at 231.

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The law will protect the hale and hearty and the dignity of the weak and lame; of the frail baby and the frail aged; of the intellectually able and the intellectually disabled. ... Human dignity requires that the whole personality be respected: the right to physical integrity is a condition of human dignity but the gravity of any invasion of physical integrity depends on its effect not only on the body but also upon the mind and self perception.⁵⁴

In considering what is to be incorporated within the term, "physical integrity", he included the psychological impact of a physical interference and the impact upon that person's human dignity, a notion well known in human rights dialogue.

Brennan J noted the idea of third party authorisation, or substituted consent, but dismissed it as a "semantic legerdemain" and the antithesis of consent, thus unreliable. However, he found utility in the distinction between "therapeutic" and "non-therapeutic", a distinction by contrast that the majority found to be imprecise. He defined treatment as being therapeutic when administered "for the chief purpose of preventing, removing or ameliorating a cosmetic deformity, a pathological condition or a psychiatric disorder, provided the treatment is appropriate for and proportionate to the purpose for which it is administered".⁵⁵ His Honour accepted that the intellectually disabled should have the same rights as others "to the maximum degree of feasibility", as proposed under the Declaration of the Rights of Mentally Retarded Persons. He held that to accord in full measure the human dignity "that is the due of every intellectually disabled girl", her right to

retain her capacity to bear a child cannot be made contingent on her imposing no further burdens, causing no more anxiety or creating no further demands. If the law were to adopt a policy of permitting sterilisation in order to avoid the imposition of burdens, the causing of anxiety and then the creating of demands, the human rights which foster and protect human dignity in the powerless would lie in the gift of those who are empowered and the law would fail in its function of protecting the weak.⁵⁶

He expressed himself loathe to endorse a "best interests" approach on the basis of its failure to offer a hierarchy of values,

which might guide the exercise of a discretionary power to authorise sterilisation, much less any general legal principle which might direct the difficult decisions to be made in this area by parents, guardians, the medical profession and courts ... the best interests approach depends upon the value system of the decision maker. Absent any rule or guideline, that approach simply creates an unexaminable discretion in the repository of the power.⁵⁷

Because of the majority decision of the High Court, the matter was remitted to the Family Court for articulation of criteria on the basis of which a decision could be made as to whether Marion should or should not be sterilised.⁵⁸ On remittal

54 Ibid at 266.

55 Ibid at 269.

56 Ibid at 276.

57 Ibid at 270-01. Brennan J accepted the need for guidelines lest the law fail the person in respect of whom the order for sterilisation is sought. He held that a non-therapeutic sterilisation could only be justifiable if its purpose was of greater value than physical integrity. He added that financial security, for example, was not "to be preferred over the equal protection of the law of the human rights of every member of the community": at 275.

58 *Re Marion (No 2)* (1994) FLC ¶92-448.

Nicholson CJ constructed the series of guidelines called for in the High Court⁵⁹ and approved her sterilisation as a step of last resort in order to minimise the potential to her of further neurological damage and in particular to stem the effects of seizures to which she was subject.

The decisions in the cases relating to Marion represent a high point in the analysis of basic and complex principles of health law in terms of rights asserted in international instruments and articulated in human rights discourse. The powerful dissent of Brennan J highlights the difficult balancing exercise when the rights of the intellectually disabled to autonomy and bodily integrity have to be placed in the scales against what objectively speaking is in the best health interests of a person unable to make their own decisions.

Reproductive rights

Article 10(2) of the ICESCR requires that "[s]pecial attention be accorded to mothers during a reasonable period before and after childbirth". Article 12, the right to health, requires reduction of the stillbirth rate and of infant mortality. Gender equity is a significant part of achieving reproductive rights and this, of course has its reflection in the CEDAW. In particular art 12 of that Convention states:

1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.
2. Notwithstanding the provisions of paragraph 1 of this article States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.

Reproductive rights are a recent concept:

One of the cornerstones of the concept of reproductive rights is the right of access to family planning. This idea has been fundamental to definitions of reproductive rights from the beginning, appearing repeatedly in population and human rights documents as the right to have the "information and means" to decide freely and responsibly the number and spacing of children. Without such access, reproductive rights have, practically speaking, no real meaning.⁶⁰

59 The relevant factors which went to determining whether sterilisation was in an intellectually disabled girl's best interests were held to be:

- (i) the condition which required the procedure or treatment;
- (ii) the nature of the procedure or treatment proposed;
- (iii) the reasons for which it was proposed that the procedure or treatment be carried out;
- (iv) the alternative courses of treatment that are available in relation to the condition;
- (v) the desirability and effect of authorising the procedure or treatment proposed rather than the available alternatives;
- (vi) the physical effects upon the person and the psychological and social implications for the person of authorising or not authorising the proposed procedure or treatment;
- (vii) the nature and degree of risk to the person of authorising or not authorising the proposed procedure or treatment; and
- (viii) the views, if any, expressed by the person's guardians; anybody entitled to custody of the person; anybody responsible for the person's daily care and control; and of the person themselves.

See also *In the Matter of P and P* (1995) FLC ¶92-615; *Re Jane* (1989) FLC ¶92-007.

60 "Reproductive Rights and Reproductive Health: A Concise Report" (United Nations, New York, 1996).

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The International Conference on Population and Development held in Cairo in 1994 defined reproductive rights as embracing:

certain human rights recognised in national and international legal and human rights documents: the right of couples and individuals to decide freely and responsibly the number and spacing of their children, and to have the information and means to do so; the right to attain the highest standard of sexual and reproductive health; the right to make decisions free of discrimination, coercion or violence.⁶¹

Expressed in this manner, reproductive rights relate to much more than the entitlement to personal inviolability. They encompass positive rights articulated more fully at the Fourth World Conference on Women in Beijing 1995.⁶² Reproductive rights might include the freedom to have a safe and satisfying sexual life, the ability to have a safe pregnancy and childbirth, the ability to control one's own fertility, access to gender-sensitive initiatives to deal with sexually transmitted diseases and to information about reproductive health and access to safe abortions. They might also be said to include the right to be free from unwanted sexual interference which is an aspect of the right to bodily integrity.

The right to reproduce was not accepted as a right independent of personal inviolability by the majority in *Marion's Case* which held that:

If the so-called right to reproduce comprises a right not to be prevented from being biologically capable of reproducing, that is a right to bodily integrity. The same applies, though in a different way, to a woman's "right to reproduce". Again, if the right is, in fact, a right to do with one's person what one chooses, it is saying no more than there is a right to bodily integrity. Furthermore, it is impossible to spell out all the implications which may flow from saying that there is a right to reproduce, expressed in absolute terms and independent from a right to personal inviolability. We think it is important, in terms of the judgment, to make it quite clear that it is inviolability that is protected, not more.⁶³

The majority classified the right to reproduce as a limited and indistinct right. It is apparent, therefore, that the approach of the majority of the High Court in *Marion's Case* is one that significantly circumscribes the extent of women's reproductive rights within Australian medical law. What this means in practice is that the range of issues regarded as coming into play in assessing whether or not there is an interference with a woman's reproductive capacity is far more limited than has been proposed by recent international forums on the subject.

Patient access to medical records

The matter of the rights of patients to medical records generated on their behalf has been a troubled and controversial one in Australia and internationally during the 1990s. It is an aspect of the privacy of the doctor-patient relationship, arguably comprehending the entitlement of the patient to know what it is that has been generated by her or his medical advisers in the course of consultations and tests

61 "Action for the 21st Century: Reproductive Health and Rights for All" (Family Care International, New York, 1994), p 10.

62 *Report of the 4th World Conference on Women, United Nations* (Beijing, September 1995), pp 4-15. See also Ch IV of the Report, Part C, paras 89-111.

63 (1992) 175 CLR 218 at 254.

conducted in order to provide advice or to facilitate decisions related to intervention or non-intervention. At an international level, it is significant that art 10 of the European Draft Convention on Human Rights and Medicine prescribes that "everyone is entitled to know any information collected about his or her health". This is stated to be subject to the qualification that "in exceptional cases" restrictions may be placed on the exercise of such rights to information, where restriction would be in the interest of the patient.⁶⁴

However, to a significant degree the issue is a limited one in Australia in light of the applicability of freedom of information legislation to records generated by public health facilities and the availability of records under prelitigation discovery, discovery and subpoena. In addition, 1997 legislation in the Australian Capital Territory has given patients significant rights to their records. However, the reasoning engaged in by the High Court in determining that patients have no common law right to their health records is of real moment for the construction of Australian health law and for understanding the nature of the doctor-patient relationship in this country.⁶⁵

In 1996 the High Court determined the issue authoritatively, holding in *Breen v Williams*⁶⁶ that patients hold no proprietary right or interest in the information contained in a doctor's medical records. Such records were determined to be the property of the doctor, enabling medical practitioners to refuse patients access to such records. As a matter of contract and fiduciary law, the High Court repudiated the contention that patients are entitled to inspect their records on demand.⁶⁷

However, Brennan CJ held that in certain circumstances information with respect to a patient's history, condition or treatment which is obtained by a doctor in the course of giving advice or treatment must be disclosed to a patient on request. He found such circumstances to arise where refusal to make the disclosure might prejudice the general health of the patient, whether the request is reasonable, having regard to all the circumstances, and where reasonable recompense for the service of disclosure is tendered or assured by the patient.⁶⁸

Dawson and Toohey JJ held that the contractual obligation of the doctor was to use reasonable care and skill in treating and advising the patient. They rejected the assertion that an incident of such duties was the provision of access to the patient's medical records. Gaudron and McHugh JJ held that a doctor does not impliedly promise to act in the best interests of the patient and found that the primary duty owed by the medical practitioner was to exercise reasonable care and skill. While they accepted that there is a tortious duty on the part of doctors to exercise reasonable care toward patients, they repudiated the implication of a general

64 See Ch III of the Council of Europe's Draft Convention on Human Rights and Medicine, reproduced in (1997) 1(1) *International Journal of Human Rights* 115.

65 *Health Records (Privacy and Access) Act 1997* (ACT). See also the position in England (s 3 of the *Access to Health Records Act 1900*) and New Zealand (*Health Information Privacy Code 1994* (NZ); *Health Act 1956* (NZ); *Privacy Act 1993* (NZ)); see McSherry, B, "Access to Medical Records: What Legislation Must Take into Account" (1997) 4 *Journal of Law and Medicine* 211; Blomberg, C, "Medical Records" in Freckelton and Peterson, above n 42.

66 (1996) 138 ALR 259.

67 For a provocative analysis of the case, see Olbourne, N "Patients' Access to Doctors' Records" (1998) 6(2) *Journal of Law and Medicine* (forthcoming).

68 Ibid. at 263.

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70 See Wilson, 21; Wilson, *Journal of Law and Mental Health and Medicine*

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contractual duty of care and held that the uncertainty of "best interests" as an obligation further militated against the general implication of such a term.

The court had been pressed by the applicant for access to the records to follow Canadian case law⁶⁹ and to find a general relationship of fiduciary and beneficiary to exist between doctor and patient. However, the court did not accept such a characterisation, preferring to maintain the traditional English and Australian approach to fiduciary law and to find that aspects of the relationship are fiduciary and will be protected by equity where a doctor, for instance, exercises undue influence over a patient to their financial detriment.

The High Court's decision in *Breen v Williams* confirms the obligations of medical practitioners to take reasonable care in the provision of treatment and advice to patients where the failure to do so could result in a foreseeable risk of harm to their patients. However, it circumscribes significantly the extent of doctors' contractual duties to their patients. Most significantly, it has declined to characterise the relationship between medical practitioners and their patients as fundamentally fiduciary in the sense of its being a relation of unequals and "trust-like". The privacy interest of patients to know what has been generated about them in terms of notes and medical records is for the most part unenforceable save where statute intervenes to provide such a right.

Rights of the mentally ill

The area of law probably most archetypally associated with the emergence of the legal protection of human rights in respect of health is that of mental health law. The past 30 years in Australia, as in other parts of the western world, have seen the emergence of substantial regulation of the circumstances in which the mentally ill can be involuntarily detained. The focus of the human rights lobby, which has been highly influential, has been to limit the autonomy of doctors to make decisions about the best interests of their psychiatric patients without being accountable and adhering to prescribed due processes, drafted to prevent the abuse or deprivation of liberty without just therapeutic cause. The past 30 years have seen the prescription of the processes of commitment by psychiatrists and the establishment of monitoring bodies, both review boards and tribunals, whose task it is to evaluate whether criteria for detention of those identified as mentally ill have been met. In addition, there has been increasing regulation of techniques of restraint and seclusion of those with mental illnesses who are housed within psychiatric institutions. Legislation has also stipulated in many jurisdictions when and how certain kinds of particularly intrusive treatment such as psychosurgery and electro-convulsive therapy can be administered.⁷⁰ To this extent, it can accurately be said that under mental health law,

69 See, in particular, *McInerney v MacDonald* (1992) 93 DLR (4th) 415.

70 See Wilson, B, "Psychosurgery: Ethical and Legal Issues" (1996) 4 *Journal of Law and Medicine* 21; Wilson, B and Freckelton, I, "Electroconvulsive Therapy: Ethical and Legal Issues" (1999) 6 *Journal of Law and Medicine* (forthcoming); Brookbanks, W, "Electro-convulsive Therapy and the Mental Health (Compulsory Assessment and Treatment) Act 1992 (NZ)" (1994) 1 *Journal of Law and Medicine* 184.

patients have been accorded statutory human rights to a degree unparalleled in other areas of medicine.⁷¹

The more prescriptive medical environment that exists in relation to mental health law has generated a more sophisticated debate in some respects about consumers' health rights. In 1992 the Commonwealth Government in its *National Mental Health Policy* endorsed the United Nations Principles for the Protection of Persons with Mental Illness. Such a step seemed to promise much for the rights of those with mental illness to better treatment and facilities. Shortly afterwards, though, the Burdekin Report⁷² in 1993 exposed an often-forgotten aspect of health rights – the fact that if adequate facilities for the provision of treatment are not available, this itself constitutes a serious impediment to a patient's potential to become well. Amongst many criticisms, the Burdekin Report made adverse findings in relation to the legislation in a number of Australian jurisdictions for having failed to ensure that the rights and freedoms of people with mental illness had been adequately protected.

Changes to legislation have taken place in most jurisdictions to implement the National Policy and to meet some of the criticisms levelled in the Burdekin Report.⁷³ However, while greater specificity now exists in a number of jurisdictions in relation to the definition of mental illness, uncertainty remains about the difficult overlap between personality disorders and mental illness. Moreover, a number of commentators have accurately observed that the mentally ill have relatively few rights in relation to treatment which will meaningfully address their health when they are discharged from compulsory detention and returned to the community. Zifcak, for instance, has conceded that civil libertarian approaches to mental health law reform, while they have improved a number of the procedures for commitment of the mentally ill and ensconced due process in procedures for challenge to commitment decisions, have achieved relatively little in improving community care facilities, staffing levels, conditions, standards of conduct and treatment regimes.⁷⁴ He has argued that mental health law now occupies a new space, influenced by the phenomena of deinstitutionalisation, mainstreaming of acute mental health services, the major provision of psychiatric services now being in the community, the decrease in funding of health services generally by governments, the role of managerialism in the delivery of health services and the requirement for efficiency as a primary factor in health service delivery.⁷⁵

The Burdekin Report lambasted State and Territory governments for the quality of the follow-up available to persons discharged from psychiatric hospitals and pointed out the levels of homelessness among those recently involuntarily detained

71 See Appelbaum, PS, *Almost a Revolution. Mental Health Law and the Limits of Change* (Oxford University Press, New York, 1994).

72 Human Rights and Equal Opportunity Commission, *Report of the National Inquiry into the Human Rights of People with Mental Illness* (AGPS, Canberra, 1993).

73 See, for instance, *Mental Health (Amendment) Act 1995* (Vic).

74 Zifcak, S. "The United Nations Principles for the Protection of People with Mental Illness: Applications and Limitations" (1996) 3(1) *Psychiatry, Psychology and Law* 1 at 5; compare Delaney, S. "The United Nations Principles for the Protection of People With Mental Illness and Victorian Law" (1992) 18 *Melbourne University Law Review* 565.

75 Zifcak, S. "Towards 2000: Rights, Responsibilities and Process in the Reform of Mental health Law" (1997) 4 *Australian Journal of Human Rights* 51 at 56-57.

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for mental illness. It also castigated the quality of boarding houses frequently resorted to by those with mental illness, the lack of support for families living with the mentally ill and the degree of poverty and discrimination against those with mental illnesses.

Little since the Burdekin Report has changed save that the process of deinstitutionalisation has hastened. While patients who are involuntarily detained now possess a number of enshrined rights that regulate the circumstances of their detention, increasing numbers of still psychotic patients are discharged under pressure for hospital beds. Problems continue to exist with the coverage of disability discrimination legislation.⁷⁶ No appreciable increase in resources has been allocated for the escalating numbers of significantly symptomatic patients cared for within the community. In such circumstances, there is a real limit upon the extent to which it can be said that those with mental illness have rights to treatment and, in particular, to adequate treatment. A real issue within mental health law, as increasingly it is within the wider area of health law, is how patients can insist, with the assistance of the law, upon being provided with the treatment that they need for the alleviation of their pain and suffering.

Few cases in relation to the rights of the mentally ill reach the courts other than those in the criminal area in relation to insanity or unfitness to stand trial. A rare exception was *In the Matter of XY*⁷⁷ where the Victorian Court of Appeal was required to determine whether an involuntary patient should be regarded as having been properly detained in a psychiatric hospital against his will and thus whether the Victorian Mental Health Review Board had jurisdiction to review his detention. The decision analysed what constituted due process for a person to be involuntarily detained and then found that if a person was in fact admitted and detained as an involuntary patient, even if technically wrongly so detained, they should not be disadvantaged by a technical illegality if they are in need of care and treatment. The court found that even if the person had not been properly detained, they should still enjoy the advantage of their status being reviewed by the Mental Health Review Board. No recourse was overtly had by the Supreme Court to human rights principles or to international human rights instruments but the decision takes its place as a precedent supporting the right of persons detained to be accorded the right to have the propriety of their continued detention reviewed by an administrative review body, notwithstanding the possibility that their initial decision may have been wrongly determined.

However, legislation in a number of jurisdictions has latterly enunciated principles of treatment and care to which psychiatric patients are said to be entitled and objectives have been legislatively enshrined for the government health departments that have the responsibility for providing such treatment and care. For instance, s 6 of the *Mental Health Act 1990* (NSW) states that the objectives of the New South Wales Health Department are to establish, develop, promote, assist and encourage mental health services which:

76 See Australian Law Reform Commission, *Making Rights Count: Services for People with a Disability*, Report No 79 (AGPS, Canberra, 1996).

77 (1992) 2 MHRBD 501 (decided 6 March 1992 by the Victorian Court of Appeal). See also *Murray v Director-General, Health and Community Services Victoria* (unreported, SC Vic, 23 June 1995) per Eames J.

- (a) develop, as far as practicable, standards and conditions of care and treatment for persons who are mentally ill or mentally disordered which are in all possible respects at least as beneficial as those provided for persons suffering from other forms of illness, and
- (b) take into account the various religious, cultural and language needs of those persons, and
- (c) are comprehensive and accessible, and
- (d) permit appropriate intervention at an early stage of mental illness, and
- (e) support the patient in the community and liaise with other providers of community services.⁷⁸

Similarly, s 4(1) sets out the objects of the Act in relation to the care, control and treatment of persons who are mentally ill and mentally disordered and s 4(2) stipulates that it is the intention of the New South Wales Parliament that every function, discretion and jurisdiction imposed by the *Mental Health Act* be performed or exercised so that:

- (a) persons who are mentally ill or mentally disordered receive the best possible care and treatment in the least restrictive environment enabling the care and treatment to be effectively given, and
- (b) in providing for the care and treatment of persons who are mentally ill or mentally disordered any restriction on the liberty of patients and other persons who are mentally disordered and any interference with their rights, dignity and self-respect are kept to a minimum in the circumstances.

In Victoria, the *Mental Health (Amendment) Act* 1995 introduced an even more extensive enshrinement of principles for the provision of services to those with mental illnesses. It listed a series of objectives for Victoria's mental health legislation, included amongst which are objects such as "to provide for the care, treatment and protection of mentally ill people who do not and cannot consent to that care, treatment and protection",⁷⁹ "to protect the rights of people with a mental disorder"⁸⁰ and to ensure that "people with a mental disorder are informed of and make use of the provisions of this Act".⁸¹ In addition, guidelines are listed for the interpretation of the legislation. These articulate values against which the legislation itself, the actions of the Department of Human Services and the behaviour of services providers and those reviewing their decisions can be measured. Important examples are that "people with a mental disorder are given the best possible care and treatment appropriate to their needs in the least possible restrictive environment and least possible intrusive manner consistent with the effective giving of that care and treatment",⁸² and that "in providing for the care and treatment of people with a mental disorder and the protection of members of the public any restriction upon the liberty of patients and other people with a mental disorder and any interference with their rights, privacy, dignity and self-respect are kept to the minimum necessary in the circumstances".⁸³

78 See also *Mental Health Act* 1996 (WA) s 5.

79 *Mental Health Act* 1986 (Vic) s 4(1)(a).

80 *Ibid* s 4(1)(c).

81 *Ibid* s 4(1)(e).

82 *Ibid* s 4(2)(a).

83 *Ibid* s 4(2)(b).

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84 *Ibid* s 6.

85 *Ibid* s 6.

86 *Ibid* s 6.

87 *Ibid* s 6.

88 *Ibid* s 6.

89 *Ibid* s 6.

90 *Ibid* s 6.

91 *Ibid* s 6.

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The legislation also states that it is the intention of the Victorian Parliament that a series of principles be given effect to with respect to the provision of treatment and care to people with a mental disorder. Included amongst these are that:

- "people with a mental disorder should be provided with timely and high quality treatment and care in accordance with professionally accepted standards";⁸⁴
- "wherever possible, people with a mental disorder should be treated in the community";⁸⁵
- the provision of treatment and care should be "designed to assist people with a mental disorder to, wherever possible, live, work and participate in the community";⁸⁶
- "the provision of treatment and care for people with a mental disorder should promote and assist self-reliance";⁸⁷
- "people with a mental disorder should be provided with appropriate and comprehensive information about their mental disorder, proposed and alternative treatments, including medication, and services available to meet their needs";⁸⁸
- "when receiving treatment and care the age-related, gender-related, religious, cultural, language and other special needs of people with a mental disorder should be taken into consideration";⁸⁹
- "treatment and care should be provided by appropriately qualified people and within a multi-disciplinary framework";⁹⁰ and
- "every effort that is reasonably practicable should be made to involve a person with a mental disorder in the development of an ongoing treatment plan".⁹¹

The significant issue from a legal point of view that arises from the existence of these provisions has not as yet been tested in the courts. What the enunciation of these principles makes possible is challenge to decisions and the provision of care on the basis that they are not in accordance with the principles set out in the legislation. For instance, where the provision of care has failed to take into account the right of a person to care that is in accordance with professionally accepted standards because of fiscal restraints, an avenue for litigation is available. Where the provision of treatment has not been fashioned so as to assist a person with a mental disorder to work or return to work, this again may open up a means of redress. Similarly, if persons are treated at a place that is convenient to the treaters but against the patient's wishes, or is significantly geographically removed from the residence of their relatives, this may afford a means of challenge where previously none existed. While these provisions are new and as yet untested, they have the potential to enable a substantial number of court challenges in respect of the compliance by service providers with the intentions of Parliament as articulated in the codified principles for the treatment and care of those with mental disorders.

84 Ibid s 6A(a).

85 Ibid s 6A(b).

86 Ibid s 6A(c).

87 Ibid s 6A(d).

88 Ibid s 6A(e).

89 Ibid s 6A(g).

90 Ibid s 6A(i).

91 Ibid s 6A(j).

CONCLUSIONS

Relatively few rights exist under contemporary Australian law to assist those disadvantaged by illness. For those who are mentally ill or intellectually disabled, support and advocacy services are so inadequate, and the availability of legal aid is now so limited, that those few rights which they might loosely be said to possess cannot any longer be said to be meaningfully accessible.

Australia is a signatory to a number of relevant international human rights instruments, but the utility of these in directly affording protection to patients or in providing to them a means of enforcing a civil remedy against those who have impoverished their health is minimal. Those rights that do exist in respect of health have been little and narrowly articulated by Australian jurisprudence. By and large, there has been acknowledgment that patients are entitled not to be subjected to treatment that affects their bodily integrity without their having provided their consent and having been advised of the risks and options in respect of the treatment. However, even with respect to so fundamental an entitlement, enforceable principally under the civil law, it has not been the subject of coherent and principled analysis within a rights discourse. Interpretation of the right has been limited to argument for the most part about whether provision of information in the context of a particular case has been adequate and whether an individual plaintiff can be said to have provided consent to treatment. This is not particularly surprising as rights for those adversely affected by medical procedures by and large exist under the civil law and only to the extent that economically quantifiable damages are available as a result of negligence, breach of implied terms of the therapeutic contract, by reason of nuisance, breach of fiduciary duty or assault to the person.

However, means for patients to assert rights not only to treatment but to treatment that accords with the principles underlying the international human rights instruments to which Australia is signatory have been created by the enactment of guidelines and objects clauses within legislation binding those supplying health care services, especially in the public sector.⁹² The advent of such provisions at least in principle is creating a way in which individual grievances about the practices and priorities within the public health care system in Australia may become actionable using human rights principles. Such legislation has for the first time provided a bridge between human rights discourse and the forensically enforceable provision of health care.

92 See Laufer, S, "A Code of Health Rights and Responsibilities: the Adequacy of Existing Recognition and Protection" (1994) 1 *Journal of Law and Medicine* 168 who instanced a range of statutory examples of the enunciation of such principles in Queensland: see, for example, *Health Services Act* 1991 (Qld) s 3.18(2)(a); *Disability Services Act* 1992 (Qld); *Medicare Agreements Act* 1992 (Cth); *Health Rights Commission Act* 1991 (Qld) ss 37(f); *Health Act* 1958 (Vic) s 119. However, it needs to be acknowledged that the attempt in *Shortland v Northland Health* (unreported, CA NZ, 10 November 1997, CA 230/97) to utilise guidelines for the provision of health care by way of an administrative law challenge was unsuccessful: see above.

This book details the impact, and potential impact, of human rights law on the major areas of Australian legal practice – criminal law, administrative law, constitutional law, immigration law, family law, labour law, environmental law and more. It includes chapters on researching human rights laws and using human rights treaties.

This book chronicles nothing less than a legal revolution. It charts the growing impact of international human rights law on Australian law. It demonstrates, in a way that even sceptics cannot ignore, that human rights law is now permeating the nooks and crannies of Australian substantive and procedural law. ...

The special value of this book is that it demonstrates this process through a series of practical instances where courts and tribunals, faced with difficult questions, have looked beyond the hitherto orthodox sources of legal authority. ...

Scarcely a week goes by in a sittings of the High Court of Australia when a case does not involve, in some way or other, an international treaty to which Australia is a party or values that find reflection in the principles of international law. ...

The most striking feature of these essays is that they demonstrate how the argument about a practical subject the study of human rights law is now becoming for the judge and lawyer in Australia.

The Hon Justice Michael Kirby AC CMG, High Court of Australia

Systematically analyses the way human rights principles are implemented in the Australian legal system. The book is an innovative blend of theory and practice and is a most valuable addition to the Australian literature on human rights.

Professor Hilary Charlesworth, Australian National University

This work is a major contribution to the development of human rights law in Australia. It will be of enormous assistance to judges, practitioners, scholars and students.

Ron Cass, University of Queensland

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