The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World

Paula Lobato de Faria

4th Biennial Institute
in Health Law and Bioethics
Lisbon 2011

FUNDAÇÃO
LUSO-AMERICANA

The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World

EDITED BY
Paula Lobato de Faria

1st Biennial Seminar
in Health Law and Bioethics
Lisbon 2005

ESCOLA NACIONAL DE SAÚDE PÚBLICA
UNIVERSIDADE NOVA DE LISBOA

The 1st Biennial Seminar in Health Law and Bioethics
as well this book was sponsered by
Fundação Luso-Americana para o Desenvolvimento
Fundação Calouste Gulbenkian
Fundação para a Ciência e Tecnologia
Ministério da Saúde

SPECIAL THANKS
Isabel Andrade

COVER
Fernando Cerqueira

PRINTED BY
Alfanumérico, Lda.

1ST EDITION
500 copies

ISBN
972-98811-4-6

LEGAL DEPOSIT
242 560/06

Contents

Health and Bioethics

FERNANDO DURÃO*

The foundations in which human life rests were severely shaken throughout the 20th century, and will be more so in the 21st century. The parameters of life, especially in the western world, changed in what concerns birth rates, which decreased, and life expectancy, which grew exponentially.

Independently of alterations in values and life styles that may account for a decrease in birth rates, there are indubitable explanations for the increase in life expectancy and these can be, in a simplified manner, summarized in two aspects: the emphasis in the right to health care, especially so in Europe under its social model, and the astonishing scientific advances in biomedical science, which in themselves have posed and continue to pose challenges that were unimaginable two decades ago.

The scientific community is engaged in debates concerning the ethical, legal and, of course, scientific aspects that determine the legitimacy and boundaries of their work.

However, there are other factors that lay beyond this debate and that I would classify as exogenous: and these are the deliberate misuse of science in ways that are detrimental to human life (bioterrorism) and the negligent use of specific technologies that are harmful to the environment.

The *Fundação Luso-Americana para o Desenvolvimento* (Luso-American Development Foundation), in the wake of a long-standing attention to these issues and aware of its responsibility as a civil

* Secretary-General of Fundação Luso-Americana para o Desenvolvimento

Saúde e Bioética

FERNANDO DURÃO*

As premissas sobre que assenta a vida humana foram fortemente abaladas no século XX, e ainda mais o serão neste século XXI. Os parâmetros da vida humana, em especial no mundo ocidental, alteraram-se no que se refere à natalidade, que baixou, e à esperança de vida, que cresceu de uma forma exponencial.

Independentemente de toda uma alteração de valores e do modo de vida que podem dar alguma explicação para o decréscimo da natalidade, existe uma explicação inegável para o incremento da esperança de vida que, de uma forma muito simplista, se resume a dois fenómenos: a atenção posta no direito à protecção da saúde, com a Europa a liderar a problemática, no âmbito das suas preocupações sociais, e o brutal avanço científico na área das ciências biomédicas, que colocaram, e colocam, problemas não imaginados há duas décadas atrás.

A comunidade científica tem-se desdobrado em reflexões de natureza ética, jurídica e, naturalmente, também científica, para tentar equacionar o que é legítimo e o que será menos, no que se refere à sua acção.

Mas existem outros factores que estão para além da formulação atrás feita, que classificaria de exógenos: que são o mau uso deliberado da ciência em prejuízo da vida humana (bio-terrorismo), e um uso negligente de determinadas tecnologias que prejudicam o seio em que se desenvolve a vida — o ambiente.

A Fundação Luso-Americana para o Desenvolvimento, assumindo a sua quota-parte de responsabilidade da sociedade civil em

* Secretário-Geral da Fundação Luso-Americana para o Desenvolvimento.

society organization, hosted the "1st Biannual Seminar in Health Law and Bioethics", and supported it. Further funding was provided by the Calouste Gulbenkian Foundation, the Foundation for Science and Technology and the Portuguese Ministry for Health.

This Seminar was the result of the joint work of the Escola Nacional de Saúde Pública da Universidade Nova de Lisboa (National Health School, New University of Lisbon), of Boston University and of the University of Pennsylvania, and benefited from the contribution of leading experts from both sides of the Atlantic.

Because of the eminent interest of the presentations, it was decided to publish them in book-form, in order to better disseminate them to those that work on these challenges.

In 2007 we expect the second seminar of the series, this time held in Boston, which will update the materials present in this volume.

Special thanks are due to Professor Paula Lobato Faria for the enthusiasm, drive and efficacy with which she led and leads this project.

February 14 2006

que se integra, na discussão desta temática, foi a anfitriã do Seminário «1st Biannual Seminar in Health Law and Bioethics», que apoiou, havendo também patrocínios da Fundação Calouste Gulbenkian, da Fundação para a Ciência e Tecnologia, e do Ministério da Saúde.

Este Seminário foi o fruto de um trabalho conjunto da Escola Nacional de Saúde Pública da Universidade Nova de Lisboa, da Boston University e da University of Pennsylvania, e contou com grandes peritos nestas matérias de ambos os lados do Atlântico.

Dado o interesse das comunicações apresentadas, foi decidido publicá-las em livro, para a divulgação das mesmas em benefício de todos os que se debruçam sobre esta problemática.

Esperamos assistir em 2007 ao segundo seminário, a realizar em Boston, subordinado ao mesmo tema, e que actualizará o que agora se publica.

Um especial agradecimento é devido à Professora Paula Lobato de Faria, pelo entusiasmo, empenho e eficácia com que liderou, e lidera, este projecto.

14 de Fevereiro de 2006

1st Biennial Seminar in Health Law and Bioethics on "The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World"

AN INTRODUCTION

Paula Lobato de Faria*

I. Genesis

From January to June 2004, benefiting of a sabbatical leave related to my position as an associate professor of the National School of Public Health of the New University of Lisbon, I did a visiting scholarship, also granted by the Luso-American Foundation for the Development (FLAD), in the Department of Health Law, Bioethics and Human Rights of the Boston University School of Public Health (BUSPH), directed by Professor George J. Annas. This experience was of a high level of interest and motivated me to give continuity to the established bonds.

One of the specific goals of my visiting scholar position, besides the deepening of my academic knowledge and skills, was to explore the possibility of building a more solid scientific bridge in the fields

---

* Associate Professor of Health Law and Biolaw, National School of Public Health, New University of Lisbon; Law Degree by the Faculty of Law of the University of Lisbon, Portugal, Master's and PhD in Health Law by the Montesquieu University, Bordeaux, France with recognition as a PhD in Public Law by the Faculty of Law of the New University of Lisbon, Portugal. I would like to thank the Directive and Scientific Councils of the National School of Public Health of the New University of Lisbon and the Luso-American Foundation for the Development for all the support in the organization of the 1st Seminar in Health Law and Bioethics. It is important to mention that the following Portuguese institutions also sponsored the seminar and this conference summary book: Calouste Gulbenkian Foundation, the Foundation for Science and Technology and the Ministry of Health.

of Health Law and Bioethics between North American and Portuguese universities and other high education institutions and professionals of the two countries. The opportunity of organizing a scientific meeting in Portugal, during the following year of 2005 sounded like a good option and the initiative was very well accepted not only by both Prof. Annas and Prof. Arthur Caplan of the University of Pennsylvania but also by the Portuguese concerned institutions, *i.e.* the National School of Public Health of the New University of Lisbon and the FLAD Foundation.

The main intention was to inaugurate a continuous programme of scientific exchange in the areas of Health Law and Bioethics between the institutions involved and the idea of launching a series of seminars for the years to come was settled. The 2005 seminar would be the first of a biannual set of meetings held alternatively in Lisbon and Boston. The embryo as well as the maturation of this idea was developed in active collaboration with all the academic staff of the BUSPH Department of Health Law, Bioethics and Human Rights, namely Professors George J. Annas, Wendy Mariner, Patricia "Winnie" Roche and Michael Grodin. I also visited for a week the Centre of Bioethics of the University of Pennsylvania, directed by Professor Arthur Caplan, and he also helped to define the contents of the first seminar's scientific programme.

The Luso-American Foundation for the Development (FLAD) has already been the sponsor and host of important international events in the field of Bioethics, such as the three FLAD-NSF International Bioethics Institute courses, summarized in a book, also co-sponsored by the FLAD, on "Bioethics for Natural Sciences" (2004)[1]. However, this is the first time that this institution has hosted a scientific event in the field of Health Law (which is intrinsically linked both academically and in practice to Bioethics[2]) and I feel that in order to better understand the content and boundaries of this subject it is desirable that this introduction contain some notes on the concept of Health Law, which is still mentioned as a

"comparatively young"[3] subject by the academic world, especially in Europe, bearing in mind that the concepts of Bioethics and Human Rights have been more explored not only by academics but also by the media, and as such are better known by the public in general.

I will also develop in the following chapter a few thoughts on the interactions of Health Law with both Bioethics and Human Rights to offer readers some points of general reference on this topic. These notes will mainly try to analyse the assertions that describe the current meaning of some of the most relevant national and international law and doctrine in the fields explored in the Seminar.

After this brief conceptual incursion I will end this introduction by presenting the reasons that led to the choice of the main theme and the specific subjects included in the 1st Biennial Seminar in Health Law and Bioethics final programme (transcribed at the end of this introduction) to allow readers to see the full structure and contents of the Seminar.

II. Health Law, Bioethics and Human Rights — a "Joint Venture" behind the Seminar

1. What is Health Law?

> *The study of health law presents a unique opportunity to apply law and legal analysis to an industry that dramatically affects our lives, is undergoing tremendous change, and is filled with challenges that the thoughtful application of law can help us to meet constructively. Few fields of applied law match the richness of health law. In* George J. Annas, Sylvia A. Law, Rand E. Rosenblatt, Kenneth R. Wing *American Health Law.* Little, Brown and Company. Boston, Mass., 1990, Preface, p. xxxi.

Health Law identifies with the more traditional part of the juridical aspects linked to health and life sciences, composed of

the juridical tools (legislation, doctrine, and jurisprudence) that apply mainly to the health care act and settings. This approach to Health Law is found in definitions such as the one below and it may explain why the term "Health Law" is sometimes used as a synonym of the expressions "Medical Law"[4], "Health Care Law" or "Biomedical Law". Nevertheless, these last terms always evoke a narrower scope and tend to be more focused on the legal problems of the medical profession, health care, and biomedical developments.

> *Law and medicine are separate professions, and attorneys and physicians often* see *their professions in conflict. There are, however, more similarities than differences between the two professions. And there are areas of mutual concern and overlap that demand the application of both legal and medical knowledge for the good of society. These areas have historically been united under the broader term of* health law. In *S. Sandy Sanbar, George J. Annas, Michael A. Grodin, Cyril H. Wecht,* "Legal Medicine: Historical Roots and Current Status" in American College of Legal Medicine, Legal Medicine, 6th Edition, Ed. Mosby/Elsevier, Philadelphia, Pennsylvania, 2004, p.3.

The study of Health Law normally covers issues such as access to care, health systems organization, patients' rights, health professionals' rights and duties, strict liability, healthcare contracts between institutions and professionals, medical data protection and confidentiality, informed consent and professional secrecy[5]. Portuguese Health Law is still not a very developed legal branch and it has some characteristics that differ from other EU countries, such as:

— Lack of a legislative health code, as it exists in France (*Code de la Santé Publique*) and mainly lack of specific legal norms applicable to some crucial issues in health care, which are sometimes found in more general and classical legal

branches (e.g. the only norms in Portuguese Law capable of identifying the parameters of a lawful medical act are in the Penal Code — articles 150, 156 and 157[6]);

— Caducity of some important health laws because of their incompatibility with the new Constitution of 1976, without their substitution by new ones (e.g. the law on the fight against contagious diseases which dates from 1949);

— Lack of sufficient jurisprudence and doctrine to allow a better interpretation and application of the Law in the health care field.

— Contrarily to French Health Law which tends to develop general statutes in more practical and detailed regulations *(circulaires),* in Portugal there is an insufficiency of "executive type" norms to better implement general laws (e.g. patients rights are too generally treated in the legislation causing difficulties to health professionals and administrators in understanding the full meaning of these norms).

All these problems found in Portuguese Health Law illustrate how important it is to expand the initiatives to explore this field in the country and why initiatives such as the 1st Biennial Seminar in Health Law and Bioethics need to be expanded to contribute to that objective.

2. Health Law and Biolaw

As a complement to a definition of Health Law, it is nowadays necessary to mention the more recent term Biolaw[7], as the legal field that treats the social consequences that arise from biotechnological developments[8]. Scientific advances or any revolutionary new technique in peoples' lives have always had strong repercussions in the Law. The industrial revolution led to civil strict liabil-

ity; the automobile created the concept of mandatory insurance; photography gave forth the right to one's image; the development of the press made it necessary to invent a right to privacy; the use of computers led to data protection laws and to the right to informational self-determination.

Recent developments in Medicine and Biology have created an even greater challenge for Law, challenging some of its traditional fundamental concepts, such as the classical dichotomies between "persons" and "things" (e.g. in which category should we place DNA?); women and men (e.g. difficulties on the civil status of transsexuals); motherhood (e.g. where to place "surrogate" mothers); life and death (e.g.today's reanimation devices allow the prolonging of life into states of vegetative life which don't differ much from death and transplantation symbolically continues the "life" of deceased donors).

In a world where science and biomedicine manipulate living creatures and transform them, Biolaw aims at regulating these actions, allowing some and forbidding others, with or without sanctions. This concept is usually linked to Bioethics as Judith Miller defines Biolaw:

> *The taking of agreed upon principles and practices of bioethics into law with the sanctions that law engenders. Biolaw includes legislation on bioethical issues, interpretation of such legislation and case law made by judges.*[9]

The transformation of Bioethics in Biolaw is, though, not an easy task. Biolaw must first of all be adaptable to the future developments of scientific knowledge that is always evolving, so its norms must be flexible or risk becoming obsolete. And, secondly, it must reflect the consensus of society and the scientific community or it may create conflicts capable of jeopardizing the applicability of its norms. As an example of the difficulties that surround the making of "bio-norms" we can refer to the French

"Lois Bioéthiques", the first version of which appears in July 1994, and was preceded by almost a decade of public debate including five exhaustive ministerial reports (*Rapports Braibant,* 1988; *Lenoir,* 1991, *Sérusclat;* 1992, *Bioulac,* 1992 and *Mattei,* 1993).

In Portugal the debate over a legal framework for medically assisted reproduction is going on for over almost 20 years now, the first steps on the regulation of this subject dating from 1986.There are at present four propositions to be discussed in the Parliament from four different political parties, fact that shows how difficult it is to achieve consensus in this field[10].

3. Health Law and Bioethics

The term "Bioethics" was first used to describe[11] a kind of ethics that would include not only our obligations to other human beings but to the biosphere as a whole (1971, Van Rensselaer Potter in his famed book *Bioethics: Bridge to the future*)[12]. Later in 1988, Potter defined Bioethics on the cover of another book (*Global Bioethics,* Michigan State University Press) as "Biology combined with diverse humanistic knowledge forging a science that sets a system of medical and environmental priorities for acceptable survival".

The concept evolved and in 1995 the *Encyclopedia of Bioethics* (USA, 1995[13]) defined bioethics as the "systematic study of the moral dimensions — including moral vision, decisions, conduct, and policies — of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting." Moral dilemmas linked to abortion, suspension of artificially supported life, surrogate motherhood, conception of children for the purpose of bone marrow donation, and more recently the use of human stem cells in animal embryos and reproductive cloning, are examples of bioethics typical issues.

Nevertheless, it is almost impossible to define the exact content of Bioethics[14] because its boundaries become wider every day. In this sense the recent UNESCO "Universal Declaration of Bioethics and Human Rights" (approved 19 October 2005) shows how Bioethics has again enlarged its scope almost returning to its primitive "ecological" dimension, an assertion that is supported by the following articles of the declaration:

- Article 16 ("Protecting Future Generations") states that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard";
- Article 17 ("Protection of the Environment, the Biosphere and Biodiversity") states that "due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to the respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity."

Bioethics is, as mentioned, intrinsically linked to Health Law and as such, evolution in this field influences the shape of the legal framework in all the overlapping areas of these two connecting fields.

4. Health Law and Human Rights

Although Human Rights have been always historically linked to medicine and health (the 1948 Nuremberg trials and Code), the introduction of Human Rights side by side with Health Law and Bioethics is based on the idea (George J. Annas, 2005) that

"in our increasingly globalized world, human rights will become the umbrella field under which the work done by both American bioethics and American health law will be linked and furthered"[15].

Human Rights have also influenced the movements that lead to establish Patients Rights as a fundamental piece of contemporary Health Law[16] and they are also the cornerstone of the 1997 Council of Europe Convention for the protection of Human Rights in Biomedicine (Oviedo Convention) and more recently to the 2005 UNESCO Universal Declaration on Bioethics and Human Rights.

However, the Oviedo Convention will be always remembered as the first international normative text to have linked so undoubtedly Human Rights to Health Law (in Portugal the Convention is part of the Law by the Presidential Decree n. 1/2001, of the 3rd of January) and it is useful and appropriate to recall its fundamental principles:

- The interests and welfare of the human being shall prevail over the sole interest of society or science (art. 2);
- Equitable access to health care of appropriate quality (art. 3);
- Relevant professional obligations and standards for any intervention in the health field, including research (art. 4);
- Free and informed consent to any intervention in the health field (art. 5);
- The right to respect the private life of the patient in relation to information about his or her health (art. 10);
- Prohibition of any form of discrimination against a person on grounds of his or her genetic heritage (art. 11);
- Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only

for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling (art. 12);

- An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants (art. 13);
- Prohibition of selecting sex by medically assisted reproduction (art. 14);
- Scientific research in the field of biology and medicine shall be carried out ensuring the protection of the human being (art. 15);
- Adequate protection of the embryo shall be ensured when the law allows it (art. 16, 1);
- Prohibition of the creation of human embryos for research purposes (art. 16, 2);
- Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness. Necessary consent must have been given (art. 19, 1);
- The human body and its parts shall not, as such, give rise to financial gain (art. 20);
- When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures (art. 21).

These principles are generally reflected in European Health Law and demonstrate how the spirit of Human Rights is present

in this legal field, which is crucial in an area where the concepts of humanity and human dignity are always at stake.

III. The Programme

1. The identification of the subjects to treat in the Seminar

A Seminar on the area of Health Law and Bioethics, punctuated with Human Rights as an indispensable background[17], could nowadays cut across a multiple and interdisciplinary sort of themes, from healthcare and scientific research issues to environmental, technological or terrorism induced threats[18]. It is clear that in the web of the ethical and legal problems brought up in these fields, the role of different named disciplines such as Ethics, Bioethics, Health Law or Biolaw becomes sometimes difficult to disentangle[19] and their frontiers are "permeable"[20]. We wanted our seminar to reflect this reality rather than be a pure conceptual forum dedicated to only one of the several mentioned scientific areas.

Being aware that our times are dramatically marked by severe, diverse and generally unexpected "menaces", which have generated ethical and legal problems that urged for solutions (e.g. AIDS, SARS, avian flu, massive terrorism, invasive new technologies, abusive biomedical research, potentially discriminatory genetic testing[21], etc.), the choice to treat the role of Health Law, Bioethics and Human Rights as tools to fight these "menaces" and to promote a safer and healthier world seemed a promising and proactive background choice for the Lisbon Seminar.

Below this umbrella the choice of the specific subjects for in the 2005 seminar was essentially based on a symbiosis of different criteria, which included variety, novelty, contemporary relevance, and utility. First we didn't want the seminar to be monothematic,

second we had a clear preference for innovative or even unexplored issues, and third the papers to be presented should have not only an academic goal but also a link to reality in the sense that they would try to present solutions to the real ethical and legal problems.

We elected four sets of "menaces" using these criteria:

a) bioterrorism and torture, issues that would be mainly treated under the human rights lens;
b) enhancing organisms and altering environments, in which the ethical problems of genetically modified organisms, cloning and nanotechnology uses would be analysed;
c) perils of clinical and research genetics, essentially focused on the threats to privacy and other patient's rights, and finally
d) new epidemics, such as avian flu and SARS, as a challenge to public health law tools.

We were aware that the majority of these subjects are still undeveloped by both jurists in the field and by Health Law doctrine, a fact that is a consequence of the relative novelty of most of the themes. Hence, we hope that this 1st Biennial Seminar in Health Law and Bioethics will help awaken the interest on the development of these subjects by jurists and academics in Portugal and allow a better understanding of the legal and ethical challenges in a changing world where not all the changes are friendly and foreseen in the Law and its traditional norms and codes.

Portuguese Health Law knowledge should be developed in a way that can help not only scientists and health professionals to undertake their activities more ethically and lawfully, but also help the lawyers and judges that deal with Health Law cases and frequently lack the appropriate theoretical background that would empower and help them to better understand this unique legal field.

2. The final programme

The final programme of the seminar was the following:

1st Panel
BIOTERRORISM, TORTURE, MENTAL HEALTH
AND HUMAN RIGHTS

Moderator: António Gentil Martins, Surgeon, Former Professor of Paediatric Surgery of the New University of Lisbon, Former President of the Portuguese Medical Association and World Medical Association.

(Bio)Terrorism, Torture and other Post-9/11 Epidemics: Must we Sacrifice Human Rights (and Bioethics) for Security?
GEORGE J. ANNAS
Edward R. Utley Professor and Chair, Department of Health Law, Bioethics and Human Rights, Boston University School of Public Health.

The Impact of Terrorism: Lawyers and Doctors working Together to Care for Survivors of Torture and Refugee Trauma
MICHAEL GRODIN
Psychiatrist and Professor of Health Law, Bioethics and Human Rights, Department of Health Law, Bioethics and Human Rights, Boston University School of Public Health.

2nd Panel
ENHANCING ORGANISMS AND ALTERING ENVIRONMENTS:
A BLESSING OR A MENACE?

Moderator: Ricardo Franco, Professor of Biochemistry, Faculty of Sciences and Technology, New University of Lisbon.

Genetically Modified Organisms — Have we Gone Too Far?
AUTUMN FIESTER
Professor of Medical Ethics, Department of Medical Ethics and Center for Bioethics, University of Pennsylvania School of Medicine.

Nanotechnology, Neurotechnology, and the Ethical Challenges of Human Interventions
PAUL ROOT WOLPE
Professor of Medical Ethics, Departments of Psychiatry, Medical Ethics, and Sociology and Center for Bioethics, University of Pennsylvania.

3rd Panel
CLINICAL AND RESEARCH GENETICS — DREAMS AND PERILS

Moderator: Jose Rueff, Vice-Dean of the New University of Lisbon, Professor of Genetics, Faculty of Medical Sciences, New University of Lisbon.

Clinical Genetics — Meeting the Challenges to Privacy
PATRICIA "WINNIE" ROCHE
Professor of Health Law and Bioethics, Department of Health Law, Bioethics and Human Rights, Boston University School of Public Health.

Patients' Rights and Research for the 21st Century
JASON KARLAWISH
Professor of Medical Ethics, Institute of Aging and Center for Bioethics of the University of Pennsylvania.

4th Panel
NEW PUBLIC HEALTH LAW CHALLENGES

Moderator: Ana Alexandre Fernandes, Vice-President of the Scientific Council and Professor of Sociology, National School of Public Health, New University of Lisbon.

Using Law to Control Epidemics: AIDS, SARS, TBA and Avian Influenza

WENDY MARINER

Professor of Health Law, Law and Socio-Medical Sciences.

School of Public Health, School of Law and School of Medicine — Boston University.

Seminar Conclusions

PAULA LOBATO DE FARIA

Professor of Health Law and Biolaw

National School of Public Health — New University of Lisbon.

General References

ANNAS, George J. *American Bioethics : Crossing Human Rights and Health Law Boundaries*. Oxford: Oxford University Press, 2005.

KENNEDY, Ian, Grubb, Andrew. *Medical Law*. Oxford : Oxford University Press, 2005.

ROSA, Humberto D. (coord.) *et al, Bioética para as Ciências Naturais*. Lisboa : FLAD, 2000-2002.

MILLER, Judith. "Is legislation in Bioethics desirable? An exploration of aspects of the intersection of Bioethics and Biolaw". In: *Bioethics and Biolaw*. Vol. I. Peter Kemp, (ed.) *et al.,* "Judgment of life", Copenhagen: Rhodos International Science and Art Publishers. Centre for Ethics and Law, 2000.

ANNAS, George J., LAW, Sylvia A., ROSENBLATT, Rand E., WING, Kenneth R. *American Health Law*. Philadelphia, Pennsylvania : Little, Brown & Company, 1990.

SANBAR, S. Sandy, ANNAS, George J., GRODIN, Michael A., WETCH, Cyril H. *Legal Medicine: Historical Roots and Current Status*. In: American College of Legal Medicine, *Legal Medicine*, 6th edition. Philadelphia, Pennsylvania : Mosby/ Elsevier, 2004.

MONTGOMERY, Jonathan. *Health Care Law,* 2nd edition. Oxford : Oxford University Press, 2003.

MÉMETEAU, Gérard. *Cours de Droit Médical,* 2nd edition. Bordeaux : Les Etudes Hospitalières, 2003.

AUBY, Jean Marie. *Droit de la Santé.* Paris : PUF, 1981.

Neirinck, Claire (coord.) *et al., De la Bioéthique au Bio-Droit.* Paris : L. G. D. J., 1994 (Collection Droit et Société).

KUHSE, Helga, SINGER, Peter (editors) *et. al., Bioethics : an Antology.* Oxford : Blackwell Philosophy Anthologies, 2001.

JONSEN, Albert R., VEATCH, Robert M., WALTERS, LeRoy (editors) *et. al.,* Source Book in Bioethics : a Documentary History. Washington, D. C. : Georgetown University Press, 1998.

ANNAS, George J. *The Rights of Patients.* 3rd ed. Carbondale : Southern Illinois University Press, 2004.

CAPLAN, Arthur. *Due consideration : controversy in the age of medical miracles.* New York : John Wiley & Sons, 1998.

LOBATO DE FARIA, M. Paula. *Données génétiques informatisées : un nouveau défi à la protection du droit à la confidentialité des données personnelles de sant.* Villeneuve d'Ascq : Presses Universitaires Du Septentrion, 1999.

Notes

[1] In the original *Bioética para as Ciências Naturais,* coordinated by Humberto D. Rosa. FLAD, Lisbon, June-July 2000-2002 (397 pages).

[2] E.g. Miller, Judith. "Is legislation in Bioethics desirable? An exploration of aspects of the intersection of Bioethics and Biolaw". In: *Bioethics and Biolaw.* vol. I. Peter Kemp, (ed.) *et al,* "Judgment of life", Copenhagen : Rhodos International Science and Art Publishers. Centre for Ethics and Law, 2000. 243-267.

[3] Ian Kennedy, Andrew Grubb. *Medical Law.* Oxford : Oxford University Press, UK, 2005. 3.

[4] E.g. the Jonathan Montgomery, *Health Care Law* (2nd edition, Oxford : Oxford University Press, 2003) and the French classical Gérard Mémeteau, *Cours de Droit Médical* (2nd edition, Bordeaux : Les Etudes Hospitalières, 2003) show very similar contents.

[5] E.g. Auby, Jean Marie. *Droit de la Santé.* Paris : PUF, 1981 or George J. Annas, Sylvia A. Law, Rand E. Rosenblatt, Kenneth R. Wing, op. cit.

[6] This happens because no legislation on the medical act has yet been approved, even if the Health Bases Law (Act n. 48/90, of the 24th of August 1990) determines that such act should exist as a complement of this same law (see base xxxii of Act n. 48/90).

[7] The term was first used by the North-American review Bio-Law (1986) and is later used in the title of a French book in 1993 (*De la Bio-éthique au Bio-Droit,* under the direction of Claire Neirinck, (ed.) L.G.D.J., Collection Droit et Société, Paris, 1994). In Portugal the term "Biodireito" is already a well known terminology in the academic field of Health Law.

[8] See e.g. Christian Lavialle, *De la Bioéthique au Bio-Droit,* ibid. 15.

[9] Ibid.

[10] See e.g. www.portaldasaude.pt

[11] For the same interpretation see *Bioethics : an Antology,* edited by Helga Kuhse and Peter Singer, Blackwell Philosophy Anthologies, 2001. 1.

[12] See also for an American and European anthropological comparison in the history of Bioethics, Maria do Céu Patrão Neves, "A fundamentação Antropológica da Bioética". *Bioética.* 1996; 4 : 1. 7-16.

[13] Quoted in Albert R. Jonsen, Robert M. Veatch, LeRoy Walters (editors). *Source Book in Bioethics : a Documentary History*. Washington, D. C. : Georgetown University Press, 1998. 1.

[14] E.g. Paula Martinho da Silva, Preface to *Bioética para as Ciências Naturais,* coordinated by Humberto D. Rosa, FLAD, Lisbon, June-July 2000-2002. 7.

[15] E.g. in George J. Annas. *American Bioethics : Crossing Human Rights and*

Health Law Boundaries. Oxford : Oxford University Press, 2005, p. xv.

[16] George J. Annas. *The Rights of Patients*. New York New York University Press, 2005.

[17] See supra II, 4.

[18] To assess the diversity of the themes explored in the fields of Health Law and Bioethics we can quote e.g. *Due consideration : controversy in the age of medical miracles* by Caplan, A. (New York: John Wiley & Sons, 1998) where the author treats in main titles "Abortion and Birth Control"; "Genetics"; "Technological Reproduction"; "The Ethics of Research"; "New Treatment/New Challenges"; "Rationing Cost"; "Managed Care"; "Starting and Stopping Care"; "Assisted Suicide"; "AIDS and other Plagues" and "Smoking and Other Bad Habits". The already mentioned work *American Bioethics : Crossing Human Rights and Health Law Boundaries,* where its author George J. Annas goes through issues such as "Bioethics and Bioterrorism"; "Human Rights and Health"; "The right to Health"; "Capital Punishment"; "Conjoined Twins"; "Patient Rights" (and others) is also a vivid expression of the transversal nature of the object of study in Health Law and Bioethics.

[19] On the analysis of the relations between Bioethics and Biolaw see e.g. Judith Miller, op. cit..

[20] Annas, G. J., ibid. xv.

[21] E.g. Lobato de Faria, M. Paula, *Données génétiques informatisées: un nouveau défi à la protection du droit à la confidentialité des données personnelles de santé*. Villeneuve d'Ascq : Presses Universitaires Du Septentrion, 1999.

Terrorism, Torture and other Post 9/11 Epidemics: Must We Sacrifice Human Rights in the Name of Security?*

GEORGE J. ANNAS, J. D., M. P. H.**

> *Our enemies are innovative and resourceful, and so are we. They never stop thinking about new ways to harm our country and our people, and neither do we.*
>
> President George W. Bush on signing the Defense Appropriations Act, August 5, 2004

Immediately after 9/11 the U. S. government closed the Statue of Liberty to the public. It took almost three years to reopen Liberty Island, just in time for the Republican National Convention. The public can again visit, but little is the same. Those wishing to take the ferry to the island, for example, must submit to airport-like screening, as well as bag checks, including bomb-sniffing dogs, upon arrival. And on the boat trip, the National Park Service has a new recorded "welcome" which asserts that although historically the Statue of Liberty symbolized freedom, it is now "a symbol of America's freedom, safety, and security". Similar screening is also required to view the Liberty Bell in Phila-

---

* For presentation at the First Biennial Seminar on Human Rights and Bioethics, Fundação Lusco-Americana, Lisboa, June 2, 2005. Portions of this text are adapted from "Human Rights and Health" (in) George J. Annas, *American Bioethics : Crossing Human Rights and Health Law Boundaries*, Oxford U. Press, NY, 2005, 19-26; Annas, G. J., Blinded by Bioterrorism : Public Health and Liberty in the 21st Century, *Health Matrix: J. of Law-Medicine* 2003; 13: 33-70; and Annas, G. J., "Puppy Love : Bioterrorism, Civil Rights, and Public Health", *Florida Law Rev.* 2003; 55: 1171-1190.

** Professor and Chair, Department of Health Law, Bioethics, and Human Rights.

delphia. We have not yet renamed the Statue of Liberty, the "Statue of Security"; or the Liberty Bell, the "Safety Bell", but safety and security have been consistently promoted as at least as important as liberty, and often more important, since 9/11.

The next stop after Liberty Island is Ellis Island, the site of screening for more than 2 million immigrants to America in the early 20th century. The most rigorous part of screening immigrants involved federal uniformed public health service physicians whose main duty was to prevent immigrants with contagious diseases from entering the country. Few federal public health officials other than the Surgeon General any longer where military uniforms, and most public health activities now are done under state or local jurisdiction. But 9/11 has affected public health as well, as public health has been called upon to prepare the nation for a "bioterrorist attack" utilizing lethal disease agents, like smallpox or anthrax. Many public health officials hope that public health can take advantage of the new funding available for terrorism preparedness, and not only do its part in national security, but also make "dual use" of the funding to help it fulfill its core missions of protecting the publics' health and preparing for "natural" epidemics.

September 11 was an event, not an epidemic, but the U. S. reacted to it as if it portends an actual epidemic of terrorist attacks against us. In this way, September 11 has been viewed by many in the public health community as a signal of a coming pandemic: akin to the rise of SARS in China, or a novel form of bird flu in Asia.[1] And public health has been asked to prepare for both natural and terrorist-induced epidemics simultaneously. Does 9/11 (and the subsequent rail attack in Madrid known as 3/11) mean we must make fundamental changes in public health practice regarding epidemic control and revert to 19th century Ellis Island-type quarantine and forced treatment? Must we trade off human rights and civil liberties for increased safety and security?

These are important and complex questions. In this article I argue that the answer to both of these questions is no, and that the movement in public health toward the adoption of a modern health and human rights ethical framework begun before 9/11 should continue.

Osama bin Laden and his homicidal Qaeda followers present a real danger to Americans, and the US should bring them to justice for their crimes. The U. S. is more vulnerable to terrorist attacks than we had believed; and we should strengthen our defenses. But we should not undermine our lives and our values by overreacting to the threat of terrorism. Preserving a human rights framework in the war on terrorists both preserves core American values, and makes it more likely that we will prevail in the long run. Ignoring or marginalizing human and constitutional rights, and treating Americans themselves as suspects or actual enemies is counterproductive and dangerous in itself — a conclusion I will support in this article with specific post-9/ll examples, such as public health preparedness plans for mass smallpox vaccination, the experiences of public health in the SARS epidemic, the enactment of new state public health vaccination and quarantine laws, and the use of torture on terrorist suspects and prisoners of war. Public health professionals are the "good guys" and rightly want to protect the publics' health. But the world has changed since the early 19th century, and reliance on coercion rather than education is no longer either legally justifiable or likely to be effective. In this regard, what might be labeled "public health fundamentalism", is as dangerous to the health and safety of Americans as Islamic religious fundamentalism.

The language of human rights also has the great advantage of being universal and thus global. Neither the fight against terrorists, nor the fight against epidemics, can be successfully waged on a local, state, or even national level alone: bother easily cross national boundaries and both can only be effectively confronted

by a global, cooperative, strategy. "Safety first" is a good thought, as is the Hippocratic injunction, "first, do no harm"; but neither safety nor inaction are ends in themselves, but only means to promote health and human rights. Sacrificing human rights for safety is almost never necessary and almost always counterproductive in a free society. Benjamin Franklin went further in expressing an American thought from "the land of the free and the home of the brave", saying, "Those who would give up an essential liberty to purchase temporary security deserve neither liberty nor security".

The Health and Human Rights Framework

The modern human rights movement, like American bioethics, was born from the devastation of World War II. The multinational trial of the major Nazi war criminals at Nuremberg following World War II was held on the premise that there is a higher law of humanity (derived from natural law rules based on an understanding of the essential nature of humans), and that individuals may be properly tried for violating that law. Universal criminal law includes crimes against humanity, such as murder, genocide, torture, and slavery. Obeying the orders of superiors is no defense: the state cannot shield its agents from prosecution for crimes against humanity.

The United Nations was formed almost immediately after World War II. Its Charter, signed by the 50 original member nations in San Francisco on June 26, 1945, spells out the goals of the United Nations. The first two are: "to save succeeding generations from the scourge of war...; and to reaffirm 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". After the charter was signed, the adoption of an

international bill of rights with legal authority proceeded in three steps: a declaration, two treaties, and implementation measures.

The Universal Declaration of Human Rights was adopted by the United Nations General Assembly in 1948 without dissent, as a "common standard for all peoples and nations". As international law expert Henry Steiner notes, "No other document has so caught the historical moment, achieved the same moral and rhetorical force, or exerted so much influence on the human rights movement as a whole".[2] The rights spelled out in the declaration "stem from the cardinal axiom that all human beings are born free and equal, in dignity and rights, and are endowed with reason and conscience. All the rights and freedoms belong to everybody."

Unlike ethical precepts that primarily govern individual conduct, human rights are primarily rights individuals have against governments. Human rights require governments to respect human rights by refraining from doing certain things, such as torture or limiting freedom of religion, to protect human rights by preventing their violation by private actors, and to fulfill human rights, such as providing education and nutrition programs. The United Nations adopted the Universal Declaration of Human Rights as a statement of aspirations. Legal obligations of governments were to derive from formal treaties that member nations would individually sign and incorporate into their domestic law.

Because of the cold war, with its conflicting governmental ideologies, it took almost 20 years to get agreement on the texts of the two major human rights treaties. The International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social, and Cultural Rights were both adopted by the UN General Assembly and opened for signature and ratification on December 16, 1966. The United States ratified the International Covenant on Civil and Political Rights in 1992, but not surprisingly given our capitalist economic system with its emphasis on private property, has yet to act on the International Cov-

enant on Economic, Social, and Cultural Rights. We have, nonetheless, signed other treaties that have special significance in the war on terror, including the Geneva Conventions, the Genocide Convention, and the Convention against Torture.

The rights spelled out in the International Covenant on Civil and Political Rights include equality, the right to liberty and security of person, freedom of movement, religion, expression, and association. The International Covenant on Economic, Social, and Cultural Rights focuses on human wellbeing, including the right to work, the right to fair wages, a decent living, and safe and healthy working conditions, the right to be free from hunger, and the right to education, and "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".

The Universal Declaration of Human Rights and the two subsequent treaties (sometimes called the International Bill of Rights) form a global human rights framework for action, and have a special relevance for global health. The relationship between health and human rights has been most persuasively articulated and most tirelessly championed by my colleague Jonathan Mann, the first director of the World Health Organization's Global Program on AIDS, whose life was tragically cut short in the September 1998 crash of Swiss Air flight 111. The World Health Organization has since adopted the health and human rights framework as its own. By broadening our perspective, human rights language highlights not only human freedoms, such as self-determination, but also basic human needs, such as equality, education, nutrition, and sanitation, whose improvement will have a major impact on improving human health.

World War II, arguably the first truly global war, led to a global acknowledgment of the universality of human rights and the responsibility of governments to promote them. Jonathan Mann perceptively noted that the AIDS epidemic can be viewed as the first global epidemic because it is taking place at a time when all

countries are linked both electronically and by easy transportation.[3] Like World War II, this worldwide epidemic requires us to think in new ways and to develop effective methods to treat and prevent disease on a global level. Globalization is a mercantile and ecological fact; it is also becoming a healthcare reality. The challenge facing medicine and health care, both before and after 9/11, is to develop a global language and a global strategy that can help to improve the health of all of the world's citizens. Clinical medicine is practiced one patient at a time, and the language of medical ethics is the language of self-determination and beneficence: doing what is in the best interests of the patient with the patient's informed consent. This is powerful, but has little direct application in countries where physicians are scarce and medical resources extremely limited.

Public health deals with populations and prevention — the necessary frame of reference in the global context. In a one-to-one doctor-patient relationship, for example, a combination of antiretroviral drugs for AIDS treatment makes sense. In the worldwide pandemic, however, such treatment may be available to fewer than 5% of the world's people with AIDS. The availability of a vaccine against a pandemic flu will also be severely limited. This is not just a matter of money, but also a matter of health care infrastructure and a lack of basic knowledge regarding how to effectively deliver drugs. In dealing with the AIDS pandemic it has become necessary to deal directly with issues of discrimination, immigration status, the rights of women, privacy and informed consent, as well as education and access to health care. Although it is easy to recognize that population-based prevention is required to effectively address the AIDS epidemic on a global level (as well as, for example, tuberculosis, malaria, and tobacco-related illness), it has been much harder to articulate a global public health ethic, and public health itself has had an extraordinarily difficult time developing its own ethical language. Because

of its universality and its emphasis on equality and human dignity, the language of human rights is well suited for public health.

On the occasion of the 50th anniversary of the Universal Declaration of Human Rights, in 1998, I suggested that the Universal Declaration of Human Rights itself sets forth the ethics of public health, since its goal is to provide the conditions under which humans can flourish. This is also the goal of public health. The unification of public health and human rights workers around the globe would be a powerful force to improve the lives of everyone. Without, I think, being seduced into wishful thinking, it should be stressed that the Universal Declaration of Human Rights is a much more powerful document than it was in 1948 because both global interdependence and human equality are much better recognized today.

Cynicism is understandable, but even our 2003 pre-emptive war on Iraq was often justified as a human rights war when weapons of mass destruction could not be found. Not only are human rights being taken more seriously by governments, but they are also increasingly a major driving force in private, non-governmental organizations (NGOs). Of course, there are different kinds of rights and more or less effective ways to enforce them. The new International Criminal Court can, for example, help to deter and punish those who engage in torture and genocide, but can do nothing to governments who fail to provide basic health care to their citizens. Moreover, to conclude that human rights is a more powerful language for good than medical ethics is not to conclude that medical ethics is irrelevant. On the contrary, medical ethics not only is necessary to make basic human rights a reality (e.g., by prohibiting physician involvement in torture and executions), but also can advance an anti-paternalistic public health agenda that supports public education and democracy in public health practice. It thus seems more fruitful to explore the ways in which bioethics and human rights can work together synergistically in

preparing for and coping with epidemics than to ignore either of them.

Bioterrorism

In the immediate aftermath of 9/11 it was easy for human rights advocates and civil libertarians to despair. Congress almost immediately passed the Orwellian-named USA Patriot Act, and authorized an international (and *1984*-like perpetual) global war on terror, and the Bush Administration also announced that it would disregard not only the United Nations but also fundamental international human rights and humanitarian law as expressed in the Geneva Conventions.

More recently, however, the tide seems to be changing, and many governmental actions are now met with considerable skepticism and even active resistance. The color-coded terrorist warning system, known by insiders as the "rainbow of doom", has been all but abandoned as too vague to do any more than scare the public. A proposal to enlist mail carriers and TV repair persons as "tipsters" (the so-called "tips" program) has been abandoned. Duct tape and plastic sheeting have done much more to enhance the routines of late night comedians than they have to enhance protection from chemical and biological agents.

We continue to be bombarded with bioterrrorism doomsday scenarios, although the major terrorist threats are not from biological agents. Rather they are from conventional weapons (e.g., firearms and bombs — including "dirty bombs", conventional explosives containing radioactive material), delivered either in trucks on by individual suicide bombers, as evidenced by terrorist activities in Israel for decades, by insurgent attacks in Iraq, and by terrorists worldwide. These create panic, but the most dangerous weapons are not chemical or biological, but nuclear. Our govern-

ment knows this. Although there were many inconsistent rationales given for going to war with Iraq, no one suggested it was because they possessed chemical or biological weapons: we have known about these weapons for more than two decades, and Iraq has actually used their chemical weapons on both civilian and military targets. It was the future prospect of possessing nuclear weapons that ultimately moved us to war.

Bioterrorism, nonetheless, continues to be hyped beyond all scientific or historic reality, even in the public health community which should know better. A leading public health lawyer, for example, has asserted that "a single gram of crystalline botulinum toxin, evenly disperse and inhaled, could kill more than 1 million people".[4] But, when looking at actual data, that same lawyer admits that in fact, when Aum Shinrikyo, the Japanese terrorist cult, actually "attempted to disperse aerosolized botulinum toxin both in Tokyo and at several military installations in Japan" the result was not millions dead, or even thousands or hundreds: rather all of these attacks "failed to kill anyone". Likewise, it has been asserted that the release of 100 kilograms of aerosolized anthrax over Washington, D. C. could kill up to three million people. The real anthrax attacks through the U. S. mails were highly effective in sowing terror in the populations, but resulted in only 5 deaths (the number killed in American hospitals by negligence every 30 minutes, or on our nation's highways every hour).

The scariest scenario involves smallpox because, unlike botulinum or anthrax, smallpox can be transmitted from one person to another. This is why the Bush administration used the threat of a smallpox attack from Iraq as one reason for us to fear Iraq, and as the almost sole justification for its massive three-phase smallpox vaccination program. That now-abandoned program was a public policy and public relations disaster, vaccinating only about 4,000 of the initially-proposed 500,000 health care workers the government planned to have vaccinated with the smallpox vaccine

during phase one (phase two would have encompassed up to 10 million first responders and public safety personnel, and phase three would have included all willing civilians).[5] Why?

I think the major reason is that the administration failed to persuade physicians and nurses that the known risks of serious side effects with the vaccine were justified given the fact that there is no evidence that Iraq (or anyone else) has both smallpox virus and the wish to use it in a terrorist attack. The information provided on this issue to the physicians and nurses was in the same spirit as the Iraq nuclear threat information, except that it contained no facts at all, not even misleading or phony ones. The Director of the CDC, and the person in charge of the smallpox vaccination program, for example, told a U. S. Senate Appropriations Subcommittee on January 29, 2003, about a month after the smallpox vaccination campaign began: "I can't discuss all of the details because some of the information is, of course, classified. But I think our reading of the intelligence that we share with the intelligence community is that there is a real possibility of a smallpox attack from either nations that are likely to be harboring the virus or from individual entities, such as terrorist cells that could have access to the virus. So we know it's not zero. And I think that's really what we can say with absolute certainty that there is not a zero risk of a smallpox attack".

This is wonderful doubletalk that proves nothing except that the CDC's director doesn't know much about the risk of a smallpox attack. Most importantly, however, is that if the U. S. government knows that an individual, group, or nation has smallpox and is working to make it into a weapon, this information should be made public. It is the terrorists who want to keep their methods and intentions secret: the best defense from a potential target is to make this information public. Since most Americans probably know this, the failure of the administration to offer any evidence at all of anyone possessing weaponized smallpox meant it was

highly probable that the administration had no such evidence. Thus the real risks of the vaccine could not be offset by any measurable benefit. Few were surprised then when after the Iraq war, in August 2003, an Institute of Medicine panel recommended that smallpox vaccination for civilians be abandoned; and by the summer of 2004 the entire effort was abandoned.[6] The bottom line is that the potential for biological terrorism is real (i.e., greater than zero), but very low, and in almost any foreseeable attack the number of deaths is likely to be low (as evidenced in the only real biological attacks to date, in which between zero and five people died). Planning is reasonable; overreaction creates more problems — including predictable adverse reactions to the vaccinations themselves — than it solves.

Bioterrorism and Epidemics

But what about a "real" epidemic, such as a new, worldwide pandemic? A repeat of the 1918 flu epidemic is likely at some point, and could prove devastating. We can and should produce vaccines against the annual flu epidemics. Our new emphasis on bioterrorism, however, has actually drained public health resources away from this effective vaccine. As the World Health Organization warned in late-2004, we need much better planning, and international cooperation, to prepare for an influenza pandemic.[7] Instead we are diverting funds away from this traditional public health concern which involves tens of thousands of deaths a year in the U. S. alone, and a predictable worldwide pandemic at some point, to trying to protect against an extremely unlikely bioterrorist attack. And it is here that we can determine whether or not "dual use" is a reality or just a marketing slogan. I agree with those who say that public health infrastructure generally must be improved for the sake of the nation's health. But where

I disagree is on what effect bioterrorism preparation will actually have on public health infrastructure.

I wrongly and naively (it turns out) expected the federal government to provide increased funding for public health in the wake of 9/11. There has been some funding for bioterrorism, but mostly public health departments have been struggling with more unfunded federal mandates and suggestions, and have had to actually divert funds from public health programs we know work to save lives and improve health, to bioterrorism preparation which has little or no public health payoff.

My own state of Massachusetts, for example, always a national leader in public health, has made major cuts in tobacco control, domestic violence prevention, and immunizations against pneumonia and hepatitis A and B. Public health dollars have shrunken $30 million in two years, during which time Massachusetts has received $21 million for bioterrorism-related activities, some of which could be categorized as "dual-use". Public health expert David Ozonoff of the Boston University School of Public Health accurately describes what is happening: "The whole bioterrorism initiative and what it's doing to public health is a cancer, it's hollowing out public health from within... This is a catastrophe for American public health".[8] This was dramatically demonstrated nationally in the fall of 2004 when the U. S. experienced a shortage of flu vaccine and was forced to ration it to Americans most at risk of death and hospitalization from the flu. Cartoonist Matt Davies caught the irony in his cartoon picturing a citizen coming to the door of the "Homeland Security Bio-Terror Readiness Unit" only to be greeted by a note pinned to the door reading, "Out with the Flu".

Other public health experts have put the weakening of public health in even most disturbing terms, noting "Worse, in response to bioterrorism preparedness, public health institutions are being reorganized along a military or police model that subverts the

relationships between public health providers and the communities they serve".[9] To the extent that these experts are correct, and I think they are, exaggerated fear of bioterrorism is resulting in overreaction that is already counterproductive in that it is harming both public health's effectiveness and its relationship with the communities public health serves.

Exaggerated risks produce extreme responses that are based more on fear than facts, so it is not surprisingly that they have unintended consequences. Public health planning should be based on science not free-floating anxiety and fear. Instead of using the tools of public health, especially epidemiology to gather data and risk-assessment, to identify most likely risks and work on them, our government seems to have adopted the bizarre notion that all threats are equal and that all states and localities should equally prepare for all of them. This philosophy has produced two interrelated epidemics in the U. S. today: an epidemic of fear, and an epidemic of security screening.

Human Rights and the SARS Epidemic

The SARS epidemic was our first, and so far only, post-9/11 contagious disease epidemic, but it also returned us to late 19th century Ellis Island days in that its cause and mode of transmission were initially unknown, there is no diagnostic test for it, there is no vaccine, and there is no effective treatment. But SARS also appeared in a society equipped with instant global communication that made management of people through information much more important than management of people through police actions. With the internet information now spreads like a virus, but much faster.

It is probably still too early to reach firm conclusions about which containment methods were or were not the most effective

in containing the disease. Nonetheless, since the epidemic has ended in all 30 countries in which suspected SARS cases were reported, and only a few countries used quarantine (detained individuals who showed no symptoms), it seems reasonable to conclude that quarantining "contacts" or even "close contacts" was unnecessarily harmful to those affected. It is not only liberty that is at stake in deciding about quarantine, but the effectiveness of public health itself in the 21st century. This is because to be effective in preventing disease spread from either a new epidemic or a bioterrorist attack, public health officials must also prevent the spread of fear and panic. Maintenance of public trust is essential to achieve this.

When any new contagious disease appears, public health officials must answer three related questions: should contacts be quarantined?, what test should be used to determine who qualifies as a "contact", and should quarantine be voluntary or mandatory? China has been rightly criticized for failing to promptly alert the international community to the existence of a possibly new and contagious virus. Had information about the initial outbreak been properly shared, SARS might never have spread beyond China. Nonetheless when, with the active intervention of the World Health Organization, the epidemic was publicly recognized, China reacted vigorously, even harshly, especially in Beijing and Hong Kong. Mass quarantines were initiated involving two universities, four hospitals, seven construction sites, and other facilities, like apartment complexes. Sixty percent of the approximately 30,000 people quarantined in mainland China were detained at centralized facilities, the remainder were permitted to stay at home. Those quarantined were "close contacts", defined as someone who has shared meals, utensils, place of residence, a hospital room, or a transportation vehicle with a probable SARS patient, or visited a SARS patient or been in contact with the secretions of a SARS patient anytime after 14 days before the SARS patient developed symptoms.

Based on the evidence available, it seems reasonable to conclude that these mass quarantines in China had little or no effect on the epidemic. Moreover, the imposition of quarantine led to panic that could have spread the disease if identification of contacts was necessary to contain SARS. When a rumor spread that Bejing itself might be placed under martial law, *China News Service* reported that 245,000 migrant workers from impoverished Henan province fled the city to return home.[10] Even in Hong Kong's Amory Gardens, the site of the initial cluster of SARS cases in Hong Kong, when officials came to relocate residents to a quarantine facility they found no one at home in more than half of the complex's 264 apartments.[11] People were able to evade the police even though the police were working closely with public health officials.

Canada had the only major outbreak of SARS outside of Asia, and it was limited to the Toronto area. Canada had about 440 probable or suspect SARS cases, resulting in 40 deaths, but many more lives were directly affected. Approximately 30,000 people were quarantined, although unlike China, almost all Canadians who were quarantined were confined to their own homes — and staying home, or "sheltering in place" seems to have become the new standard for isolating and protecting individuals in public health emergencies, at least in democracies.

Canadian officials were generally level-headed in their advice to the public, but seem to have overreacted on two occasions. In mid-April, 2003, before Easter, Ontario health officials published full-page newspaper ads asking anyone who had even one symptom of SARS (severe headache, severe fatigue, muscle aches and pains, fever of 38 Celcius or high, dry cough and shortness of breath) to stay home for a few days. Ontario's health minister said, "This is a time when the needs of a community outweigh those of a single person".[12] Again, in June, during the second wave of infections in Ontario, the health minister, responding to reports

that some people were not completing their 10 day home quarantines, said "I don't know how people will like this, but we can chain them to a bed if that's what it takes".[13] While the request may have arguably been reasonable, the threat was not. At a June 2003 WHO meeting on SARS, Health Canada's senior director general, Paul Gully, noted that intra-hospital transmission was the "most important amplifier of SARS infections" and wondered aloud about the utility of the widespread home quarantines during the Canadian epidemic. His reasoning was that very few of those quarantined wound up exhibiting symptoms of SARS.[14]

There were few cases of SARS in the U. S. and no deaths. The Centers for Disease Control and Prevention (CDC) worked with the World Health Organization and other countries to identify the SARS virus, and by issued guidelines and recommendations in press conferences and on its website. Perhaps the most important recommendationss involved travel. In this category the CDC issued both travel alerts (which consists of a notification of an outbreak of a specific disease in a geographic area and suggests ways to reduce the risk of infection and what to do if you become ill), and travel advisories (which include the same information, but further recommend against nonessential travel because the risk of disease transmission is considered too high). No attempt was ever made to prohibit Americans from traveling anywhere, although the federal government probably has the authority to do this for international travel (e.g., through passport limitations) should the risk of disease become extreme. Nor do there seem to have been any attempts in the U. S. by public health officials to quarantine asymptomatic contacts of SARS patients.

The CDC also issued reasonable guidance to businesses with employees returning from areas affected with SARS, recommending that while in areas with SARS those "with fever or respiratory symptoms should not travel and should seek medical attention" and upon return asymptomatic travelers "should be vigilant for

fever and respiratory symptoms over the 10 days after departure". Most important, the CDC noted that "those persons need not limit their activities and should not be excluded from work, meetings, or other public areas, unless fever or respiratory symptoms develop". In bold letters on its guidelines it underlined the point: "At this time, CDC is not recommending quarantine of persons returning from areas with SARS". The president did, nonetheless, add SARS to the outdated federal list of "quarantinable communicable diseases" on April 4, 2003, and customs and immigration officials were given the authority to detain those entering the U. S. who were suspected of having SARS. This authority, which has recently been expanded to include avian flu, was not exercised.

Of course, the public can overreact on its own, and in some cases clearly did — as restaurants in Chinatowns in New York and Boston were virtually empty for a time. The worst offenders were not the uninformed public, however, but academic institutions, some of which forbade their faculty and students to travel to areas that had SARS cases, or required them to spend ten days after they returned in self-imposed quarantine and obtain a physician's certificate that they did not have SARS before returning to campus. Academic institutions with similar policies included both Harvard and Boston University, even though the Boston Public Health Commission had reasonably advised on April 9, 2003:

> *At this point there is no evidence to suggest that a person without symptoms may infect others with SARS. In the absence of fever or respiratory symptoms, anyone who has traveled to high-risk areas or has been exposed to SARS patients may continue normal activities — isolation or quarantine is not recommended. Persons should not be excluded from school or work.*

Anita Barry, director of communicable disease control at the Boston Public Health Commission had warned only four days

earlier: "The biggest challenge for now with SARS is fear and rumor and panic".[15]

As a general matter, local public health officials acted very responsibly, even under extreme pressure. Although there were no quarantines in the U. S., there were cases in which isolation of symptomatic individuals was advised or mandated by local public health departments. In New York, 27 people were advised by the city health department to stay home for a period of ten days after their SARS fever had returned to normal. In addition, two individuals in New York City and one in Dallas were ordered to be isolated in hospitals because it was suspected they had SARS. The first of these was a young student on a tour around the world. He sought medical care in a New York City hospital and was diagnosed as a suspect case. He would have been quarantined at home, but had none, so he was ordered by the Department to remain in the hospital for ten days after his fever abated, and an unarmed security guard was posted at his door to enforce the order. He was offered an attorney to advise him about fighting the order, but refused. Ten days after the resolution of his fever he left town and has not been heard of since. The second case involved a person who was voluntarily in the hospital, but who became restless and wanted to leave before the ten days was up. He was ordered to stay, and put under guard as well.[16]

The third case, from Dallas, also sought care in a hospital and was diagnosed as a suspect case. He gave a false address. The Dallas County Department of Health and Human Services sought and obtained a court order requiring him to remain in the hospital for ten days. At the hearing all in attendance (including the judge) "were provided with protective gear to wear to avoid any possible exposure to the disease while in the presence of the patient".[17] This alone made it virtually certain that the judge would find the patient a potential danger to the public and order continued isolation, which he did.

In the midst of the SARS epidemic, New York City did, however, change its health code to permit the city's health commissioner to order the quarantine of individuals who "may" endanger the public health because of smallpox, pneumonic plague or other severe communicable disease. In addition, a contact may also be quarantined: someone who "has been or may have been" in "close, prolonged, or repeated association with a case or carrier". This change in the code from permitting the quarantine of people who actually pose a danger to the public health and who have actually been in close contact with infected individuals, to those who "may" pose a danger and those who "may" have been in close contact with them is breathtaking in its invitation to arbitrariness. Given this, it is disturbing that not one person showed up to testify at the April 28, 2003 public hearing on this change. In the case of SARS, for example, which the revised rules specifically reference in a section on "post-publication changes", the new regulation would have permitted the department to quarantine New York's entire Chinatown area since all residents there "may" have been in contact with someone who "may" have SARS. No one (thankfully) seems to have even suggested such a rerun of the totally arbitrary San Francisco Chinatown quarantine, allegedly for plague. Nonetheless, it is worth noting that even 19th century US courts, while granting extremely broad powers to public health agencies, condemned the arbitrary use of quarantine, even for smallpox, requiring public health officials to show "facts which warranted isolation".[18]

SARS may return, but the CDC is to be commended for providing the U. S. with a credible and open official (the CDC director, Julie Gerberding, herself) who informed Americans about what they could voluntarily do to avoid contracting or spreading the disease. Nationally, encouragement of sensible voluntary responses became policy, and no state invoked any emergency powers, including quarantine, in response to SARS. As a general rule,

sick people seek treatment and accept isolation to obtain it—people do not want to infect others, especially their family members, and will voluntarily follow reasonable public health advice to avoid spreading disease. SARS, like the threat of a birth flu pandemic, emphases that effective public health today must rely on actions taken at the national and international level, and that public health should be seen primarily as a global issue. Virtually every country in the world had to take some action to limit the exposure of its people to the disease.

SARS was a major public health challenge; but it is no less a medical challenge. At the beginning of the 21st century, sick people seek medical care. Individuals believed to be infected with the disease were (and continue to be) cared for one-by-one by physicians and nurses in hospitals. In fact, one of the salient aspects of the SARS epidemic is that many (in some countries, most) infections were actually acquired in hospitals, and many of those infected, and some who died, were physicians and nurses who cared for the patients. The dedication of the physicians and nurses who treated SARS patients was exemplary. Neither public health nor medicine alone could have effectively dealt with SARS. The old distinctions between medicine and public health are blurring, and perhaps the most important message is that public health and medicine must work together to be effective.[19]

Of course, SARS is not HIV/AIDS, which is not smallpox, which is not plague or tuberculosis or bioterrorism. Each infectious disease is different, and epidemiology provides the key to any effective public health and medical response to a new disease. The rapid exchange of information, made possible by the internet and an interconnected group of laboratories around the world (set up primarily for influenza identification and tracking), were critical to combating fear with knowledge. Information really does travel faster than even a new virus, and managing information is the most important task of modern public health officials. People

around the world, provided with truthful, reasonable information by public health officials who are interested in both their health and human rights will follow their advice.

Isolating sick people seems to have been critical to containing SARS, but better infection-control techniques in hospitals, and adherence to them, are equally necessary. Quarantining contacts, where it was attempted, seems to have been both ineffective (in that many, if not most, contacts eluded quarantine) and useless (in that almost none of those quarantined developed SARS). Mass quarantine is a relic of the past that seems to have outlived its usefulness. Attempts at mass quarantine, as evidenced by the experience in China, are now likely to create more harm than they prevent. They do this both by imposing unnecessary restrictions on liberty on those quarantined, and by encouraging potentially infected people to flee from public health officials.

In the midst of concern over bioterrorism, but after the SARS epidemic, the New York Academy of Medicine did a survey of the American public asking how they would respond to two types of terrorist attacks: smallpox and a dirty bomb. Published in September 2004, the surveys results support two lessons that were apparent on 9/11: (1) the primary concern Americans have in a crisis is the safety of their family members; and (2) the most important predictor of whether they will follow the advice of public officials is if they trust them to be telling the truth and to be guided by their welfare. Specifically, the survey found that only 40% of Americans would go to a vaccination site in a smallpox outbreak if told to do so, and only 60% would shelter in place for as long as they were told to in the event of a dirty bomb explosion.

The reasons given for not following advice are instructive. In the smallpox scenario, 60% had worries about the safety of the vaccine itself—twice as many who worried about getting smallpox themselves. The respondents also suggested ways to make them

more likely to cooperate. For smallpox, overwhelming majorities (94% and 88%) wanted to speak with someone who knew a lot about smallpox and who they trusted to want what was best for them. A physician not working for the government would fit the bill. In the dirty bomb case, the primary concern respondents had was the safety of their family members. 75% of those who would not shelter in place said they would do so if they could communicate with people they care about or if they knew they were safe. Overall the study concluded that "people are more likely to follow official instructions when they have a lot of trust in what officials tell them to do and are confident that their community is prepared to meet their needs if a terrorist attack occurs".[20]

These survey results are consistent with past bioterrorist exercises as well. As Senator Sam Nunn, who played the part of the president in the smallpox exercise, Dark Winter, in which mass quarantine failed: "There is no force on earth that can make Americans do something that they do not believe is in their own best interests and that of their families". On 9/11 itself, for example, many who survived in the twin towers did so only because they ignored the advice they got from the 911 operator to "stay where you are, help is on the way", and left the buildings (more than 2,500 by elevator) before they collapsed.

Given the data from real world events, public opinion surveys, and mock exercises, it is quite remarkable that some public health officials are still at home with draconian 19th century quarantine and compulsory treatment methods. This is likely because public health officials, who believe all their actions are designed to protect the public, are much more concerned with false positives (failing to treat of detain someone who actually has a communicable disease) than with false negatives (detaining someone who actually does not have a communicable disease), and believe that brute force can effectively control the behavior of Americans in an epidemic or bioterrorist attack. To the extent this faith in

coercion remains alive in the public health community, it is predictable that public health officials with the power to arbitrarily quarantine large numbers of people in an emergency will use it immediately, whether it is warranted or not. From their perspective, protecting public health is more important than protecting liberty, and as public health officials they may really believe they have nothing to lose. But abuse of power will predictably destroy public trust and instill panic. Even totalitarian dictatorships like China cannot control their populations in epidemics by fear alone in the 21st century.

It cannot be emphasized enough that the primary goal and purpose of public health is prevention of disease in the first place. In the case of bioterrorism, this means prevention of the attack is much more important (to public health) than responding to it after the fact. And contemporary public health prevention of epidemics and bioterrorism is not primarily a local or state issue at all, but is fundamentally a global security issue that must be dealt with by the community of nations working together. National laws and treaties, with realistic inspection and sanctions, devoted to preventing the development and production of biological weapons are the most important tool in the prevention of bioterrorism. We are also right to want to modernize the World Health Organization's International Health Regulations: but, as WHO recognizes, to be effective revised regulations must be founded on respecting and protecting human rights, not trampling them.

State laws, no matter what they say, and no matter what the CDC says, simply cannot prevent or control bioterrorism. Moreover, by seeming to grant unconstitutional power over citizens lives and liberty, bad state public health emergency laws undermine public trust and are thus a danger to public health itself. Florida's crude summary of CDC's-sponsored "model act" which seeks to trade off human rights for safety and security, provides the coun-

try's starkest example, and thus helps illustrate why honoring rather than destroying human rights is essential to effective public health action in the 21st century.

Florida's Public Health Emergency Statute

There has been an epidemic of new state laws addressing public health powers in the event of a bioterrorist attack or epidemic since 9/11. Florida's is by far the most extreme. Perhaps because it was the site of the first anthrax letter attack, Florida was fertile grounds for all sorts on so-called antiterrorist legislation. Within a year of September 11, the Florida legislature passed, and Governor Jeb Bush signed, 21 bills related to terrorism. One of these 21 bills (2002-2269) was based at least in part on the CDC-sponsored model, adopting the scheme of declaring a public health emergency to trigger additional government powers, and vesting this power in the state's "health officer". That model bill itself was heavily influenced by Portugal — one of its chief draftsmen reporting that he had just finished reading Jose Saramago's *Blindness,* and that the quarantine of the blind in the novel scared him to death. He apparently missed the section of the novel in which Saramago reported, "Oh yes, the quarantine did not work".

The state officer's emergency powers are in four categories: (1) the shipment of drugs in the state, (2) the provision of bulk drugs by pharmacists, (3) the temporary licensing of certain health care practitioners, and (4) power over individuals.

There are major problems will all of the provisions (especially the extraordinarily broad definition of "public health emergency" which, for example, would include the annual flu epidemics and HIV disease), but section 4, on the power over individuals, is so out of step with anything else in the rest of the country, and so

inconsistent with basic human rights and constitutional law, that it warrants scrutiny. The operative section gives the State Health Officer the following power over individuals in a public health emergency:

> 4. *Ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to quarantine.*
>
> a) *Examination, testing, vaccination, or treatment may be performed by any qualified person authorized by the State Health Officer.*
>
> b) *If the individual poses a danger to the public health, the State Health Officer may subject the individual to quarantine. If there is no practical method to quarantine the individual, the State Health Officer may use any means necessary to treat the individual.*
>
> *Any order of the State Health Officer given to effectuate this paragraph shall be immediately enforceable by a law enforcement officer...*[21]

This section of the Florida law can be usefully contrasted to a Minnesota law on the same subject, which rather than trading off civil liberties for security, takes a human rights and health approach. Specifically, the Minnesota law provides: "individuals have a fundamental right to refuse medical treatment, testing, physical or mental examination, vaccination, participation in experimental procedures and protocols, collection of specimens and preventative programs" even in a public health emergency.[22]

All four parts of this provision are extreme, and each shows how public health can drastically overreact to a perceived threat in ways that are counterproductive to public health and devastating to human rights. The first part, relating the "ordering an individual to be examined..". makes no public health sense at all, because there is no characteristic of the individual that gives rise

to any suspicion or reason to believe that the individual either has the disease in question or has been exposed to the disease. Instead, the mere presence of a disease in Florida that the state health officer designates as creating a "public health emergency" authorizes anyone designated as "qualified" by the state health officer to order anyone to be "examined, tested, vaccinated, treated or quarantined". Mere refusal results in quarantine, without *any* evidence even of exposure to disease, let alone that the person is a threat to others. This is not public health, but authorization for a public health police state. This police-suspect model is the core mistake of the entire approach: Americans (Floridians) are not the enemy in a bioterrorist attack, and to prearrange a response that has the police seek out, confine, and forceably inject innocent Floridians is makes no scientific or public health sense. The enemy is the bioterrorist — although neither current law nor this Florida statute would permit police to do the things to a suspected bioterrorist it authorizes police to do to innocent Floridians. This law not only misses the target, in shots in the wrong direction altogether.

But the third part, 4(b), is the most extreme and offensive and it is difficult to believe that anyone in the legislature actually read it. The first sentence makes perfect sense, and summarizes the law in virtually every state: "If the individual poses a danger to the public health, the State Health Officer may subject the individual to quarantine", at least so long as the phrase "provided this is the least restrictive alternative available" is understood. But the second sentence has no legal pedigree at all (at least outside of totalitarian states): "If there is no practical method to quarantine the individual, the State Health Officer may use any means to vaccinate or treat the individual". This could be labeled the "torture exception". If the risk is big enough to society, we can torture bioterrorists (and their victims!). But governments cannot engage in torture (or slavery or murder) under any circumstances under

applicable international human rights treaties, even where the very survival of their country is at risk. Article 7 of the International Covenant on Civil and Political Rights is unambiguous: "No one shall be subjected to torture or to cruel, in human or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation". And article 7 is one of the articles from which no derogation is permitted, even "in time of a public emergency which threatens the life of the nation". Because this section authorizes the violation of international law prohibition on torture, it is shocking to see it as part of a public health law.

For almost all potential bioterrorist agents there is neither a vaccine nor an effective treatment; and even for garden variety new epidemics that could qualify as public health emergencies under the statute, like SARS, no approved treatment exists. So, what can this provision possibly mean? That the state health officer can compel the use of potentially dangerous experimental drugs? But this is a fundamental violation not only of international law, but also of basic US constitutional law, and US federal drug law. No state law can, of course, overturn any, let alone all, of these higher laws. Even assuming that there is an approved vaccine that could also serve as a treatment if delivered to an exposed person quickly (the smallpox vaccine seems to have been what whoever drafted this language was likely thinking about), what justification can there be for forcing the vaccination "by any means"? The state gives only one, "if there is no practical method to quarantine the individual". But the entire statute is based on the premise that state public health officials know how to respond to a public health emergency, and should have the power to quarantine if needed.

This provision undercuts that assumption that state public health officials have done any planning at all, and instead assumes that the state will not be able to even provide quarantine facilities

where needed — although it can also be read more cynically, to say the state need not provide quarantine for vaccination refusers but can simply force vaccination on everyone. Either way, there is no constitutional or human rights justification for forced treatment. Americans have a constitutional right to refuse any medical treatment, even lifesaving treatment. It is also a fundamental principle of medical ethics that patients have the right to informed choice, and the right to refuse any medical intervention. An emergency may justify very short periods of confinement of individuals who public health officials believe pose a risk to others, but nothing justifies this type of "treatment".

Perhaps the only good news about the Florida statute is that even in the wake of 9/11 and the drumbeat of the threat of a possible smallpox attack, no other state has passed anything like it. The Florida legislature, and its governor, should be ashamed.

Terrorism and Torture

My use of the word "torture" in the context of public health emergencies may strike readers as extreme. In the post-9/11 context, however, Florida's public health law can be seen as consistent with Bush administration anti-terror policy, that has condoned torture in other contexts, and that has only been subject to serious court reviews in 2004. So far most American courts have, rightly I think, insisted that U. S. constitutional rights, and international human rights, must be respected, even when dealing with a suspected terrorist. In the wake of the September 11, the White House legal counsel, who has since been promoted to Attorney General, argued that the Geneva Conventions (which prohibit not only torture, but all inhumane and degrading treatment) do not apply in the war on terror, with specific application to the prisoners held at Guantanamo;[23] and Justice Department lawyers went

even further, arguing that the president as commander in chief had the authority to order torture of prisoners, and that obeying such an order would be a valid defense to a war crime or crime against humanity charge. In the language of the memorandum, the criminal anti-torture statute "does not apply to the President's detention and interrogation of enemy combatants pursuant to his Commander-in-Chief authority".[24] This memorandum was only officially withdrawn and replaced at the end of 2004, just before the hearings on the nomination of Alberto Gonzales to be Attorney General.

The road to the Abu Ghraib torture scandal began when the president decided in February 2002 that the Geneva Conventions would not apply to "enemy combatants" jailed in Guantanamo.[25] This decision was made over the strong objections of the Secretary of Defense, Colin Powell, and without any meaningful input from the career lawyers in the armed forces, all of whom objected to jettisoning the Geneva Conventions, a treaty we had honored for more than 50 years.

The reason given for taking prisoners to Guantanamo was that the global war on terror was a "new kind of war" that made the Geneva Conventions inapplicable, and that Guantanamo could and should be used as an interrogation center outside the jurisdiction and thus the oversight of the U. S. courts. The rationale was that if neither the U. S. Constitution nor international law applied in Guantanamo, the administration could write its own rules of conduct for the prison, and it did. Secretary of Defense Donald Rumsfeld, for example, specifically approved types of torture that could be used in the interrogations there, and involved physicians in it by requiring that prisoners obtain "medical clearance" prior to having these techniques applied to them. In the words of his directive, the new techniques can only be used after, among other things, "the detainee is medically and operationally evaluated as suitable

(considering all techniques to be used in combination)".[26] Although these torture techniques were only approved for Guantanamo, they ultimately made their way to Abu Ghraib.

The Geneva Conventions were to apply in Iraq, according the administration. Had they been followed, the torture and abuse of prisoners at Abu Ghraib would not have occurred. Had the physician and nurse military officers at Abu Ghraib been more knowledgeable about the Conventions, and more confident about their roles as both healers and officers, it is also likely that the abuses would have been halted much sooner than they were. No only do the conventions prohibit torture and abusive and humiliating treatment of prisoners of war, the protocols also specifically protect physicians who follow medical ethics.

In the early summer of 2004, the U. S. Supreme Court ruled that prisoners at Guantanamo could bring habeas corpus actions in U. S. courts.[27] It thus rejected the position of the Bush administration as stated in oral argument before the Ninth Circuit that even if the U. S. was engaged in "murder and torture" at Guantanamo, U. S. courts could not interfere. In another case decided that same day, the U. S. Supreme Court ruled that a U. S. citizen captured on the battlefield, and originally held at Guantanamo, had a right to a fair hearing under the U. S. Constitution to contest his status as an "enemy combatant".[28] The prisoner who brought this case, Yaser Esam Hamdi, has since been released without charges ever having been filed against him. Although it did not have to rely on it for its conclusion, in its opinion the U. S. Supreme Court cited provisions of the Geneva Convention III (relative to prisoners of war) as authoritative on the "law of war". More recently a U. S. District court has ruled explicitly that the Geneva Conventions must be followed at Guantanamo.[29]

It is important for U. S. courts to continue to recognize international law as our own, and to provide even non-U. S. citi-

zens with a judicial remedy for extreme unlawful acts such as torture and murder. Thus, prisoners at Abu Ghraib and Guantanamo who were tortured can sue their torturers in U. S. courts for money damages.[30] Compensation is important to victims, as is having their day in court. Of course, torture and abuse of prisoners is also a crime, and the perpetrators can be prosecuted — as some of the soldiers involved in the abuses at Abu Ghraib have been. Most important, however, is prevention.

Torture, like terrorism, remains widely practiced around the world, even though both are rightfully and universally condemned. Amnesty International, for example, estimates that 150 countries may condone torture. Physicians, unlike the Red Cross, are present in almost every prison in the world; and because torturers often rely on physicians to help them, physicians are in a unique position to prevent torture. Under international medical ethics, international law, including the Geneva Conventions, and U. S. military doctrine, and no other profession has the moral and societal warrant to be effective in torture prevention. Lawyers also have special obligations to help protect physicians — because of their role in upholding the rule of law, including international humanitarian law. The challenges of the war on terror present an opportunity for medical and legal professional organizations to work together transnationally to uphold both medical ethics and international humanitarian law.

Federal policies that violate international human rights and humanitarian law are both illegal and immoral. I think the same can be said for the states that have adopted provisions that make public health officials immune from lawsuits for any action taken during a public health emergency that injures members of the public — even for forced "treatment" amounting to torture. Immunity encourages unlawful and arbitrary action, neither of which have any place in public health or medicine.

Conclusion

At the outset of the 21st century bioterrorism, although only one threat to public health, can be the catalyst to effectively federalize and integrate much of what is now uncoordinated and piecemeal state and local public health programs. This should include a renewed effort for national health insurance, national licensure for physicians, nurses, and allied health professionals, and national patient safety standards. Federal public health leadership will also encourage us to look outward, and to recognize that prevention of future bioterrorist attacks and even ordinary epidemics will require international cooperation. As the SARS epidemic illustrates, it is time to not only federalize public health, but to globalize it as well. And universal human rights is the proper foundation for a global public health ethic.

Our new kind of war against bioterrorism should be built on a goal of protecting liberty, not depriving Americans of it. There is a knee jerk tendency in times of war and national emergencies to restrict civil liberties as the most effective way to counteract the threat. But history has taught us that such restrictions are almost always useless and often counterproductive, and we usually wind up with deep regrets for our action. The tendency to return to the days before liberty and informed consent were taken seriously has been evident both in the immediate aftermath of 9/11. Arbitrary and unlawful responses have not, however, helped make Americans safer or more secure, instead they threaten the very liberties that make our country worth protecting. It is wrong and dangerous for our government to treat its citizens either as enemies to be controlled by force or children to be pacified with platitudes. We will not prevail in the modern war on terrorism by relying on medieval torture, nor will we prevail in preventing pandemics by relying on quarantines from the dark ages.

America is strong because its people are free, and to be both moral and effective public planning for war and public health emergencies must be based on respecting freedom and trusting our fellow citizens. The United States should join with the international community in proclaiming a new, global public health, based on transparency, trust, and science, and most importantly, based on respect for human rights. We don't need a new Statue of Security: the Statue of Liberty is just fine.

Notes

[1] See generally, Markel, Howard. *When Germs Travel : Six Major Epidemics that have Invaded America Since 1900 and the Fears they have Unleashed.* New York: Pantheon Books, 2004; and Garrett, Laurie. *The Coming Plague : Newly Emerging Diseases in a World out of Balance, Farrar,* New York : Straus and Giroux, 1994.

[2] Steiner, H. G. Securing Human Rights, *Harvard Magazine* 1998; Sept.-Oct., 45-46.

[3] See generally, *Health and Human Rights: a Reader* (Mann, Jonathan M. (editor) *et al.,*) New York : Routledge, 1999 and Mann, Jonathan, Gostin, Lawrence, Gruskin, Sofia *et al.,* "Health and Human Rights"*, Health and Human Rights.* 1994; 1.

[4] Gostin, L. O., "When Terrorism Threatens Health: How Far are Limitations on Personal and Economic Liberties Justified", *Florida Law Review* 2003; 55: 1105-1169.

[5] Stevenson, Richard, Stolberg, Sheryl Gay "Bush Lays Out Plan on

Smallpox Shots: Military is First", *New York Times*, Dec. 14, 2002, 1A; and McNeil, Donald "2 Programs to Vaccinate for Smallpox are 'Paused", *New York Times,* June 19, 2003, A13.

[6] See also Calabresi, M., August, M., "Was Smallpox Over-hyped?", *Time,* July 26, 2004, 16.

[7] See, e.g., *WHO Consultation on Priority Public Health Interventions* (available at www.who.org)

[8] Stephen Smith, "Anthrax vs. the Flu: As State Governments Slash Their Public Health Budgets, Federal Money is Pouring in for Bioterror Prepardedness", *Boston Globe,* July 29, 2003, C1, C4.

[9] Cohen, H. W., Gould, R. M., Sidel, V. W., "The Pitfalls of Bio-terrorism Preparedness: the Anthrax and Smallpox Experiences", *American Journal of Public Health,* 2004; 94: 1667-1671.

[10] Hutzler C., "China Reverts to Top-down Rule with Heavy Hand to Fight SARS", *Wall Street Journal,* May 8, 2003, Al; Chang, L., "In the Face of SARS, Beijing reverts to a Quite Village", *Wall Street Journal,* May 12, 2003, A1.

[11] Pottinger, M. *et al.,* "Quarantine Quandary", *Wall Street Journal,* April 1, 2003, B1; Eckholm, E., "Thousands Riot in Rural Chinese Town over SARS", *New York Times,* April 28, 2003, A1.

[12] Altman, L. K., Fearing SARS, "Ontario Urges Wider Quarantines", *New York Times,* April 18, 2003, Al.

[13] "'Bed Chains' for Canada SARS Violators", *BBC News,* June 1, 2003.

[14] Cohn, M. R., *Nations must stay on SARS Alert : WHO, Hamilton Spectator* (Ontario, Canada), June 18, 2003, D1; and personal communication, July 16, 2003.

[15] Smith, S., "US allows for SARS Quarantines", *Boston Globe,* April 5, 2003, A2.

[16] Altman, L. K., "Public Health Fears Cause New York Officials to Detain Foreign Tourist", *New York Times,* April 28, 2003, A5, and personal communication with M. Layton and W. Lopez, July 24, 2003.

[17] Press release, *CDC says Possible SARS Patient Test Results are Negative for SARS,* Dallas County Dept. Health and Human Services, July 14, 2003.

[18] Department of Health and Mental Hygiene, New York City Board of Health, Notice of Adoption of Amendments to Sections 11.01 and 11.55 of the New York City Health Code.

[19] Mariner, W. K., "Public Health and Law: Past and Future Visions", *J. of Health Politics, Policy and Law.* 2003; 28: 525; 550.

[20] New York Academy of Medicine, *Redefining Readiness: Terrorism Planning through the Eyes of the Public,* Sept. 14, 2004 (prepared by Roz D. Lasker). (available at www.nyam.org)

[21] Florida Statute Sec. 381.00315 (2002) (Public Health Emergency Act).

[22] Minnesota Statute Sec. 12.39 (2003) (2002 Minnesota Chapter Law 402, singed by the governor on May 22, 2002).

[23] Memorandum for the President from Alberto R. Gonzales. Decision re application of the Geneva Convention on prisoners of war to the conflict with Al Qaeda and the Taliban. Jan. 25, 2002. Torture is absolutely prohibited by the Covenant on Civil and Political Rights, and there are no exceptions to the prohibition, even when the "survival of the nation" is at stake (which it *never* is in a bioterrorist attack in any event). Caleb Carr makes the case that to have any hope of finally ending it, terrorism must be categorized in the same absolute prohibition terms in international law (i.e. as a crime against humanity) as torture, slavery, and genocide, in his The Lessons of Terror: A History of Warfare Against Civilians, Random House, New York, 2002.

[24] Memorandum for Alberto R. Gonzales, Counsel to the President, from Jay S. Bybee. Re: Standard of conduct for interrogation under 18 U. S.C. sections 2340-2340A. August 1, 2002. (replaced with new Justice Dept. Torture memorandum in the last week of December, 2004).

[25] Memorandum from the President. Humane Treatment of al Qaeda and Taliban Detainees. February 7, 2002. See also, Golden, T. After "Terror, a Secret Rewriting of Military Law". *New York Times,* October 24, 2004, Al; Miles, S. H., Abu Ghraib: Its Legacy for Military Medicine. Lancet 2004; 364: 725-729; and Beam, T. E., Sparcino, L. R., Pellegrina, E. D., Hartle, A. E., Howe, E. G. (editors) *Military Medical Ethics.* 2 vols., Uniformed Services. Bethesda, Md., University of the Health Sciences, 2003.

[26] Memorandum from Secretary of Defense for Commander, U. S. Southern Command. Counter-Resistance Techniques in the War on Terrorism. April 16, 2003. See also, Schlesinger, J. R., Brown H., Fowler, T. K., Horner, C. A., Final Report of the Independent Panel to Review DoD Detention Operations. August, 2004. And see Annas, G. J., "Unspeakably Cruel: Torture, Medical Ethics, and the Law". *New England J. Medicine*. 2005; 352 : 2127-2132.

[27] Rasul v. Bush, 2004; 124 S. Ct. 2686.

[28] Hamdi v. Rumsfeld, 2004; 124 S.Ct. 2633.

[29] Hamdan v. Rumsfeld, 2004 D.D.C; 344 F. Supp. 2d 152

[30] Sosa v. Alvarez-Machain, 2004; 124 S. Ct.

Caring for Survivors of Torture and Refugee Trauma in the United States and Portugal

MICHAEL A. GRODIN, M. D.*

Despite attempts by the world community to address human rights violations, torture and ill treatment are still practiced in more than 150 countries[1]. Unfortunately, physicians are known to have been involved in torture, both by assessing prisoners before and during torture, and also by falsifying medical certificates and autopsy reports[2]. With rapid globalization and increasing numbers of refugees and asylum seekers, physicians and lawyers in Portugal will encounter growing numbers of torture survivors. However, many physicians and lawyers may not be comfortable discussing physical, sexual, or psychological abuse with their patients and clients respectively[3]. Moreover, survivors may find it difficult to reveal their prior torture experiences to these professionals[4]. In this article, we respond to professionals' and survivors' needs by presenting a sensitive approach to identifying and caring for survivors of torture.

---

* Departments of Health Law, Bioethics, and Human Rights; Psychiatry; and Socio-Medical Sciences and Community Medicine, Boston University Schools of Public Health and Medicine, and the Boston Center for Refugee Health and Human Rights.

Presented at the Luso-American Development Foundation's conference: "The Role of Health Law, Bioethics, and Human Rights to Promote a Safer and Healthier World", June 2-3, 2005.

Paper adapted from Piwowarczyk L, Moreno A, Grodin M. Health Care of Torture Survivors. JAMA 284 : 539-541. The author would like to thank Rebecca Scudiere for assisting in the preparation of this manuscript.

What is torture?

The United Nations *Convention against Torture and Other Cruel, Inhuman, and Degrading Treatment or Punishment* defines survivors of torture as those who have endured acts "by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him [or her] or a third person information or a confession, punishing him [her] for an act he [she] or a third person has committed or is suspected of having committed, or intimidating or coercing him [her] or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or any other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in, or incidental to lawful sanctions"[5].

The goal of torture is to break down political opposition partially through coercion and humiliation. Although torture is typically practiced to stifle democracy by keeping the general population silent, it may also be used to coerce neutral parties — effectively making torture an instrument of ethnic cleansing[6]. Torture is often viewed as only affecting an individual, but it also impacts the family of the victim, his/her community, and society at large.

In response to more aggressive human rights monitoring, methods of torture have become more psychological in nature, so as not to leave physical signs[7]. The Center for Victims of Torture in Minneapolis, MN, USA, reports that heightened psychological damage is inflicted by methods such as sham executions, sexual torture, disappearance of a loved one, threats against family members, prolonged arbitrary detention — especially with sensory deprivation, and being forced to witness the torture of others[8].

Torture has the capacity to destroy fundamental human capacities, including the general abilities to trust another human

being and engage in life[9]. More specifically, Silove[10] suggests that torture threatens psychological functioning in the areas of personal safety, attachment and bond maintenance, identity and role functioning, justice, and existential meaning. Illustrating the extreme impact of torture on victims' personal values, Susannah Sirkin from Physicians for Human Rights reports that when a South African survivor of torture was released from prison, he indicated that if he had to choose between 10 years in prison and one hour of torture, he would choose 10 years in prison (oral communication, April 2000). Regarding torture's effects on social functioning, psychiatric co-morbidity in refugees — who often have histories of torture — has been associated with disability independent of age, the degree of trauma, and health status[11]. Also, the potential long-term psychological sequelae of torture have profound implications on quality of life, economic self-sufficiency, social reconstruction, and adjustment to a new country.

Torture and Refugee Trauma in the United States

Recent data indicate that more than 400,000 survivors of torture are now living in the United States and that this number is likely to increase[12]. Several risk factors are associated with a history of torture (Table 1)[13]. The overall prevalence of torture among refugees has been estimated to range from 5%-35%[14]. Other information about the prevalence of torture is based on local surveys.

From a sample of 735 ambulatory care patients who sought services at a large urban medical center between 2000 and 2004, fully 603/735 (82%) reported a history of being personally tortured, while 312/735 (42%) said they endured sexual trauma (unpublished data). Also, 54% of respondents had a family member

Table 1: Risk Factors for Torture

• Refugee or asylee status
• Leader of an opposition organization
• Relative of a victim
• History of arrest or detention
• Originating from or having lived in a flash-point country (i.e. Bosnia, Rwanda)
• Prisoner of war
• Immigrant from a country with a totalitarian or military regime
• Member of a minority group (religious, ethnic, political)
• Originating from or having lived in a country engaged in civil war

Adapted from Weinstein *et al.*

experience torture (unpublished data). In a previous study at the same medical center involving 142 foreign-born internal medicine ambulatory care patients, 18 subjects reported personal experience of torture. The UN definition of torture was met in 16 (89%) of these cases, revealing a torture prevalence of 11% (16/142, 95% confidence interval 6-17%). While most patients in this previous study (15/23, 67%) reported discussing their experience of torture with a health care provider, 8/23 (33%) reported that this survey was their first disclosure to anyone in the USA[15].

Torture and Refugee Trauma in Portugal

Amnesty International was founded in 1960 partially in response to two Portuguese students who received seven-year prison sentences for raising their glasses in a toast to freedom. The allegations of torture and ill treatment in Portugal continue to this day.

There have been reports of illegal detention and ill treatment during arrests and identity checks. Between 1996-1999, there were 14 deaths in police custody as a result of severe beatings and

shootings. In prisons, guards reportedly have abused inmates based on race. There have also been cases of prisoners being brutally beaten and kicked. Insufficient prison staff and overcrowding have contributed to an unhealthy, chaotic environment in prison facilities: Poor hygiene and sanitation allow for cockroach, flea, and rat infestations, while prisoners lack access to adequate health care. As a result of poor living conditions and medical neglect, infectious disease and substance abuse are commonly found among inmates. Some improvements have been made, yet further efforts are still necessary[16].

Portugal has the fewest asylum applications of all European Union nations. This country does not offer any reunification procedures or resettlement programs. For a nation of its size, Portugal has a disproportionately low number of asylum applicants. For instance, in 2003, Greece had 5,000 asylum applications and Denmark had 12,000; Portugal had only 88 asylum applications that year — a 50% decrease from 2002. Of the 88 asylum seekers in Portugal in 2003, only 2 were granted asylum, while 11 were given residence permits on humanitarian grounds. The other 75 asylum seekers, or 85%, were deported[16].

In April 2003, the Portuguese Refugee Council (PRC) and CAVITOP (Centro de Apoio a Vitimas de Tortura — Portugal) signed a protocol to provide free, systematic, and continuous psychological and psychiatric care to survivors of torture. The PRC will identify symptoms of torture among refugees and then refer them to CAVITOP for evaluation and treatment. Results have been positive thus far.

An Approach to Caring for Survivors of Torture

We suggest that every patient who is a refugee should be treated as having a possible history of torture. Kinzie *et al.,*[17]

suggest a chronological method for interviewing refugees about these issues. According to this approach, clinicians should ask sequentially about the following[17]:

- Life in the home country before leaving and the problems and stresses that occurred there
- The escape process: Why did he/she leave, who came and who stayed, were there any dangerous situations or losses along the way?
- Refugee camp problems and difficulties
- Attitudes about being in the USA: Problems, difficulties, successes
- Current worries and views of the future

Within the clinical context, health professionals may ask about the experience of torture. In fact, the clinician may be the first person with whom the survivor of torture shares his/her story. Patients' disclosure of their persecution requires sensitivity on the part of the health professional, as well as a firmly established trust-based relationship. Thus, physicians should be aware of this patient population's special needs. Furthermore, they should individualize the depth, manner, and timing of inquiry in each case. Health care professionals should also give careful explanations and educate their patients throughout the interview and exam processes[4]. Note that overly aggressive questioning may recapitulate prior traumatic events. Similarly, the examination room may simulate the torture experience. Needles, instruments, EKG electrodes, prone or angled positions, pelvic and rectal exams, and loud noises may all serve as retraumatization initiators.

In addition to knowing potential triggers, health professionals working with refugees should be aware of other difficulties embedded in the complex process of clinically assessing and caring for this patient population. For instance, an initial denial of torture

does not necessarily negate the possibility of such a history. In their work with Southeast Asians, Mollica and Caspi-Yavin[18] report that "changes in the reporting of torture events may be due to (*a*) high emotional arousal with associated hyperbole or defensiveness for some individuals in reporting the torture events; (*b*) impaired memory secondary to psychiatric and neurological impairments (e.g., beatings to the head and subsequent head injury); (*c*) culturally prescribed sanctions that allow the trauma experience (e.g., rape trauma for Indochinese women) to be revealed only in highly confidential settings; and (*d*) coping mechanisms that use denial and the avoidance of memories or situations associated with the trauma". Moreover, unless clinicians understand their own discomfort with listening to recounts of torture, they may either unknowingly communicate that it is inappropriate to discuss such material or actually take pleasure in hearing graphic descriptions of violence.

If health care professionals acknowledge the reality of the psychological and physical consequences of torture[19], become familiar with the special needs of refugees and survivors of torture, and engage in self-reflection, they can create a therapeutic climate of trust. In addition to taking a complete trauma history, it is also appropriate for health care professionals to perform physical and mental health examinations, update vaccinations, conduct nutritional and dental assessments, and screen for anemia, tuberculosis, intestinal parasites, malaria, syphilis, hepatitis, and human immunodeficiency virus.

The Psychological Impact of Torture

Posttraumatic stress disorder (PTSD) symptoms are commonly found among refugees and survivors of torture. Development of PTSD is related to the perceived severity of torture, the impact of captivity on family and other life areas, and other post-captivity

stressors[20]. Several factors are potentially protective: prior knowledge and preparedness for torture, strong commitment to a cause, immunization against traumatic stress as a result of repeated exposure, strong social supports[21]; belief systems[22]; political commitment, social support in exile, prior knowledge and preparedness for confinement and torture, and Buddhist spirituality[23]. Not all torture survivors are functionally disabled, and further research must be done to better understand some survivors' resiliency.

Mental Health Treatment

Although psychiatric morbidity, especially PTSD, is associated with exposure to torture, mental health services are perceived as undesirable in certain cultures. Thus, familiarity with best practice guidelines for the treatment of PTSD is advised[24]. These guidelines emphasize culturally acceptable education about the impact of trauma, acute stress reactions, and PTSD; the importance of patients' telling their stories; and the provision of social support for survivors.

Selective serotonin reuptake inhibitors (SSRIs) are considered the first line treatments for PTSD[25]. Although earlier studies recommended a trial of 8 to 12 weeks before changing medications, more recent investigations — especially with SSRIs — have found symptomatic improvement within 2 to 5 weeks. Medications are also frequently considered if psychological sequelae of torture are severe or persistent, or if there is impairment in functioning. Other indications for medication include severe insomnia, associated co-morbidity — including depression, anxiety, suicidal thoughts, and ongoing stress — and persistent symptoms despite psychotherapy. Referral for psychiatric care should be considered when symptoms have not abated with one medication; if suicidal ideation or behaviors continue; if adverse effects of medication

do not abate; when psychiatric co-morbidities do not improve with treatment; if substance abuse problems or other stressors exist; or if a person has limited social support[26].

Social Responsibilities of Physicians and Lawyers

Documentation of torture can act as a deterrent. The *Istanbul Protocol* presents international guidelines for the assessment of those who may have experienced torture and ill treatment (Tables 2 & 3). Health professionals are cautioned to not over-medicalize psychological effects, while encouraged to consider individual beliefs and cultural norms[27]. Practitioners in the United States and Portugal have a role within the asylum process by providing medical and psychiatric evaluations[28]. Broadly speaking, health and

Table 2: Common Physical Symptoms Found in Survivors of Torture

Skin	Generalized skin disease including signs of Vitamin A, B, and C deficiencies, pre-torture lesions, lesions inflicted by torture (abrasions, contusions, lacerations, puncture wounds, burns from cigarettes or heated instruments, electrical injuries, alopecia, nail removal)Lesions — localizations, symmetry, shape, size, color, surface
Face	Palpation for evidence of fracture, crepitation, swelling, or pain Examination of all cranial nerves including motor and sensory
• Eyes	Conjunctival hemorrhage, lens dislocation, subhyeloid hemorrhage, retrobulbar hemorrhage, retinal hemorrhage, visual loss
• Ears	Rupture of the tympanic membrane, hearing loss, otorrhea

• Nose	Alignment, crepitation, and deviation of the nasal septum
• Jaw, oropharynx, neck	Mandibular fractures and/or dislocations, temporomandibular joint syndrome, crepitation of the hyoid bone or laryngeal cartilages, lesions in the oropharynx, gingival hemorrhage, gum condition
• Oral cavity, teeth	Tooth avulsions, fractures of the teeth, dislocated fillings and broken prostheses, dental caries, gingivitis, lesions
Chest and abdomen	Lesions of the skin; pain, tenderness, and discomfort related to injuries of the musculature, ribs, or abdominal organs; retroperitoneal, intramuscular, and intra-abdominal hematomas Anal region — fissures, rectal tears, disruption of the rual pattern/scarring, skin tags, purulent drainage
Musculoskeletal system	Musculoskeletal aches and pains including changes in mobility of joints, pain with motion, contractures, strength changes, compartment syndrome, fractures with or without deformity, dislocations
Genitourinary system	In females — bruises, lacerations, tears, bleeding or vaginal discharge, echymoses; sexually transmitted diseases including HIV, scarring, deformity in males — pain and sensitivity, hydrocele and hematocele, testicular torsion, erectile dysfunction, atrophy of the testes, scarring
Central nervous system	Cognitive and mental status changes, motor and sensory neuropathies related to trauma, vitamin deficiencies, other diseases, brachia plexopathy, radiculopathies, cranial nerve deficits, hyperalgesia, parasthesias, hyperaesthesia, change in position and temperature sensation, motor function, gait and coordination disturbances

Adapted from the *Istanbul Protocol*[27].

Table 3: Common Psychological Responses to Torture

• Posttraumatic stress disorder
• Somatic complaints, such as abdominal pain and headaches
• Depressive disorders
• Substance abuse
• Neuropsychological impairments
• Psychosis
• Enduring personality change
• Generalized anxiety disorder
• Panic disorder
• Acute stress disorder
• Somatoform disorders
• Bipolar disorder
• Phobias

Adapted from the *Istanbul Protocol*[27].

legal professionals are asked to assess whether the clinical presentation is consistent with the patient/client's narrative involving torture or other trauma[27].

Collaboration

In June 2005, the National School of Public Health and Luso-American Foundation came together at a meeting titled "The Role of Health Law, Bioethics, and Human Rights to Promote a Safer and Healthier World". This conference established a formal collaboration between the Boston Center for Refugee Health and Human Rights and the Centro de Apoio a Vitimas de Tortura. As a result, the first step has been forged in engaging these two centers in cooperative educational research and service projects on behalf of refugees and survivors of torture.

Notes

[1] Amnesty International Internal Secretariat. *Amnesty International Annual Report 2005: the State of the World's Human Rights*. London, England : Amnesty International Publications; 2005.

[2] British Medical Association. "Medical involvement in torture". In: *Medicine Betrayed The Participation of Doctors in Human Rights Abuses*. Atlantic Highlands, NJ : Zed Books, Ltd; 1992; 33-63.

[3] Sugg, N. K., Iniu, T. "Primary care physicians' response to domestic violence: opening Pandora's Box". *JAMA*. 1992; 267 : 3157-3160.

[4] Jacobsen L., Vesti P. "Treatment of torture survivors and their families: the nurse's function". *Int Nurs Rev*. 1989; 36 : 75-80.

[5] United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. Adopted and opened for signature, ratification and accession by General Assembly resolution 39/46 of 10 December 1984 (gender inclusion [her] not in original document)

[6] Reyes H. "Torture and its consequences." *Torture*. 1995; 5 : 72-76.

[7] Gudjonsson, G. "Custodial confinement, interrogation and coerced confessions". In Forrest, D. (ed.). *A Glimpse of Hell: Reports on Torture Worldwide* (36-45), Amnesty International UK. New York: New York University Press, 1996.

[8] Jaranson, J. "Government-sanctioned torture: status of the rehabilitation movement". *Transcultural Psychiatric Research Review*. 1995; 32 : 253-286.

[9] Doerr-Zegers, O., Hartmann, L., Lira, E., *et al.,* "Torture: psychiatric sequelae and phenomenology". *Psychiatry*. 1992; 55 : 177-184.

[10] Silove, D. "The psychosocial effects of torture, mass human rights violations, and refugee trauma : toward an integrated conceptual framework". *The Journal of Nervous and Mental Disease*. 1999; 187 : 200-207.

[11] Mollica, R., McInnes, K, Sarajlic, N., *et al.,* "Disability associated with psychiatric co-morbidity and health status in Bosnian refugees living in Croatia". *JAMA*. 1999; 282: 433-439.

[12] Antolak K., for the Center for Victims of Torture. "Recognizing and caring for survivors of torture". Presented at: Caring for Torture Survivors Conference; October 22, 1999; Minneapolis, Minn.

[13] Weinstein, H. M., Dansky, L., Iacopino, V. "Torture and war trauma survivors in primary care practice". *West J Med*. 1996; 165 : 112-118.

[14] Baker, R. "Psychosocial consequences for tortured refugees seeking asylum and refugee status in Europe". In: Basoglu, M. (ed.). *Torture and its consequences: current treatment approaches* (83-106). Cambridge, Eng-

land: Cambridge University Press, 1992

[15] Crosby S., Norredam M., Paasche-Orlow M., Piwowarczyk L., Grodin M. *The prevalence of torture survivors among foreign-born patients presenting to an urban ambulatory care practice.* (in press 2005).

[16] Amnesty International. *Portugal: "Small problems...?" : a summary of concerns.* August 31, 2001. Available at http://web.amnesty.org/library/index/ENGEUR380022001.

[17] Kinzie, J. D. "Evaluation and psychotherapy of Indochinese refugee patients". *American Journal of Psychotherapy.* 1981; xxxv: 251-261.

[18] Mollica, R. F., Caspi-Yavin, Y. "Measuring torture and torture-related symptoms". *Psychological Assessment: A Journal of Consulting and Clinical Psychology.* 1991; 3 : 002.

[19] Pope, K., Garcia-Peltoniemi, R. "Responding to victims of torture: clinical issues, professional responsibilities, and useful resources". *Professional Psychology Research and Practice.* 1991; 22 : 269-276. Reyes, H. "Torture and its consequences". *Torture.* 1995; 5: 72-76.

[20] Basoglu, M., Paker, M., Ozmen, E. *et al.,* "Factors related to long-term traumatic stress responses in survivors of torture in Turkey". *JAMA.* 1994; 272 : 357-363.

[21] Basoglu, M., Paker, M., Paker, O., *et al.,* "Psychological effects of torture: a comparison of tortured with non-tortured political activists in Turkey". *American Journal of Psychiatry.* 1994; 151 : 76-81.

[22] Basoglu, M., Ozmen, E., Sahin, D., *et al.,* "Appraisal of self, social environment, and state authority as a possible mediator of posttraumatic stress disorder in tortured political activists". *Journal of Abnormal Psychology.* 1996; 105 : 232-236.

[23] Holtz, T. H. "Refugee trauma versus torture trauma: a retrospective controlled cohort study of Tibetan refugees". *The Journal of Nervous and Mental Disease.* 1998; 186 : 24-34.

[24] Foa, E. B., Keane, T. M., Friedman, M. J. (eds.). (in press) In: *Effective Treatments for PTSD: Practice Guidelines from the International Society for Traumatic Stress Studies.* New York: Guilford Press.

[25] Friedman, M. J., Davidson, J. R. T., Mellman, T. A., Southwick, S. M. (in press Pharmacotherapy) In: E. B. Foa, T. M. Keane, M. J. Friedman (eds). *Effective Treatments for PTSD: Practice Guidelines from the International Society for Traumatic Stress Studies.* New York: Guildford Press.

[26] Culpepper, Larry (ed.). "Primary Care Treatment Guide for Post-traumatic Stress Disorder. In: Treatment of Posttraumatic Stress Disorder The Expert Consensus Guideline Series". E. B. Foa, Davidson, R. T., Frances, Allen (eds). *The Journal of Clinical Psychiatry.* 1999; 60, Supplement 12.

[27] Iacopino V., Ozkalipici O., Schlar C, *et al., Manual on the Effective Investigation and Documentation of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (The Istanbul Protocol)*. Submitted to the United Nations Office of the High Commissioner for Human Rights. August 9, 1999: 49-64. Available at http://www.phrusa.org/.

[28] Boston Center for Refugee Health and Human Rights, Boston Medical Center, Dowling 7, One Boston Medical Center Place, Boston MA 02118. www.bcrhhr.org Centro de Apoio a Vitimas de Tortura (CAVITOP), Campo Grande 28 — 7.º C, 1700-093 Lisboa, Portugal. cavitop@sapo.pt

Genetically Modified Animals: Have We Gone Too Far?

AUTUMN FIESTER, PHD*

Introduction

The science of animal cloning and transgenesis is progressing at lightening speed. Projects underway run the gamut from pet cloning to biopharming to xenotransplantation to the preservation of endangered species. While the science of animal biotechnology advances undeterred, the ethical discussion about the boundaries the public might want to set is at the most nascent stage. While some commentators favor a blanket prohibition of animal cloning and transgenesis that is unlikely to be imposed on the biotechnology industry, most others view this science as having a continuum of moral permissibility, with some projects being justified and others not. So one central question in approaching cloning and transgenesis is: how far should we go? Which of the animal cloning and transgenic projects are ethically permissible, and which ones cross an important moral line?

In this essay, I explore one method for conducting an ethical analysis of particular animal biotechnology projects. Using the approach of casuistry, I examine two different transgenic projects with medical applications: the "biopharming" of transgeneic goats to harvest proteins in the milk; and the creation of transgenic pigs for the long-term goal of xenotransplantation. On this casuistical approach, I will use the project of transgenic goats as the paradigm case to conduct an ethical analysis and then use

* Senior Fellow, Center for Bioethics University of Pennsylvania.

the moral insights gleaned from this case to reflect on other current animal biotechnology projects, focusing on the case of transgenic pigs. Before conducting this analysis, I want to review the progress in cloning and transgenic science since its beginning in 1995.

History of Cloning & Transgenic Science: How Far Have We Come?

Although the first successful attempt at animal cloning occurred in 1995 with the birth of two lambs, "Megan" & "Morag", this new science first caught the public's attention with the dramatic announcement of the birth of "Dolly". The explanation for the significant difference in the drama surrounding the two projects was that Megan and Morag were cloned from an early embryo – not from an adult cell like Dolly. In the summer of 1995, the two lambs were cloned at the Roslin Institute in Edinburgh, Scotland from cultured cells from a nine-day old embryo. Though this was a feat at the time, it paled in comparison the Institute's accomplishment of achieving Dolly, who was created by taking the nucleus of an adult ewe's skin cell and inserting it in an enucleated donor egg. Basing techniques on that breakthrough, the science exploded, and a series of difference species were cloned over the next several years, including mice, cows, goats, pigs, rabbits, mules, horses, and, also famously, "CC", the calico cat.[1]

At the same time Dolly was being cloned to be the identical twin of her donor, another sheep, Polly, was created as the first "transgenic" clone, a clone engineered to possess genetic material from another species, in this case, a human being. Polly was born in the summer of 1997, and her genome included a human gene that would enable her to secrete a human protein in her milk that

could be extracted from the milk and used to manufacture a drug to treat a particular disease; in this case, the hope was a treatment for hemophilia.[2] This achievement launched a slew of transgenic projects intended to produce pharmaceuticals or other treatment modalities for a range of human diseases,[3] for example, transgenic animals that might be used to treat lung diseases or manufacture vaccines.[4] This type of animal biotechnology is now referred to as "biopharming". Transgenic science has had agricultural applications as well. Scientists are working on cloning goats with less fatty milk, chickens with no feathers to reduce the environmental costs of poultry farming, and pigs whose manure has less phosphorus and helps reduce environmental pollution.[5] At Texas A & M University, scientists have cloned cows resistant to brucellosis.[6]

Medical and agricultural applications are now not the only motivation for cloning or transgenic projects. Conservationists, for example, are hoping to use cloning techniques to either preserve endangered species or bring back extinct ones.[7] To date, these projects have had very little success. In January 2001, a gaur, a type of wild ox on the verge of extinction, was cloned, but the calf died soon after birth. Researchers say the bull died from dysentery unrelated to the cloning process, but no successful gaur clone has been achieved.[8] There have also been projects attempting to clone the extinct thylacine, the Asian cheetah, and the wooly mammoth.[9]

One of the latest uses of cloning and transgenic science is the creation of animals for private sale, either as novelty animals or companion animal clones. The first such creature, a rabbit named "Alba", is a transgenic animal that is green and glows under special lighting.[10] It was commissioned by Chicago-based artist, Eduardo Kac, whose goal is the creation of "a new art form based on the use of genetic engineering to transform natural or synthetic genes... to create unique living beings".[11] Using the same technology, Yorktown Technologies began marketing the "Glofish" in January 2004.[12] The Glofish is a transgenic zebrafish

that has had the green florescent protein (GFP) of the jellyfish and the red florescent protein (RFP) of the sea anemone added to it to make it glow under special lighting. They are currently being sold in the United States for $5.00 each.

A more upscale commercial project using cloning technology is pet cloning, made famous by the firm Genetics Savings and Clone, which has already produced and sold a handful of cat clones and hopes to make a dog clone in the near future. Clients of the company can get the identical twin of a beloved pet for a price of about $30,000 (down from $50,000 a year ago). Using eggs harvested from removed ovaries procured from spay clinics and surrogate cats that are adopted into homes after delivering the clone, a genetic copy of the original cat — its later-born twin — is produced and sold to the client. Despite the seemingly prohibitive price-tag, hundreds of potential clients have paid to have their animal's DNA banked with the firm.

As this overview of the various types of cloning and transgenic projects shows, animal biotechnology is being pursued for a myriad of reasons, involving varying degrees of animal suffering, alteration, or modification. As the public reflects on these different uses of cloning and transgenesis, it is imperative that projects be assessed on a case-by-case basis since the moral permissibility likely involves a continuum created by the facts surrounding the individual projects. To begin to carve out this continuum, I will look at two different projects in the area of biopharming, i.e., transgenic animals created to aide in the production of pharmaceuticals or other treatment options for human disease.

Casuistical Analysis of Animal Biotechnology

To assess these two projects, I want to appeal to a well-known method of bioethical analysis called "casuistry". First used in the

Middle Ages, casuistry was considered a viable approach to moral judgment until the 17th century, when it fell out of favor. It has recently been revived in contemporary bioethics because of its reliance on paradigm cases – a strategy akin to the use of legal precedent — which functions well in a field that often advances its thinking based on reflections about particular clinical or research ethics cases. Casuistry, then, is a bioethical approach to ethical analysis in which moral permissibility is determined by analyzing a paradigmatic case that highlights general ethical considerations which can be analogized to other cases.[13] Here, I will argue for the acceptance of a particular project in transgenesis as the paradigm case of moral permissibility for animal transgenesis, and I will claim that the moral considerations generated in that case offer insight to move to other places on the animal biotechnology continuum.

The case I want to deem paradigmatic is technically speaking a hypothetical one. Since the details of concrete projects can change so rapidly, it only makes sense to talk about project-types, though I will construct the cases around real (and therefore viable) projects; I will use projects that have, in fact, been conducted, staying faithful to the way in which they were or are conducted. This means, of course, that the moral permissibility of a certain project will depend on those particular facts or details that are cited in the analysis. In other words, one project using the same technology, for the same purpose, with the same species may be morally permissible, while another similar project is not.

So let's start with a transgenic project involving the modification of goats for the purpose of biopharming. Take the following case: transgenic goats are produced that secrete a human protein in their milk that will be harvested to treat a disease, which has no other effective treatment; the goats are created by introducing a human protein into the early embryo of a goat and implanted into a surrogate; only a handful of goats are produced this way: once

the founder herd is produced, the goats are naturally bred and the offspring will express this same protein in their milk; the protein is harvested by normal means of milking; there are no additional restrictions on the herd due to their biopharming function: they are kept in pastures, in groups; the transgenic goats are confined so that they do not breed with other goats used in agriculture; and, no detectable differences exist between the health status of the GM goats and non-GM goats.[14]

To use this as a paradigm case, we need now to offer an ethical analysis of a transgenic project of this type, conducted in this way. The first thing to note is that the genetic modification does not cause significant pain and suffering in the animal, and the "species-life" of the animal is protected, despite being an animal designed for a pharmaceutical purpose. Assuming that "quality of life" for a goat — what I am calling "species-life" — means being able to roam free, uncaged, without being separated from other members of that species, then these transgenic goats in the project I am describing have a quality-of-life no different from domestic goats raised for agricultural purposes on farms that pay close attention to animal welfare issues, i.e., that adhere to the highest standards of animal husbandry. Because the intended product of transgenic goats is the milk, which is the same product in conventional, non-GM farming of goats, there need be no extra restrictions placed on the lives of these goats, so the herd need not be treated differently from non-GM goats. It is only after the milk is procured that the special process of harvesting the protein in the milk is begun. Additionally, because this milk is not going to be consumed as milk (it is only the protein that will be used, and only after extensive clinical trials that test for safety and efficacy), and the goats will not be used for meat, there are no concerns here about potential risks to human beings in consuming such GM products. Similarly, since the confinement of these GM goats is easy to achieve, the

breeding with non-GM goats (a potential environmental hazard) is easy to avoid.

If we now assess the moral permissibility of this project, it appears to have enormous potential benefits to the human recipients of these pharmaceuticals (assuming the research succeeds in producing new treatments for disease), little, if any, sacrifice on the part of the animals used in the process, and no risks to the environment. In an ethical cost-benefit analysis, this project appears to have all gain and no cost.[15] On pure consequentialist or utilitarian terms, the moral valuation of this project is overwhelmingly positive.

We can analyze this project from another ethical perspective, namely, a deontological one,[16] but I believe that the moral evaluation will be the same. Of course, the moral assessment from a deontological perspective depends on the principle one deems most salient in a particular case — and there are principles that judge all types of genetic modification to be morally impermissible[17] — but I will argue that on the principle most illuminating in the case, this project passes ethical scrutiny. The principle I believe is most salient here is that animals ought only to be treated as "means" to some human purpose if they are also treated as "ends" at the same time. Although this principle is Kant[18] — inspired (in fact, it is a version of what he called the second formulation of the Categorical Imperative), it is not a principle Kant used to talk about our obligations to animals, and he would not have endorsed it for this purpose. In fact, he specifically writes, "Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end".[19] But as we struggle to define the proper relationship between human beings in animals and the proper treatment of animals, I believe this principle offers us a reasonable standard and safeguard: using animals for our purposes is morally permissible as long as we

respect them as sentient beings in their own right, which require species-specific conditions in order to thrive. In this redefinition of what it means to be an "end in itself", animals are entities worthy of respect, i.e., worthy of being treated as an end, because they have a certain constellation of needs, desires, and interests that unfulfilled make them suffer.

If this principle is indeed applicable to animal life, then it appears to me that the transgenic project described above recognizes the particular species-interests of the GM goats and grants them the conditions under which they thrive, while at the same time utilizing them for a noble and important human purpose. In Kantian terms, it treats them as an end, and not a pure means only.

Returning to our casuistical approach, then, this instance of biopharming serves as the paradigm case that sets the standard against which other projects in biopharming or other arenas of animal biotechnology can be measured. If we think about the creation of a moral continuum on which various animal biotechnology projects can be located according to their level of moral permissibility or impermissibility, then I have argued that this type of transgenic project would be located on the far end of moral permissibility. In answering the question, "How far should we go in the genetic modification of animals?", we would begin with that point on the continuum and judge how far out on the continuum we ought to travel. As a contrast point on the continuum — a point I believe to be located at the far other end — I want to consider a transgenic project in the area of xenotransplantation.

Take as our contrast case a project involving the genetic modification of pigs that are designed to be organ factories for human beings. The background to this project is an international shortage of human organs for transplant and thousands of people dying every year waiting for one of these scarce resources. Given the

dire circumstance that lies behind this transgenic project, it is clear that the scientific motivation is noble and pure: there is a profound human need and the use of transgenic animals may provide one possible solution. But at what cost, both to the animals involved in this research and to the human recipients and non-recipients of the organs?

We begin this analysis by focusing on the particular conditions and restrictions imposed on GM pigs due to the requirement that they be pathogen-free. In order for xenotransplantation to be safe for the human recipients, GM pigs cannot harbor diseases,[20] either swine — based or human-based, that they could pass on to immune-compromised patients receiving the organs. In order for these animals to avoid transmissible or communicable diseases, they must live in as close to a sterile environment as is possible. But meeting this high bar requires a dramatic undermining of the conditions under which pigs thrive. Pigs, it turns out, are highly social animals, extremely intelligent, with a curiosity that, unfulfilled, turns into self-destructive or aggressive behavior. They form social bonds and require social relationships. In xenotransplantation research, the alteration of the pigs' environment begins at birth: the pigs are delivered from the sow inside the uterus via cesarean section and placed in a sterile incubator. They are not allowed to suckle; in fact, they have no contact with the mother at all, and she is euthanized after the birth. In their sterile containers, there are no objects to fill the pigs' natural need for rooting or intellectual stimulation. They are kept confined, often alone.

In addition to the restrictive environment imposed on the pigs, they may suffer in other ways due to the modifications required for the xenotransplantation research itself. In order to create biocompatibility with the organs' future human recipients, the pigs may need to be altered in size, for example. This level of alteration may cause a whole host of physical problems not seen in the

transgenic goats who receive an insertion of a simple human gene. Lack of ethical oversight in the biotechnology industry of the countries at the forefront of this research makes it difficult to assess the level of the suffering of these animals, but it appears unlikely that there would be no physical cost to the animals being used in this research.

What, then, can we say about the moral permissibility of a project with a strong possibility that the genetic modification causes significant physical pain and suffering in the animal and a certainty that the species-life of the animal is completely disrupted by the research? On a consequentialist, or utilitarian, calculus of the ethical cost versus ethical benefit, it might seem as if the need for organs outweighs all other considerations on the part of the animals being used. But the benefit-side of the equation is not so clean: the risk of transmission of an undetected pathogen to the human recipient (perhaps a lethal, transmissible, and incurable one) is not insignificant, and many bioethicists[21] (and advocacy groups[22]) argue against the strategy of xenotransplantation on this ground alone. Add to this that there may be another scientific solution to the scarcity of organs problem that has no risk of introducing a foreign pathogen and will not require this dramatic alteration of animals, namely, stem cell research. If stem cells can be programmed to produce the needed organs, it might be possible to generate organs in a Petri dish and grow them, using the recipient's own genetic material, to be completely biocompatible with the recipient. So it isn't the cost-benefit analysis, part of the equation is the possibility of a future alternative to the course we are now on. On balance, the cost to animals and the questionable benefits to human beings make this use of transgenesis morally unjustifiable.

On a deontological analysis, the proponents of xenotransplantation will not fare any better. Using the principle that we ought to treat animals as a means only if we also treat them as an end

(that is, we ought to never treat them as a pure means only), it is obvious that this project will not pass ethical scrutiny. Xenotransplantation research shows no respect for the integrity of the animals being used and there is no consideration given to the quality-of-life of the transgenic pigs — at least in the countries like the United States and Korea that are on the cutting edge of this research. In contrast to the biopharming projects using transgenic goats where there appeared to be ethically "all gain and no cost" and a demonstrable respect for the species-life of the animals, the xenotransplantation projects using GM pigs appear to have questionable gain (if organs can actually be produced on the scale required to meet the demand), tremendous cost (certainly to the pigs and possibly to human beings), and no respect for the species-life of the pigs. This puts xenotransplantation research on the opposite end of the moral continuum from the transgenic goats project.

To this criticism of xenotransplantation, the proponents like to offer the following rejoinder: what is the moral difference between using pigs for food and using them as an organ source? Surely, they argue, it is a much more noble purpose to use pigs to save human lives than to use pigs to satisfy our base appetites, given all of the non-animal foods we could use to nourish our bodies. They add to their case the argument that the pigs in this research are certainly treated better than the pigs subjected to factory farming, which is the most common type of farming in the industrialized West today — at least they are disease-free and kept in hygienic conditions.

The response to this argument is that the proponents of xenotransplantation are using the wrong comparison: on the question of organs versus food, we can't compare a morally impermissible method of farming with (I have argued) a morally impermissible method of medical research; we need to compare the case of humane farming with this type of medical research. There is no

necessity in raising pigs by means of factory farming; the quality of the pork is not undermined by allowing pigs to be kept in their natural habitat under conditions that meet their natural needs — it might even be enhanced. The reason pigs are subjected to factory farming is to keep the yield high and the price low. But, again, eating as much pork as we do is not necessary to sustain human life; in fact, we would probably be healthier if we ate less meat, and the increase in price that would correspond to instituting better conditions for agricultural animals might thus serve us well. So in order to make a legitimate comparison between using pigs for organs and using pigs for food, we need to compare the best means possible to produce the organs and the best means possible to produce the pork. If the restrictive conditions are necessary to safely produce organs for transplant, but natural conditions are possible to produce food, then the production of pork by humane farming methods appears to be morally permissible where the production of organs for transplantation does not. If it turns out that pigs can be raised in less restrictive conditions for xenotransplantation, then the ethical analysis may look different. For now, based on the methods and protocols of current xenotransplantation research, this biotech solution to the scarcity of organs problem is morally suspect. This type of transgenic project can be located at the opposite end of the moral continuum from the project of biopharming using transgenic goats.

Conclusion

The construction of a continuum of moral permissibility for the area of animal biotechnology offers us a way to assess individual projects in transgenic science or animal cloning by taking into account all of the relevant moral considerations of a particular case. Against the backdrop of a science progressing faster than

the public can react to it, it is easy to ask the question "Have we gone too far with animal biotechnology?" But this is the wrong question because it assumes that we can judge entire categories of animal biotechnology (e.g., transgenesis, pet cloning, gene transfer) rather than evaluating specific projects on their own merits. I have argued that moral permissibility or impermissibility is found within those details that get lost in blanket acceptance or rejection of this new science. A better question is, "Are we moving too quickly with animal biotechnology?", and the answer is undoubtedly "Yes". To safeguard both animal and human life, the animal biotech industry ought to pause for a project-by-project ethical analysis and review.

Notes

[1] *Texas A & M Clones First Cat.* February 2, 2002. Texas A&M University. http://www.tamu.edu/aggiedaily/press/020214cc.html. Since CC, four more cats have been cloned by the pet cloning firm Genetics Savings and Clone (www.savingsandclone.com), which is currently attempting to clone the first dog.

[2] Bonnicksen, A. "First Dolly, Now Polly: Policy Implications of the Birth of a Transgenic Cloned Lamb", Klotzko, A. (ed.) *The Cloning Sourcebook*. New York: Oxford University Press, 2001. 267.

[3] Behboodi, E., *et al.,* "Transgenic Cloned Goats in the Production of Therapeudic Proteins". In: Principles of Cloning. Elsevier Science (USA).

[4] See, for example, Meade, H. M. *et al.,* "Expression of recombinant Proteins in the Milk of Transgenic Animals". In: *Gene Expression Systems: Using Nature for the Art of Expression,* Fernandez J. M., Hoeffler, J. P. (eds.) Academic Press, 1999; Avidan, M. S. *et al.,* "A Phase III, Double-Blind Placebo-Controlled Multicenter Study on the Efficacy of Recombinant Human

Antithrombin in Heparin-Resistant Patients Scheduled to Undergo Cardiac Surgery Necessitating Cardiopulmonary Bypass", *Anesthesiology,* 2005, 102: 276-284; Zhou, Q. *et al.,* "Effect of Genetic Background on Glycosylation Heterogeneity in Human Antithrombin Produced in the Mammary Gland of Transgenic Goats", *Journal of Biotechnology,* 2005, 117: 57-72; Atowers, A. W., "A Recombinant Vaccine Expressed in the Milk of Transgenic Mice Protects Aotus Monkeys from a Lethal Challenge with Plasmodium Falciparum", *Proceedings of the Natural Academic of Sciences of the United States of America,* 2002; 99 : 1. 339-344.

[5] *Cloned and Genetically Engineered Animal,* Thomas, T. The Human Society of the United States. Available at http://www.hsus.org/ace/15401.

[6] *Disease-Resistent Bull Cloned at Texas* A & M, Phillips, K. December 18, 2000. Available at http://www.tamu.edu/aggiedaily/press/020214cc.html.

[7] See, for example, *Cloning Hopes for Extinct Species* and *Project to Clone Extinct Cheetah Gets a Boost.* AgBiotechNet. Available at http://www.agbiotechnet.com.

[8] See http://www.bbc.co.uk/science/genes.

[9] *Cloning Hopes for Extinct Species* and *Project to Clone Extinct Cheetah Gets a Boost.* AgBiotechNet. Available at http:www.agbiotechnet.com.

[10] Allmendinger, U. 2001. "One Small Hop for Alba, One Large Hop for Mankind", *NY Arts Magazine* 6 and, see also, Boyce, N. "Pets of the Future", *U. S. News & World Report,* March 11, 2002.

[11] Kac, E. *GFP Bunny.* Available at http://www.ekac.org/gfpbunny.html# gfpbunnyanchor. Kac would disagree with this depiction of the project, protesting, "I have never thought of Alba [the transgenic rabbit] as an art object in the sense that one would create a sculpture or a painting. It's not about making an object. I invent situations".

[12] See http://www.glofish.com/default.asp.

[13] See Jonsen, A., Toulmin, S., *The Abuse of Casuistry: a History of Moral Reasoning.* University of California, 1988.

[14] This claim about the health status of GM goats reflects what appears to be the case in current transgenic science. It is too early to determine whether the long-term health of these animals will mirror naturally bred animals. But if transgenic goats suffer decreased lifespan or other as-yet — undetected congenital abnormalities, it is likely that the comparison case — transgenic pigs bred for possible xenotransplantation — will suffer a similar fate; therefore, the comparison will be unaffected. However, depending on the severity of the problem and the suffering that accompanies it, this

compromised health status may indeed alter our assessment of moral permissibility — in both cases.

[15] This will change, of course, if it turns out that there is a great deal of suffering on the part of the animals due to the genetic modification. As I argued earlier, it will be quite sometime in two we have long-term data on the health and well-being of these animals. For now, it appears that these animals are healthy.

[16] Deontology is the moral theory that holds that actions are wrong because they violate a particular duty or moral principle. Many philosophers argue that there are two basic moral perspectives through which one can analyze a moral problem: consequentialism or deontology. Above I argued that this project using transgenic goats was morally permissible on consequentialism. Now I am arguing that we would reach the same conclusion based on deontology.

[17] For example, if I hold the view that any genetic modification of animal life is "playing God" and that such action is prohibited by God, then, of course, this transgenic project would be morally impermissible. But this is a radical view; we have been modifying animal life for millennia, by either high-tech or low-tech means, and it is difficult to find an argument that justifies our prior manipulations of animal life (like selective breeding) that prohibits our more recent interventions.

[18] Immanuel Kant was an 18th-century moral philosopher whose most famous work is the *Groundwork for the Metaphysics of Morals.* He is considered the founding father of modern deontology.

[19] Kant, Immanuel *Groundwork for the Metaphysics of Morals,* H. G. Paton, translator (Harper & Row, 1956). 97.

[20] We will return to this issue below, when we discuss the possibility of swine-based pathogens that are as yet undetected and could, potentially, cause some type of epidemic, or even pandemic.

[21] Singer, P. "Xenotransplantation and speciesism" *Transplantation Proceedings,* 1992; 24 : 728-732.

[22] See, for example, *The Campaign for Responsible Transplantation.* Available at: http://www.crt-online.org/

Nanotechnology, Neurotechnology, and the Ethical Challenges of Human Interventions

PAUL ROOT WOLPE, PH. D.*
LINDSEY WU, B. A., B. A. S.**

Introduction

Ethical issues do not arise in isolation from the broad social implications of a technology, but rather emerge from the ways that a technology becomes embedded in society. All new technologies bring with them challenges, some of which are recognized and others of which only become understood after the technology becomes integrated into social life. Who could have understood early in their development the many ways the automobile, or television, or the personal computer would so transform our lives? We are notoriously poor at predicting how new technologies will spread and how they will affect us. However, it is morally incumbent upon us to try and prevent or mitigate whatever adverse consequences that we can reasonable expect from new technologies as they develop.

Nanotechnology has become the newest technological buzzword. Countries are competing to be the leaders in nanotechnology and companies are searching their products for any that use nanoscale particles so that they can claim that they, too, are nanotech companies. However, while some fundamental concepts may differ, in many cases, the addition of a nano- prefix only denotes the extension of an already existing technology into the nano-scale

* Department of Psychiatry and Center for Bioethics, University of Pennsylvania.

** Candidate, M. Sc., London School of Economics.

domain: microelectromechanical systems, more popularly known as MEMS, become nanobots, while fabric treatment is transformed into stain-defending nano-particles. Similarly, it is an open question whether the ethical challenges of nanotechnology are significantly different than technologies of the past. This popularization of the nanotech name muddles perception of the entire emerging field, as it is harder to separate any truly new technologies from incremental progress. In fact, nanotechnology is a socially constructed field — its definition is based more on social perceptions than any common application or functionality (Arnall, 2003).

Because of its social nature, adding nano- to the name of a new or existing technology can effectively polarize public sentiment. As Eric Drexler (1986) extols the endless possibilities of self-replicating nanofabricators, Bill Joy (2000) foresees an imminent apocalypse due to the same technology. While, outside of academia, Michael Crichton (2002), in his novel *Prey*, writes about a self-aware cloud of nano-particles that wreaks havoc in a laboratory, US military forces envision networks of nanodust spreading over a battlefield to enable better communication (Davies 2001). This dichotomy between the perceived usefulness and fearfulness of nanotechnology can be compared to the initial public reception of genetically modified (GM) foods: while many heralded GM foods as the savior of the poor and starving, others feared its effect on the health of both human consumers and the ecosystems surrounding agricultural land.

In light of mounting effort to avoid the mistakes of GM proponents, policymakers in the US have created several well-funded bodies to asses the ethical, legal, and social issues surrounding nanotechnology and to disseminate this information to the public. One of the most important and well-funded of these bodies is the National Nanotechnology Initiative (NNI), a program created to synchronize the effort of 23 federal agencies in the development of nano-scale technology, science and engineering. This body, with an

annual budget approaching $1 billion, has devoted $43 million to developing educational resources for the public and researching the ethical, social, and legal implications of nanotechnology for the 2006 fiscal year (NNI 2005). Attention to these kinds of issues by national policymakers has been increasing (U. S. House of Representatives, May 6, 2003; Senate of the United States, January 16, 2003). Societal implications of nanotechnology have been identified as a research thrust within the NSF Nanoscale Science and Engineering (NSE) program since inception in 2001. Despite this, however, NSF has funded relatively few research projects on societal implications of nanotechnology to date. The few that have been funded include projects at the University of South Carolina, UCLA, Michigan State University, and the University of Virginia.

Ongoing research on the societal implication of nanotechnology at these and other institutions is addressing a wide range of important topics, such as the effects of concern about societal implications on the quality of nanotechnology research, patenting, licensing, and commercialization of nanotechnology, public perceptions about nanotechnology, nanotechnology risk assessment, the effectiveness of images as representations of nanotechnology concepts, alternative treatments of nanotechnology across academic disciplines, and others. A somewhat larger number of separate research activities are also underway aimed at understanding environmental implications of nanotechnology (Roco, 2003). As important and impressive as these efforts are, there is a need for expansion of such activities across the board, and for greater integration of research and education on the societal and environmental implications of nanotechnology.

At this point, many of the ethical implications of nanotechnology are unknown and perhaps indiscernible. The potential of this new class of technology is vast, however, which has led both to hyperbole and scare mongering. Focusing primarily on a projected set of radical nanotechnologies, one side promises that

nantoechnology will rebuild the human form and end starvation, poverty, and death (Drexler 1986); the other side fears that self-replicating nanobots could multiply at a rate that would abolish life on earth (Joy, 2000). Clearly, both the nanophiles and nanophobes exaggerate any impact nanotechnology will have. Yet the novel physical properties of nano scale phenomena promise to profoundly change materials science, drug delivery, medical interventions, information technology, energy generation, agriculture, and a host of other areas of human endeavor.

Novel technologies that will be integrated into the medical and social lives of human beings often raise interesting new bioethical questions. Perhaps no technology has had more attention paid to it in its infancy than nanotechnology. Critics of nanotechnology have raised concerns from the threat the technology poses to human beings who inhale it, to invasions of privacy through the development of nanoscale surveillance technologies, to disruptions of the world economy should only the wealthy countries develop this technology (Connelly 2002). Nanotechnology, like many overhyped technologies, will probably not fulfill either the promises of its advocates or the fears of its opponents. However, it is a technology that has the potential to create novel products and manufacturing processes, and as such, it challenges the ethicist with the task of predicting the technology's trajectory and its ethical repercussions.

Toxicity

One of the most publicized criticisms against nanotechnology is the fear of nanoparticle toxicity. Researchers have suggested that when released into the environment, nanomaterials could pose serious health problems if they infiltrate the human body. At a recent meeting of the U. S. Environmental Protection Agency (EPA), the ETC group reported that nanoparticles could pen-

etrate living cells and accumulate in animal organs. Specifically, the possibility of toxic elements attaching to harmless nanomaterials inside bacteria and making their way into the bloodstream was of concern (ETC Group 2002a).

Scientists have proposed several possible effects of nanomaterials on living systems. One possibility is that proteins in the bloodstream could attach to nanoparticle surfaces, changing their shape and function, thus leading to harmful effects such as blood clotting. Another possibility is that nanoparticles are able to slip past the human immune system undetected (ETC Group 2002a). While this is advantageous for drug delivery systems, it is another way in which dangerous substances can reside in the body via nanosized particles.

In particular, public concern has focused on the toxicity of carbon-carbon nanotubes (a material ten times as strong, but only one seventh the weight of titanium) (Georgakilas 2002) due to its structural resemblance to asbestos fibers. Both are long, extremely durable and could potentially remain in the lungs for extended periods of time (Arnall 2003). A recent study by the National Aeronautics and Space Administration (NASA) suggests that breathing in large quantities of nanotubes causes damage to the lung tissue in mice (Service 2003).

Another preliminary study on nanoparticle toxicity at the University of Rochester suggested that macrophage cells responsible for clearing out foreign material have difficulty dealing with smaller particles such as carbon nanotubes. Further studies also found that inhaled nanoparticles in rats were able to reach olfactory bulbs and migrate throughout the brain (Service 2003). Scientists believe that inhaled nanoparticles could end up in other areas such as the liver, central nervous system and cardiovascular system as well (Dagani 2003). However, research is still limited concerning the possible health effects of nanotube absorption into the human body or the potential adverse effects at these

specific sites. Experts are quick to warn against drastic action. Vicki Colvin of Rice University points out that there are issues of risk with every new technology (Service 2003).

One issue to weigh against potential nanoparticle toxicity is that the ability for these extremely small particles to escape detection by the immune system is crucial for drug delivery techniques. The large majority of current drugs cannot cross the blood-brain barrier, which shields the brain from toxins in the bloodstream. In order to treat disorders such as Alzheimer's, Parkinson's, stroke and brain cancer, it is necessary for a drug to cross this interface into the brain. Researchers have been working on the development of nanoparticles that can successfully cross the blood-brain barrier and deliver therapeutic agents to specific parts of the brain (Dagani 2003). Up until now, data on the adverse effects of drug carrying nanoparticles at the blood brain barrier are conflicting. Some preliminary studies in animals suggest these particles can be injected without causing damage or affecting the uptake of normal brain nutrients (Dagani 2003).

In fact, the use of nanotechnology in medicine holds great promise on many fronts. The miniaturization of existing medical devices could mean vast improvements in drug delivery, disease monitoring and detection, and treatment. The ability to scan the body for signs of cancers or precancers very early in the progression of the disease could allow us to intervene and treat diseases before they become problematic (Klausner 2001). Furthermore, developments in nanomedicine could allow us to reverse disease, repair or regrow human tissues, or possibly even enhance human performance (Stupp 2001).

Science fiction fears of self replicating nanobots and 'grey goo' aside, the need to control the replicating processes of nanotechnology does have a more realistic and grounded angle. Some nanosystems will be manufactured, while some envision that other nanosystems will be created through self-assembly,

similar to the way in which biological systems self assemble. The ability to replicate poses several ethical and scientific challenges. Richard M. Satava, Professor of Surgery at the University of Washington School of Medicine, writes that these types of nanotechnology processes must be controlled to prevent certain mutations, particularly those that could lead to cancers or autoimmune disease (Satava 2003). Furthermore, he wonders if it is possible that these nanosystems could become so effective with treatment so as to render physicians obsolete. Another ethical concern is the question of human enhancement, a similar concern that arose with the development of tissue and genetic engineering. Should nanotechnology be used to give humans enhanced capabilities or longevity (Satava 2003)? The challenge remains for researchers, physicians, policymakers and society to adequately balance the harms and benefits of these emerging technologies.

While most critics focus on safety and toxicity concerns, there are some other issues that might be of ethical concern as nanotechnological products begin to reach market. Nanotechnology might be useful for security or military applications or surveillance, might be integrated into products for inventory tracing (which raises privacy issues), and might be used for medical purposes which could raise medical ethics concerns. While these concerns are widely known there has been little systematic effort made to refine the exact nature of the ethical and social challenges nanotechnology raises, to explore options for responding to those challenges and to engage the public in understanding the nature both of the challenges and the responses.

Nano-neuro interfaces

The development of nanotechnology could potentially revolutionize the field of neuroscience. Nano-scale neurotechnology

opens up a wide range of possibilities that extend beyond simply moving across the blood brain barrier for effective drug delivery. Many in the field have touted the concept of "NBIC Convergence", the melding of nanotechnology with biotechnology, information technology and cognitive science (Morris 2004). The ability to access the brain technologically, whether to understand its inner workings, detect thoughts or feelings, or to enhance its function, is a project garnering great attention in neuroscientific circles. It also raises a host of ethical issues.

Nanotechnology could play a large role in several areas of human cognitive enhancement. Neurological diseases such as Alzheimer's and Parkinson's often result in the loss of neural function and damage to cognitive ability. Thus, implantable devices that make use of cell-electrode interfacing have been used to alleviate the symptoms of these disorders (Medtronic). Nanotechnology introduces the possibility of smaller systems that are able to withstand longer periods of implantation. This becomes especially beneficial in the context of implantable drug release systems that must remain biologically and electronically viable over many years. Scientists believe these types of implantable devices will play a large role in enhancing the quality of extended life (Connelly 2002).

Recent advances in nanotechnology could also impact the development of brain machine interfaces. Currently, researchers Miguel Nicolelis of Duke University and Mandayam Srinivasan of the Massachusetts Institute of Technology (MIT) are collaborating on technology that will merge actuators and sensory devices with voluntary expressions in brain activity (Nicolelis 2002). Their goal is to create artificial devices that are integrated into the brain, allowing us to control these devices simply with our minds the same way neural commands control our own bodies. These devices thus bring the field of prosthetics to a new level. Nicolelis and Srinivasan write that nanotechnology makes this type of sci-

ence possible by allowing us to establish direct links between neuronal tissue and machines, enhancing the ability to use neuronal activity to control mechanical, electronic and virtual objects as if they were extensions of our own bodies (Nicolelis 2002). Similarly, John Donoghue (Donoghue *et al.,* 2004) has created a human neural prosthetic that has been used in a man who is a quadreplegic, but who is now able to move a cursor on a computer screen or open and close a prosthetic hand entirely with his mind.

The convergence of artificial devices, the human body and, ultimately, human cognition challenges existing definitions of the human body and individual autonomy. What will be the psychological as well as physiological effect of having machines and technology integrated into our anatomy? Will our concept of what it is to be human begin to change?

Nanoethics

Nanotechnology has the opportunity to begin the ethical conversation early and avoid the backlash of public confusion or opposition later on. Such a conversation, however, must be predicated on a systematic and deep examination of the realistic potentials and likely challenges that nanotechnology will pose to humankind. The dominance of radical opinions on both sides of the issues has polarized the discussion of nanotechnology prematurely; as the technology itself is in its infancy, and as few of the promises or threats about which both sides take such licenses are imminent, the arguments are racing far ahead of the technology. Reasoned discussion is difficult in such a polarized environment, and ethical and policy decisions must first cut through hyperbole to fact and reasoned opinion. Scholars need to differentiate not only those advances that are plausible, but also those that are

likely to be pursued and accepted from those that either have little commercial value or are socially undesirable enough to make their development improbable.

Nanotechnology will probably fracture into several related fields over time, each with its own set of ethical concerns. Safety and toxicity of manufacturing will be one, surveillance and privacy another. But perhaps no area of concern will raise public attention more than the nano-bio interface, and the integration of nanotechnology into our physiology. There the understanding of the ethical, social, religious, and economic implications of nanotechnology are crucial.

References

ARNALL, Alexander Huw. *Future Techologies, Today's Choices: Nanotechnology, Artificial Intelligence and Robotics; A technical, political and institutional map of emerging technologies.* London : Greenpeace Environmental Trust, July 2003.

CONNELLY, Patricia. "Nanobiotechnology and Life Extension". In: *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science.* NSF/DOC-sponsored report. Roco, Mihail C.; Bainbridge, Williams Sims (eds.). Arlington, VA : National Science Foundation, June 2002. 182-190.

CRICHTON, M. *Prey.* New York : HarperCollins, 2002.

DAGANI, Ron. "Nanomaterials: safe or unsafe?" *CENEAR.* 2003; 81 : April 28. 30-33.

DAVIES, G. "Nanotechnology: what is it, what can it do". In: *Foresight/CRISP workshop on nanotechnology: What is nanotechnology? What are its implications for construction?* London : Foresight Institute, 2001.

DONOGHUE, J. P., NURMIKKO, A., FRIEHS, G., BLACK, M. J. Development of a neuromotor prosthesis for humans. In: Hallett, M., Phillips II, L. H., Schomer, D. L., Massey J. M. (eds.) *Advances in Clinical Neurophysiology, Sup-*

plements to Clinical Neurophysiology. Vol. 57. Chapter 63, 2004. 588-602. [Proceedings of the 27th International Congress of Clinical Neurophysiology, AAEM 50th Anniversary and the 57th Annual Meeting of the ACNS Joint Meeting, San Francisco, CA, USA, 15-20 September 2003]

DREXLER, K. E. *Engines of Creation*. New York : Anchor Books, 1986.

ETC Group. No Small Matter! Nanotech Particles Penetrate Living Cells and Accumulate in Animal Organs. *ETC Group Communique* 2002a; 76 : May/June. Available at http://www.etcgroup.org/documents/Comm_NanoMat_July02.pdf

GEORGAKILAS, V., PELLARINI, F., PRATO, M., GULDI, D. M., FRANCO, M Melle., ZERBETTO, F. "Supramolecular self-assembled fullerene nanostructures". *Proc Natl Acad Sci*. 2002; April 16, 99 : 8. 5075-5080.

JOY, B. "Why the future doesn't need us". *Wired Magazine*. 2000. 8 : 4. Available at http://www.wired.com/wired/archive/8.04/joy.html. Accessed July 15, 2005.

KLAUSNER, R. D. "Challenges and Vision for Nanoscience and Nanotechnology in Medicine: Cancer as a Model". In: Roco, M. C., Bainbridge, W. S. (eds.) *Societal Implications of Nanoscience and Nanotechnology*, Arlington, VA : National Science Foundation, March 2001. 161.

Medtronic, Inc.. *Questions and Answers About Activa Parkinson's Control Therapy?* Available at http://www.medtronic.com/neuro/parkinsons/activa_qa2.html#1 (Accessed July 2005).

MORRIS, Kelly "New-wave neurotechology: small-scale makes big promises". *The Lancet*. 2004; April 3 : 202.

NICOLELIS, Miguel A. L., SRINIVASAN, Mandayam A. "Human-Machine Interaction: Potential Impact of Nanotechnology in the Design of Neuroprosthetic Devices Aimed at Restoring or Augmenting Human Performace". In: Roco, Mihail C., Bainbridge, Williams Sims, (eds.) *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science*. Arlington, VA : National Science Foundation, June 2002. (NSF/DOC-sponsored report) 251-255.

NNI. National Nanotechnology Institute. Available at http://www.nano.gov/html/society/home_society.html. Accessed July 15, 2005.

SATAVA, Richard M. "Biomedical, Ethical, and Moral Issues Being Forced by Advanced Medical Technologies". *Proceedings of the American Philosophical Society*. 2003; September 147 : 246-258.

SERVICE, Robert F. "Nanomaterials Show Signs of Toxicity". *Science*. 2003; 300 : April 11. 243.

STUPP, S. I. "Nanotechnology in Medicine". In: Roco, M. C., Bainbridge, W. S. (eds.) *Societal Implications of Nanoscience and Nanotechnology*. Arlington, VA : National Science Foundation, March 2001. 161-162.

Clinical Genetics: Meeting the Challenges to Privacy

PATRICIA A. ROCHE, J. D., MED.*

Introduction

In the United States, the Human Genome Project was originally promoted to Congress and the public on the premise that it would achieve two grandiose goals: revolutionize how we detect, treat and prevent disease and establish biotechnology's presence in the marketplace. Since the inception of the Project our understanding of the relationship between genes and disease has certainly increased but this knowledge has hardly resulted in a "revolution" in clinical care. One notable change is the expansion of genetic testing beyond tests for rare single gene disorders and chromosomal abnormalities to tests for predicting the risks asymptomatic individuals have for developing more common diseases. Tests have, for example, been developed to identify individuals susceptible to some types of breast and ovarian cancer, colorectal cancer and Alzheimer's disease. The clinical utility of such tests may be limited since some, like Apolinpoprotein E (APOE) genotyping for Alzheimer's disease, may not be reliable predictors of disease or indicate increased risk of developing diseases for which no specific, effective interventions have yet been

* Assistant Professor of Health Law, Department of Health Law, Bioethics and Human Rights, Boston University School of Public Health

Presented at *The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World,* Lisbon, Portugal, June 2-3, 2005.

Co Sponsored by the Luso-American Foundation and Boston University School of Public Health.

developed.[1] Nevertheless, physicians are using some susceptibility tests in clinical practice, presumably because the resulting information impacts upon the care and advice they give their patients. As more susceptibility tests are developed and marketed directly to patients as well as clinicians over the next decade,[2] we can anticipate an increased use of genetic testing and genetic information in health care.

Most physicians have had limited clinical experience with genetic testing, but those with experience have encountered situations that call established standards of practice into question. Circumstances that implicate privacy standards have been the subject of several case reports in medical literature.[3] These reports involved patients who were similarly situated despite their differences in age, gender, and medical history. In each case, their physician or the genetic counselor informed them that results of their genetic tests had implications for the patient's relatives and recommended that the patient disclose the information to those relatives. Nevertheless, the patients rejected that advice and expressed a desire to keep the information strictly confidential. Consequently, the providers involved felt they had to choose between conflicting legal and ethical obligations: their duty to maintain patient confidentiality and a duty to warn family members about their genetic risks.

The discussions accompanying these case reports echoed a question that has been debated since the inception of the Human Genome Project: whether clinicians need any new privacy rules or standards as a result of the increasing availability of genetic tests and genetic information in clinical practice. In this essay I will posit that practitioners' experiences with genetic testing argue for a strengthening of patient rights to privacy and against the establishment of a duty to disclose genetic information directly to relatives. To explain why, I will focus on the situations described above and the suggestion by others that we should rethink strict

adherence to patient confidentiality and routinely permit or even require practitioners to disclose information to family members regardless of the patient's insistence on confidentiality.

When contemplating any changes to legal duties (or corresponding rights) relative to patient privacy, it is important to bear in mind why they came to be established. In the patient centered model of care the physician/patient relationship is recognized by law as fiduciary in nature and the goal of the relationship is do what is in the patient's best interests.[4] As a consequence, the physician is the one who has duties (to the patient) and the patient has rights in relation to his or her care. Among those are a duty to keep information learned in the course of treatment confidential and a corresponding patient right to confidentiality that may be enforced by an action in tort.[5] Imposition of this duty encourages patients to speak candidly with their physicians thereby benefiting from the relationship and demonstrates societal support for patients seeking care. This is especially important when care involves sensitive, embarrassing or potentially stigmatizing information.

Together these laws demonstrate strong public policy in support of fostering the physician/patient relationship and a reluctance to undermine it. Absolute adherence to confidentiality may, however, in some circumstances conflict with other societal goals. Therefore, exceptions to this general rule of confidentiality have also been established by common law and statute. For example, all states have mandatory reporting statutes that don't just permit, but require that physicians report certain diseases to designated public authorities and typically provide immunity from breach of confidentiality suits in relation to such reporting.[6] Other statutory exceptions permit disclosures for law enforcement[7] purposes, to comply with court orders,[8] or to facilitate medical research.[9]

In questioning whether the establishment of a new exception to patient confidentiality is warranted, it is important to understand why genetic information would be at the heart of the con-

flicting obligations described by clinicians in the previously noted cases. We also need perspective on how often the conflict is likely to arise in actual practice, what the barriers to intra family disclosures are, and how individuals and society would benefit from the exception.

Why the Concern over Genetic Information?

As the cases depicting the conflict over disclosures of genetic information indicate, patients (or at least some patients) are particularly reluctant to share genetic information with others, even family members. This suggests that they perceive genetic information to be uniquely private and distinguishable from other medical information. As my colleagues and I have previously maintained, there are aspects of genetic information that support the view that genetic information can be distinctively private.[10] Results of genetic testing that reveal information beyond an individual's medical history or current health status and relate to the individual's probable risks for suffering from a condition in the future, are especially private. In the absence of genetic testing, that information would remain secret and hidden unless or until symptoms of the relevant disease became manifest. Additionally, DNA and genetic information (whether rightly or wrongly) has been endowed with a power that exceeds other personal information.[11] Consequently, an individual's outlook on the future can be significantly affected by the results of susceptibility testing.[12] Finally, although we share parts of our genetic makeup to differing degrees with genetic relatives, except for those of us who are identical twins, our genomes are unique to us as individuals. Given these characteristics, it is reasonable for patients to expect that providers will take as much, if not more, care to keep genetic information private.

Hypothetical Cases Versus the Reality of Practice

There are many reasons why patients might choose to keep their genetic information private from family members as well as strangers. A study by Angus Clarke and his colleagues of patient encounters in Australia and the UK provides data on how often patients choose not to share information within families and why.[13] Out of the 40,000 clinical consultations they analyzed, providers encountered only 65 patients (< 1%) who decided not to pass information on a genetic condition to other family members, despite suggestions and even strong recommendations from providers that they share the information. Of those non-disclosing patients, 39 specifically declined to discuss information with their adult children, 22 patients declined to disclose information to siblings or other relatives, and 4 declined to pass information to partners or expartners.[14] Although this is not the only study of disclosures of genetic information within families,[15] the results may be particularly informative about the frequency of the problem given the sample size, the range of genetic information involved (genetic susceptibilities for Huntington's disease and breast, ovarian or colon cancer) and the fact that the results were based upon real encounters between providers and patients over a 12 month period, rather than responses to questionnaires about hypothetical situations. Of course, we should be cautious in concluding from their findings that patients almost always disseminate information within their families and therefore withholding information is a non-issue. For one thing, professionals may not be aware of the extent to which communication in families does or does not occur and the incidents of non-disclosure may have been underreported by patients to the providers in this study.[16] Furthermore, communications patterns in families (and in health care) may differ in the United States and influence disclosure rates. Nevertheless, it appears that non-disclosure in families may

not be as prevalent an issue as it is sometimes portrayed. Regardless of whether non-disclosure would occur infrequently or rarely, we need to understand why patients decide not to share genetic information when determining the direction of law and policies for this area of clinical practice.

Some commentators assume that estrangement between family members would account for most cases of non-disclosure of genetic information within families. That assumption has been borne out to some extent by research with genetic counselors in the United States.[17] Clarke's study confirmed as well that problematic family relationships can be a reason for non-disclosure, but more importantly showed that it is neither the sole reason, nor the one most frequently given for non-disclosure. In fact, one of the concerns most often raised by those patients was a desire to spare the family member who would receive the information from anxiety.[18] Other reasons included perceptions that others would not be interested in the information, might change their future plans (including marriage) in reaction to the information, or would be better off not knowing.[19] Fears over the patient's own loss of privacy and fear of blame as a consequence of disclosure were also cited.[20]

Clarke's research tells us that most patients, regardless of whether they ultimately decide to share genetic information or not to, do in fact take the well being of their family members into account. The problem is that no one, even a close family member, let alone a stranger can correctly predict how another person would value or respond to almost anything, including information derived from genetic testing. If we have learned anything from the history of genetic testing thus far, it is that similarly situated individuals make different choices about pursuing genetic information when the option for testing is presented to them. For example, despite predictions that most people in families affected by Huntington's disease would choose to undergo predictive testing

for the disease, that has not been the case in clinical practice.[21] The highly individualized and subjective nature of the decision to pursue genetic information is demonstrated by the rates of uptake of testing for other diseases as well, including conditions for which interventions are available.[22] Some individuals will prefer to live with ambiguity, rather than confirm whether they have a genetic susceptibility or not.

If we are contemplating permitting (or requiring) providers to disclose information to relatives over the patient's objections, we should therefore be mindful not only of the effect this would have on the patient's privacy interests, but the possible effects on the privacy and autonomy of the recipients of information. Intrusion on their spatial privacy seems inevitable when conveying unsolicited information, and depending on what information is conveyed, violations of what has been called a "right not to know" one's genetic status may result as well.[23] It may be difficult for those who see value and utility in genetic testing and knowing one's genetic status to entertain the idea that others may see it differently and feel intruded upon, rather than grateful when given unsolicited information. No doubt this contributes towards the frustration that providers express when they discuss or write about patients who refuse to share their information with relatives and the lengths some providers take to overcome such refusals.

An anecdote from Kenneth Offit, a clinician who has dealt with the issue in practice, vividly demonstrates that relatives won't necessarily welcome the message or the messenger. After one of his patients died from a genetic form of breast cancer Offit tried to contact her daughter so that he could warn the daughter of her own potential risks. Failing that, he located his patient's mother, who told him: "Enough of this talk about cancer. I don't want my family to hear any more of it".[24]

If providers contact families directly and over the objection of their patients, they should be aware that they may in fact be sac-

rificing their patient's confidences and trust as well as family privacy in vain. Nevertheless, there may be occasions when some good might conceivably come (to others) from acting wrongly in regard to the patient's privacy interests. In 1994, the Institute of Medicine's Committee on Assessing Genetic Risks recommended that anyone contemplating breaches of confidentiality in this context should be prepared to justify the breach and to assume the burden of doing so on the basis of stringent criteria.[25] The criteria they devised were:

> *[A]ttempts to elicit voluntary disclosure fail, there is a high probability or irreversible or fatal harm to the relative, the disclosure of the information will prevent harm, the disclosure is limited to the information necessary for diagnosis or treatment of the relative and there is no other reasonable way to avert the harm.*[26]

Nothing that we have learned about genetic testing and clinical practice in the intervening eleven years provides sufficient reason for adopting any less stringent criteria by law or in policies for clinical practice.

Fear of Liability

From a practitioner's point of view, one of the difficulties with honoring a patient's wishes for strict confidentiality in regard to genetic privacy is the fear that relatives may succeed in holding them liable for failing to warn them of their risk for genetic disease. This concern is often paramount when practitioners debate whether or not to breach confidentiality and disclose genetic information to a patient's family. However, state courts have only begun to address the common law obligations physicians have to genetic relatives in this context and in no

state have all issues been fully litigated or ruled upon by the courts.

Courts in two states (Florida and New Jersey) have overruled dismissals of lawsuits alleging a duty to warn genetic relatives, allowing the cases to go forward to trial.[27] However, an analysis of the facts, reasoning and rulings in these cases doesn't support the conclusion that practitioners in those states or else where have an established duty to directly warn relatives when that necessitates breaching patient confidentiality. In the Florida case, *Pate v. Threlkel,*[28] Marianne New had been treated for medullary thyroid carcinoma in 1987 by James Threlkel, M. D. Three years later her adult daughter, Heidi Pate, discovered that she had medullary thryoid carcinoma. Pate subsequently sued Threlkel (and his employers) claiming that he knew or should have known that his patient's children would have inherited the same condition and that he had a duty to warn the patient that her children should be tested. Pate further claimed that had she been tested in 1987, her condition would more likely than not have been curable and the physician's negligence was the direct and proximate cause of her suffering from advanced disease. The defendants filed a motion for dismissal on the basis that no professional relationship existed between the plaintiff (Pate) and the physician and therefore the physician owed her no duty of care. The judgment of the trial court granting the defendant's motion was appealed to the Superior Court.

The question on appeal was: "Does a physician owe a duty of care to the children of a patient to warn the patient of the genetically transferable nature of the condition for which the physician is treating the patient?"[29] The Court read this as encompassing two separate issues. First, whether the physician has a duty to warn the patient of the nature of the condition and second, to whom does that duty run? In answering the first question, the Court reasoned that under the Florida malpractice statute plain-

tiffs, including Pate, have the burden of proving that actions of a defendant represent a breach of the prevailing professional standard of care, which is further defined as "the level of care, skill, and treatment... recognized as acceptable and appropriate by reasonably prudent similar health care providers"[30]

The plaintiff had not yet introduced expert testimony because the appeal arose on a motion to dismiss the complaint. Based on the assumption that the plaintiffs would be able to prove through expert testimony that a reasonably prudent health care provider would warn a patient of the genetically transferable nature of the patient's condition, the Court turned to the second question. Relying on other cases that recognized the rights of identified third party beneficiaries to recover from a professional despite an absence of privity, the Court concluded that "when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties".[31] Although not part of the question on appeal, the Court went on to address the obvious related issue of how the duty is it to be discharged and stated:

> *Our holding should not be read to require the physician to warn the patient's children of the disease. In most instances the physician is prohibited from disclosing the patient's medical condition to others except with the patent's permission... Moreover, the patient ordinarily can be expected to pass on the warning. To require the physician to* seek *out and warn various members of the patient's family would often be difficult or impractical and would place too heavy a burden upon the physician. Thus, we emphasize... that duty will be satisfied by warning the patient.*[32]

Pate's suit was therefore not barred by a lack of privity and the case was remanded to the trial court. Having survived a dismissal

of the action, the plaintiff still faced the challenge of meeting her evidentiary burden of proving not just the physician's duty, but breach of that duty and the causal link to her injuries. No further appellate rulings in the case have been reported. For providers in Florida therefore, it seems clear that any fears of being held liable for failure to inform patient's family members about genetic susceptibility when they have fully informed the patient about the implications the information has for their children, are unfounded.

The New Jersey case, *Safer v. Pack,*[33] involved similar (but somewhat more problematic) facts and allegations as in *Pate*. In *Safer,* the plaintiff sued the estate of a doctor who had treated her father for colon cancer more than thirty years earlier. Her father died in 1964. Safer, who was 10 years old when her father died, was 36 when she brought suit and two years prior to the case she had been diagnosed and treated for colon cancer. Subsequent to her diagnosis, she obtained her father's medical records and allegedly discovered the nature of his illness for the first time. In her suit Safer alleged that when her father had been treated the hereditary nature of his illness was known to the defendant, that the defendant was required by the then prevailing medical standards to warn those at risk so they could be provided with an opportunity to take steps to avoid the consequences of the condition, but he had failed to do so. The trial court dismissed the action and the issue on appeal was whether a legal duty to warn those known to be at risk of avoidable harm from a genetically transmissible disease existed. In holding that it did, the New Jersey Court stated:

> *Although an overly broad and general application of the physician's duty to warn might lead to confusion, conflict or unfairness in many types of circumstances, we are confident that the duty to warn of avertable risk from genetic causes... is sufficiently narrow to serve the interests of justice.*[34]

As for the issue of how that duty was to be discharged the Court further stated:

> *We need not decide, in the present posture of this case, how, precisely, that duty is to be discharged, especially with respect to young children who may be at risk, except to require that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit.*[35]

This Court was mindful of the ruling in *Pate*, but cautious of likewise holding that in all circumstances that duty would be satisfied by informing the patient.[36] Instead, the Court left that issue to be resolved if and when the question was ripe for review, acknowledging that it might be necessary (at that point) "to resolve a conflict between a physician's broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of disease".[37]

In this case, as in *Pate,* several factual questions were left to be resolved at trial. Given that neither the defendant nor the defendant's patient in *Safer* would be available to testify and the events at issue took place decades earlier, the plaintiff faced a considerable burden of proof. No further rulings in this (or any similar cases) in New Jersey have been reported.

We can draw several conclusions from the few reported cases on the duty to warn genetic relatives. First and foremost, common law doctrine on duty to warn genetic relatives is far from settled. Second, to the extent that a duty to warn may exist, no court has held that it would always take precedence over the physician's duty of confidentiality. It would, therefore, be a mistake for providers to think that if they were to breach confidentiality to inform relatives of genetic risks that they need not be concerned about liability. Liability (for breach of confidentiality) would still be an issue. Whether any court would recognize an

exception to disclose information to a family member if it were raised as a defense in an action for breach of confidentiality is unknown. There is precedent that permits disclosures (to employers) when the patient is the source of a "serious danger" to self or others.[38] Whether any court would extend that to include family members is highly questionable, given that here the source of potential risk (a genetic predisposition) doesn't spring from the patient. Moreover, other avenues for obtaining the information would likely be available to family members, such as undergoing genetic testing themselves, or discussing family history with their own providers.[39] Lastly, the *Pate* and *Safer* cases indicate that courts are hesitant to establish by law the specifics of the relevant standard of care and development of the prevailing standard is still a matter to be addressed by and within the profession.

With this last point in mind, it is interesting to note that the plaintiffs in both of the reported cases were children of the defendants' patients and in the study conducted by Clarke and associates discussed above, 39 of the 65 non-disclosing patients, specifically declined to discuss information with their adult children. This seems to indicate that professionals may well be advised to take a more active role in assisting with patient disclosures when the information has implications for the future health of the patient's children, recognizing that those disclosures may be the most difficult for patients.

Reluctance to Breach Confidentiality

As previously discussed, a primary danger in creating a duty to disclose to relatives is the negative affect fulfilling that duty would have on the relationship between a patient and provider. Research indicates that clinicians are highly cognizant of that consequence.

When given the choice of risking that relationship in order to fulfill their responsibility towards others, most practitioners are not actually willing to sacrifice the relationship by contacting relatives. In Clarke's study for example, none of the physicians or genetic counselors went so far as to breach patient confidentiality in order to satisfy the responsibility they felt to protect or warn family members.[40] These results appear to be representative of genetic counselors in the United States as well where a similar study showed that although some counselors seriously considered breaching confidentiality by contacting a family member, only one did.[41]

Conclusions

The information derived from some genetic testing can have real utility in clinical care and for future life planning. Creation of a legal duty to warn or inform family members of genetic information would do little, if anything, to ensure that individuals and society benefit from that information, or to relieve the burden practitioners feel as custodians of that information. It is important that we develop other means to ease that burden. We should focus upon ways that promote sharing and understanding of genetic information without sacrificing privacy rights, provider/patient relationships and patient centered practice.

Acknowledgment

I thank Stephen Schauder, Boston University School of Law Class of 2007 and Carolyn D'Aquila, Boston University School of Public Health Class of 2007 for their able assistance in preparing this manuscript.

Notes

[1] Burke, W. *et al.,* "Genetic Test Evaluation: Information Needs of Clinicians, Policy Makers, and the Public". *Am. J. Epidemiol.* 2002; 156 : 311, 315.

[2] NHGRI. NIH. *Direct to Consumer Marketing of Genetic Tests,* (March 23, 2004). Available at www.genome.gov/12010659; S. Gollust, S, Hull, B. Wilfond, "Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing" 288 *JAMA* 1762, 1762-1767 (2002).

[3] See Porfiri, E. "'Secrets and Lies' : the Difficulties of Communicating within Families with Inherited Cancer Syndromes". *Clin. Gen.* 2004; 66: 476-477; Offit, K. *et al.,* "The 'Duty to Warn' : a Patient's Family Members About Hereditary Disease Risks". *JAMA* 2004; 292 : 1469-1473; Parker, M., Lucassen, A. "Genetic Information: a Joint Account?" *BMJ* 2004; 329 : 165-167.

[4] *Hammonds v. Aetna Casualty & Sur. Co.*, 243 F. Supp. 793, 802-803 (N. D. Ohio 1965); *Yates v. El-Deiry*, 513 N.E.2d 519, 522 (Ill. App. Ct. 1987).

[5] *Alberts v. Divine,* 479 N.E.2d 113, 118 (Mass. 1985).

[6] Annas, G. J. *The Rights of Patients.* Illinois : Illinois University Press, 2004. 246-254.

[7] See e.g., *Ohio Rev. Code Ann.* § 3701.24 (D) (2005) permitting release of HIV & AIDS information in connection with criminal investigations without the patient's consent.

[8] See e.g., *Me. Rev. Stat. Ann.* tit. 22, § 1494 (2005) authorizing release of occupational disease information as required by court order.

[9] See e.g., Cal. Health & Safety Code § 103865(f) (3) (2005) permitting access to confidential medical information by some researchers.

[10] Roche, P. Annas, G., Glantz, L. "The Genetic Privacy Act: A Proposal for National Legislation". *Jurimetrics* 1996; 37 : 1; Roche P., Annas, G. "Protecting Genetic Privacy", 2 *Nat. Rev. Gen.* 2001; 392-396.

[11] Nelkin, D, Lindee, M. *The DNA Mystique: The Gene as a Cultural Icon* (W.H. Freeman, 1995).

[12] Dudokde, Wit A., *et al.,* "Distress in Individuals Facing Predictive DNA Testing for Autosomal Dominant Late Onset Disorders, Comparing Questionnaire Results With In-depth Interviews". *Am. J. Med. Gen.* 1998; 75 : 62-74; Michie, S., Bobrow M., Marteau, T. M. "Predictive Testing in Children and Adults: a Study of Emotional Impact". *J. Med. Ethics* 2001; 38 : 519-526; Almqvist, E. W., Brinkman, R. R., Wiggins S., Hayde, M. R. "Psychological Consequences and Predictors for Adverse Events in the First 5 Years After Predictive Testing for Huntington's Disease". *Clin. Genet* 2003; 64 : 300-309.

[13] Clarke, A. *et al.,* "Genetic Professionals' Reports of Nondisclosure

of Genetic Risk Information Within Families" 13 *Eur. J. Hum. Gen.* 2005; 556-562.

[14] *Id.* at 558.

[15] See e.g., Lehman, L. S. *et al*, "Disclosure of Familial Genetic Information: Perceptions of the Duty to Warn"*, Am. J. Med.* 2000; 109 : 705-711; Planting, L. *et al*, "Disclosure, Confidentiality, and Families: Experiences and Attitudes of Those With Genetic Versus Nongenetic Medical Conditions". *Am. J. Med. Gen.* 2003; 119C : 51-59; Dugan, R. B. *et al.,* "Duty to Warn At-Risk Relatives for Genetic Disease: Genetic Counselors' Clinical Experience". *Am. J. Med. Gen.* 2003; 119C : 27, 27-34.

[16] Clarke, *supra* note 13, at 560.

[17] Dugan, *supra* note 15, at 31.

[18] This reason was cited by 18 of the 65 non-disclosure cases reported by Clarke *et al.,* Clarke *supr*a note 13, at 559.

[19] Non-interest in having the information was cited 11 times; possible impact on the marriage plans (of the other family member) was cited 4 times, and a belief that it was better not to know was cited 8 times. *Id.*

[20] Fears of adverse consequences to themselves because of a loss of privacy were cited 6 times; fear of blame was cited 5 times. *Id.* In similar studies in the U. S., an additional concern of patients was that their relatives would be discriminated against by insurers or employers. Dugan, *supra* note 13 at 31.

[21] Hayden, M. "Predictive Testing for Huntington's Disease: the Calm After the Storm". 356 L*ancet* 2000; 1944-1945.

[22] See Claes, E. *et al.,* "Predictive Testing for Hereditary Non-polyposis Colorectal Cancer: Motivation, Illness Representations and Short-term Psychological Impact". *Patient Education and Counseling.* 2004; 55 : 265-274; Lodder, L. *et al.,* "Attitudes and Distress Levels in Women at Risk to Carry a BRCA1/BRCA2 Gene Mutation Who Decline Genetic Testing". *Am. J. Med. Gen.* 2003; 119A : 266-272.

[23] Laurie, G. "Obligations Arising From Genetic Information : Negligence and the Protection of Familial Interests". *Child. and Fam. Quart.* 1999; 11 : 109-124.

[24] Tanner, L. "Genetic Testing Challenges Medical Ethics". *Science-Associated Press.* Sept. 22, 2005. Since Offit's patient was not alive when he contacted the relative he wouldn't have been concerned that the patient would end the relationship and/or bring an action for breach of confidentiality and therefore been less hesitant to contact the family directly. For a discussion of post mortem confidentiality see Berg, J. "Grave Secrets: Legal and Ethical Analysis of Postmortem Confidentiality", 2001; 34 *Conn. L. Rev.* 81

[25] Committee on Assessing Genetic Risks, Institute of Medicine, *Assessing Genetic Risks, Implications for Health and Social Policy* (National Academy Press 1994) at 278.

[26] *Id.*

[27] *Pate v. Threlkel*, 661 So. 2d 278 (Fla. 1995) and *Safer v. Pack,* 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996). A third case in Minnesota, *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004) has also been the source of attention and discomfort on the part of physicians. I am not addressing it here because the facts of the case involve a negligent failure to do a genetic test and relay results to a child's parents. It therefore doesn't fit the circumstances of a failure to warn cause of action.

[28] 661 So. 2d 278 (Fla. 1995).

[29] *Id.*

[30] FLA. STAT. ANN. § 766.102 (1989).

[31] *Pate v. Threlkel,* 661 So.2d at 282.

[32] *Id.*

[33] 677 A.2d 1188 (N. J. Super. Ct. App. Div. 1996).

[34] *Id.* at 1192.

[35] *Id.*

[36] *Id.*

[37] *Id.* at 1192-1193.

[38] Alberts v. Devine, 471 N.E. 2d at 119.

[39] For a discussion of common law exceptions to confidentiality see Annas, G., Glantz L., Roche, P. *Genetic Information and the Duty to Warn,* The Genetic Privacy Act And Commentary, App. available from the authors at Boston University School of Public Health, Boston Mass. (1995).

[40] Clarke, *supra* note 13, at 560.

[41] The one reported breach of confidentiality involved some unusual circumstances: a family member who was also a client of the provider and information was disclosed to avoid unnecessary testing. Dugan, *supra* note 15 at 32.

The Role of Law in Controlling Epidemics: Lessons from TB, HIV and SARS

WENDY K. MARINER*

I. Introduction

Marilyn Chase's history of the bubonic plague that struck San Francisco in the United States one hundred years ago recounts the different approaches taken by federal public health officers to stop a potential epidemic that could have killed thousands and cost millions of dollars in lost business.[1] When Dr. Joseph Kinyoun, a bacteriologist, suspected that plague caused the death of a man from the "Chinese quarter", he quarantined the area,

* Professor of Health Law, School of Public Health, Professor of Law, School of Law, Professor of Socio-Medical Sciences and Community Medicine, School of Medicine, Boston University. J. D Columbia University School of Law; L. L. M New York University School of Law; M. P. H. Harvard School of Public Health. I am grateful to Kaley Klanica, Health Law & Bioethics Fellow, J. D. 2004 Boston University School of Law, M. P. H. 2005 Boston University School of Public Health, and to Elizabeth Wilkins, second year student at St. Louis University School of Law. for research assistance. I also thank Boston University School of Public Heath Department of Health Law, Bioethics and Human Rights; National University of Lisbon School of Public Health; and Luso-American Foundation for providing an opportunity to present a version of this paper at the Seminar on Health Law and Bioethics, 3 June 2005, Lisbon, Portugal.

Draft 14 July 2005.

Parts I and III and major portions of Parts II and V of this article are excerpted, with some revisions, from Wendy K. Mariner, "Law and Public Health: Beyond Emergency Preparedness", *Journal of Health Law* (2005).

where about ten thousand people of Chinese ancestry lived, terrifying the residents.[2] The quarantine fence serpentined around to exclude properties owned by Caucasians on the theory that the Chinese were genetically susceptible to plague.[3] A federal court struck down the quarantine order as a violation of the equal protection clause of the Fourteenth Amendment.[4] It also found that keeping healthy people fenced in with the few who had been exposed to plague increased, rather than decreased, the likelihood of an epidemic.[5] When Dr. Kinyoun responded by ordering the entire city quarantined, the business and political community ran him out of town and persuaded President McKinley to lift the quarantine.[6] Dr. Kinyoun's successor, Dr. Rupert Blue, engaged the community in an active effort to clean up old buildings and eradicate the rats that carried plague-infected fleas.[7] The process was laborious, but effective.[8] Dr. Blue later became Surgeon General of the United States.[9]

This story is a reminder of the many sources of risks to health, the different tools available to prevent or control disease, and the many factors that influence which tools are effective. Of course, much has changed in the past one hundred years.[10] Infectious diseases are no longer the leading cause of death in the United States or the developed world.[11]

Preliminary data for 2003 indicate the leading causes of death in the United States (see next page).

Environmental changes have eliminated many sources of contagion.[12] Scientific advances have produced vaccines to prevent many infectious diseases and therapies to cure or manage other illnesses. A more educated population is better able to understand health risks and how to protect themselves.[13] Modern public health programs are wide-ranging and complex. Yet, the lessons of the Barbary plague remain relevant today, when popular perceptions of contagious disease may be powerfully shaped by the fear of terrorism or possible natural pandemics like avian influenza.[14]

CAUSE OF DEATH	TOTAL NUMBER OF DEATHS
All causes	2,443,930
1. Heart disease	684,462
2. Malignant neoplasms (cancers)	554,643
3. Cerebrovascular diseases (stroke etc.)	157,803
4. Chronic lower respiratory disease	126,128
5. Accidents (unintentional injuries)	105,695
6. Diabetes mellitus	73,965
7. Influenza and pneumonia	64,847
8. Alzheimer's disease	63,343
9. Nephritis, nephritic syndrome and nephrosis	42,536
10. Septicemia	34,243
11. Suicide	30,642
12. Chronic liver disease	27,201

This Article examines the role of law in controlling contagious diseases today. Part II summarizes the vast array of modern programs under the public health umbrella and how complex social factors, including globalization and bioterrorism, affect them. It also highlights differences and similarities between medicine and public health to point out how different definitions of a problem affect the choice of law needed to solve public health problems.

Part III describes the many domains of law that can be used to control contagious diseases and protect public health in general. It then offers a conceptual choice of law framework, based on the International Bill of Human Rights, for identifying the types of law relevant to health issues.[15] There is a striking correlation between the three duties of States Parties to the International Bill of Human Rights to "respect, protect and fulfill" the human right to health and the three major categories of national and local laws: those governing individual rights and duties; those setting safety and health standards; and those establishing service and benefit programs. Regardless of whether the International Bill of Rights ap-

plies directly to national law in any country, these categories of law offer a useful framework for practitioners. The International Bill of Rights is also the lens through which most of the developed world examines public health and which scholars use to determine which legal strategies are justified to achieve specific public health goals.

Part IV examines the effect of different types of law in controlling outbreaks of infectious diseases, using tuberculosis, HIV, and SARS as examples. I argue that the U. S. government's focus on terrorism has overshadowed the need for protection against naturally occurring contagious diseases. This has encouraged three errors in the use of law: sacrificing human rights for illusory "security"; substituting personal responsibility for social responsibility for protecting health; and substituting criminal laws to control individuals for effective social programs, resources, and education to control disease outbreaks. Instead, the lessons we should learn from these experiences with contagious diseases are first, that human rights are necessary for both health and security, and second, social programs and resources can control epidemics more effectively than criminalizing personal behavior.

I conclude that law creates the foundation for controlling contagious diseases around the world by authorizing and regulating the social institutions that protect public health. Thus, it is essential to choose the most effective type of law to respond to different risks of disease. Lawyers have a unique role to play in ensuring that the legal principles chosen to promote health also preserve justice.

II. The Scope of Public Health

A. Defining Public Health

Public health has been both broadly and narrowly defined, usually as a function of its political influence.[16] Broad definitions

offer a more accurate description, as in the classic definition by C. E. A. Winslow:

> *Public Health is the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community effort for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery to insure everyone a standard of living adequate for the maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity.*[17]

This broad description still accurately depicts the wide range of activities of people who work in the field of public health.[18] It is also consistent with the broad range of laws enacted in the name of public health. Given such a broad scope, public health might be equated with any public policy that serves in any way to prevent physical or mental harm or to maintain or improve health.[19] This may pose some definitional problems for those seeking a unifying vision of public health. But, the fact that different groups working within public health define their own territory more narrowly should not deter lawyers from recognizing the broad scope of issues relevant to health.

When the United States first became a nation, protecting the public against contagious diseases fell within the general responsibilities of most town officials. The field of "social hygiene" began with the nineteenth century recognition that environmental hazards, as well as poor personal hygiene, could cause illness.[20] Sanitary engineers, perhaps the first real public health workers, eliminated cholera and other water-borne diseases by creating systems for sewerage and purifying the water supply; other infectious diseases by regulating waste at animal slaughter houses and dockyards and pasteurizing milk; and dramatically reduced tuber-

culosis by cleaning up slum housing.[21] The increase in life expectancy from forty-seven years in 1900 to seventy years in 1960 can be attributed largely to these public health programs.[22] Many public health pioneers were social reformers, who sought to reduce the hazardous living and working conditions in nineteenth century cities and factories. Their motives varied, from genuine concern for the disadvantaged, to the economic benefits of hiring healthier workers, to forestalling class rebellion by the poorer classes.[23]

The field of public health continues to expand as more is learned about what affects health. Today, empirical research offers growing evidence that socioeconomic factors, such as the distribution of wealth and income, political inequality, education, employment, and housing, can affect health.[24] Known as the "social determinants of health", these factors recall the concerns of early public health reformers and remind us that contagious disease is not the sole threat to health in the United States. Attention to the social determinants of health poses a challenge to defining public health as a unified or recognizable field. Yet, scholars in public health have made significant contributions to research identifying social and environmental factors affecting the health of populations.[25] As a practical matter, it may be difficult, if not impossible, to improve health significantly in the future without addressing these social factors. For example, the rise of tuberculosis in New York City in the mid-1980's was exacerbated by the rise of unemployment and a decline in affordable housing, which left more people homeless, on the street, or in shelters where the disease could be easily transmitted.[26] Some critics argue that research on wealth as it affects health is still too crude to produce useful information for making policy[27] and there are dangers in medicalizing so many social issues.[28] Nonetheless, it is increasingly difficult to avoid recognizing how broad social policies, such as those concerning immigration, drug abuse and housing, affect health. Better research to identify the relationships should inform future law and policy.

Increasing interdependence among global economies is pushing the public health field more firmly into the international sphere.[29] Research is increasingly international, with scientists in different countries sharing insights and techniques to study everything from contagious diseases to genetics to management. As companies expand their operations around the world, they are beginning to recognize the need for consistent international standards in product safety, environmental controls, and occupational hazards.[30] Sales of goods over the internet raise questions about which product safety standards and marketing rules should apply. Climate change and natural disasters require a coordinated global response from many countries. Disasters like the December 2004 Tsunami create financial and logistical challenges, from identifying the dead to housing and feeding the displaced, that no single country can meet alone. Even war is increasingly recognized as an international public health concern, which requires multinational efforts to provide for the health and safety of civilians, who are often targets of military or terrorist violence.[31] Here, especially, the international human rights movement has brought attention to the positive relationship between human health and respect for human rights.[32]

Infectious diseases remain a global health concern, despite remarkable progress in preventive vaccine and drugs for treatment.[33] International travel and migration enable viruses and parasites to become world travelers, as SARS demonstrated most recently. [34] In the United States, however, efforts to prevent the spread of contagious diseases have focused primarily on the possibility that a terrorist might use a biological agent to kill large numbers of people.[35] When letters containing (noncontagious) anthrax killed five people soon after September 11, 2001, federal officials warned that terrorists might bring smallpox into the country next.[36] In the United States, the combination of terrorism and disease has simultaneously concentrated much needed attention on public health and perversely narrowed public appreciation of public health largely to

bioterrorism.[37] The most positive response has been new federal funding to shore up the perennially neglected "public health infrastructure", the collection of public and private programs that study, prevent, and treat health problems that affect communities large and small.[38] Less positive has been the emphasis on emergency preparedness to the detriment — some would say exclusion — of the less glamorous, ordinary tasks of public health practitioners, which may offer better protection against illness and death.[39]

B. Medicine and Public Health

Most lawyers working in the health field are more familiar with legal issues in medicine than with those in public health. People working in public health have traditionally distinguished their field from medicine by emphasizing that physicians treat individual patients while public health practitioners "treat" entire populations.[40] Public health's emphasis on population groups, rather than individual patients, has produced several differences between medicine and public health, as summarized in Table 1 (see next page) below. One should not overemphasize these differences, however. As noted below, many are becoming less relevant to today's health concerns, especially contagious diseases.

Physicians are an identifiable professional group. Like the legal profession, the medical profession is defined by a common knowledge base derived from generally uniform methods of education and training.[41] These skills can be used to achieve many different goals. In contrast, public health tends to be defined by its general goal, improving health, not by the methods it employs, which are many. All kinds of people, with and without professional training, work in public health — physicians, nurses, engineers, educators, counselors, laboratory technicians, statisticians, restaurant inspectors, pest control workers, and many others.[42] They have very dif-

Table 1: Medicine and Public Health Compared

	MEDICINE	PUBLIC HEALTH
Knowledge base	Uniform professional training, knowledge and skill	Multiple professionals and non-professionals with different training and skills
Goals	Medical treatment Act in individual patient's best interests	Risk prevention Improve health for largest number of people
Focus	Individual patient	Populations
Relationship	Personal	Statistical
Measure of success	Process: patient choice	Outcomes: fewer deaths, diseases per population
Methods	Autonomy, informed consent	Persuasion; coercion
Use of information	Confidentiality	Information sharing
Ethical principles	Autonomy Bioethics	Social justice Human rights

ferent skills and methods. What they share is a common goal: preventing deaths and improving health for large groups of people (defined by geography, sex, or race, for example).

A related distinction between public health and medicine arises from the difference between defining health goals in terms of an entire population as opposed to an individual patient. Success in public health depends on improving the health of the entire population, which can be measured only in aggregate statistics, such as life expectancy and rates of death (mortality), disease (morbidity), and disability. Practising physicians deal with one patient at a time and measure success patient by patient. Although physicians want to save lives and prevent or cure disease, they have an obligation to

do what the individual believes to be in her own best interest.[43] Thus, physicians are also successful when their patients succeed in making their own decisions. This kind of individual "success" does not necessarily count as success in public health terms. Patients who refuse life-saving therapy because they find it too burdensome may adversely affect population mortality rates. Public health programs that focus on aggregate outcomes for a population cannot account for individual values in the same manner as medicine.

Medical ethics has focused on the personal relationship between a physician and a patient, emphasizing the principles of individual autonomy and nonmaleficence.[44] The doctrine of informed consent epitomizes both the process for making decisions about treatment and the patient's right to autonomy and self-determination within a quasi-fiduciary relationship, where the physician has no power to force a patient to do anything.[45] With few exceptions, the physician must keep personal information about the patient confidential.[46] Public health's focus on aggregate results necessarily subordinates individual choice to statistical outcomes. To identify health risks and means of prevention, public health practitioners often rely on collecting and sharing information about people. Methods for improving health range from environmental regulation to public education to coercion in the form of laws requiring or forbidding particular behaviors. The ethical principles to guide public health endeavors thus require principles that address the relationship between the individual and the State. For this reason, the International Bill of Rights, specifically the Universal Declaration of Human Rights, is well suited to public health, because it recognizes people's individual rights within the context of the State as a whole.[47]

Despite their differences, medicine and public health have often worked in synergistic ways, both to identify opportunities for research and to translate new technologies into practice. Discovery of bacteria and the germ theory by researchers gave public health its first scientific credibility, as laboratories began to identify specific

causes of disease. Medical research also produced the vaccines that enabled public health immunization programs to eradicate or control many infectious diseases, and physicians and nurses, in private practice as well as public clinics, administered the vaccines.[48] Public health research on the distribution of HIV infection in the early 1980's helped academic scientists target their research to identify the virus and also helped practicing physicians counsel their patients about how to prevent transmission of the infection.[49] Public health screening programs, like those for cholesterol or diabetes, are intended to encourage people to get medical care to control their condition. These are only a few examples of essential and productive links between medicine and public health.

The distinctions between medicine and public health are rapidly blurring. Some occupational groups within medicine and public health have greater affinity with each other than with other specialists in their own field. For example, academic researchers have similar research methods and values, whether they conduct laboratory experiments with cells or epidemiological studies using large databases. Physicians who treat patients in private practice and public health workers who offer substance abuse treatment use similar methods to help individuals, just as physicians and public health workers who offer preventive services share similar methods and concerns.[50] It is often difficult to disentangle medicine from public health simply by looking at what people do. This suggests that, whether they acknowledge it or not, public health and medicine are already integrated to a remarkable degree,[51] and that it would be counterproductive to insist on complete separation.

C. Summary

Despite current public attention to bioterrorism, the field of public health is in fact wide-ranging. It reaches around the world

because both risks to health and ways to protect health are increasingly global, requiring more coordinated international attention, especially to the social determinants of health. This will be especially important in the prevention and control of contagious diseases. Although public health has traditionally considered contagious disease control as its special province, in fact, both physicians and public health practitioners will be engaged in future research and other efforts to prevent the spread of disease. As the distinctions between medicine and public health diminish, it may be time to change our terminology. Instead of medicine and public health, the world sees a field of Health, writ large, with shared components of research, prevention, and treatment throughout. The lingering different professional and conceptual orientations of medicine and public health, however, raise questions about which paradigm will dictate health policy and the regulatory framework for controlling contagious diseases.

III. Public Health, Human Rights, and Law

The law that applies to public health matters is as wide ranging as public health or health itself. Public health issues arise in antidiscrimination law, administrative law, antitrust law, constitutional law, criminal law, employment law, evidence, environmental law, family law, insurance law, mental health law, municipal law, patent law, property law, and tort law.[52] Like lawyers in any applied field of law, health lawyers use whatever laws are relevant to the subject matter in a given context.

A. Laws Affecting Health

The laws affecting health can be sorted into three categories familiar to most lawyers: (1) laws that target individual conduct —

requiring or prohibiting specific actions; (2) laws that set health and safety standards — regulating products or companies that affect health by reducing health risks arising from products or the social or working environment; and (3) laws that affirmatively create benefit programs — offering healthcare, services, or information that individuals are free to accept or refuse.

The first category includes criminal laws, such as those prohibiting the sale or possession of illicit drugs (e.g., heroin and cocaine), or prohibiting smoking, as well as the more obvious crimes such as homicide and assault. It also includes civil laws, such as those that require immunization against certain contagious diseases and authorize the involuntary detention of people who are likely to transmit contagious diseases to others and people who are likely to harm others because of mental illness. At the same time, it includes laws that protect civil rights, such as informed consent, privacy, and nondiscrimination.

The second category includes laws that prevent the conduct of business in ways that could harm customers, workers, or the general public, such as safety standards for workplaces.[53] Sanitary standards for conducting businesses that can harbor and spread disease have existed since colonial times, applying to animal slaughtering operations and mortuaries, for example.[54] More modern examples include standards for the preparation of food in restaurants and sterile equipment in tattoo parlors. Laws requiring licensure of health professionals, hospitals, and other medical facilities are intended to ensure that those who are granted the privilege of providing care have at least a minimal level of competence and skill. Other laws set standards for manufacturing pharmaceuticals, biologics, food, and cosmetics, require safeguards for potentially dangerous products, and measures to limit pollution emission. To administer such laws, legislation has created numerous national and local agencies, from the agencies that regulate pharmaceuticals to the local septic system inspection office.[55] This category also includes both statu-

tory and common-law liability for causing injury, such as products liability and professional liability or medical malpractice.

The third category includes laws that create the multitude of national and local programs to purify the water supply, organize disaster relief, and provide medical care. It also includes public programs for those without health insurance, and funding for public and private health programs like family planning clinics, child nutrition programs, diabetes screening services, substance abuse treatment centers, and refugee care facilities. Finally, it includes public support for biomedical and epidemiologic research and public information programs.

This categorization scheme is admittedly somewhat crude. Some laws, like professional licensure, overlap categories. The framework is more consistent with the source of law than with its ultimate purpose. Thus, it is not possible to distinguish prevention from treatment solely on the basis of the type of law. (Nor is it useful to limit one's legal tools to prevent disease to one type of law.) This contrasts with public health's characterization of programs, which often relies on intent and ultimate goal, not the type of law used to achieve the goal.

B. The Human Right to Health Framework of Laws

The above three categories of law parallel the obligations of nations (States Parties) to "respect, protect, and fulfill" the right to health pursuant to the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR).[56] The most comprehensive statement of the human right to health is found in Article 12 of the ICESCR:

> *1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*[57]

This admittedly aspirational language captures the breadth of factors that affect health. The Committee on Economic, Social and Cultural Rights of the United Nations Economic and Social Council (ECOSOC) recognized that the "right to health is not understood as a right to be healthy", something no one can guarantee.[58] But, it does establish expectations for steps that the signatory States Parties, including the United States, should take as a matter of international law, including official conduct and national legislation.[59] This framework is less one of rights, in the sense typically used in American law, than of social obligation. It describes the social obligations of government to achieve the human right to health for its population.[60]

General Comment No. 14 makes clear that, like all human rights, "[t]he right to health contains both freedoms and entitlements".[61] States Parties must not interfere with personal freedoms, and they must provide, to the extent feasible, the care and protection necessary to ensure the health of everyone in their populations. The ICESCR imposes three types of duties on States Parties, "the obligations to respect, protect, and fulfill" the right to health.[62] More specifically, the obligations are to (1) *respect* personal freedoms, (2) *protect* people from harm from external sources or third parties, and (3) *fulfill* the health needs of the population.[63]

The duty to *respect* personal freedoms requires the State to "refrain from interfering directly or indirectly with the enjoyment of the right to health".[64] This means that the State may not deny equal access to health services or health information, or initiate or enforce discriminatory practices. It also means that States must respect individuals' freedom to choose the type of care they obtain and to refuse care they do not want.

The obligation to *protect* requires affirmative action, by legislation or other means, to ensure that health professionals meet appropriate quality and competence standards, that food, medi-

cines, and health-related products are manufactured and marketed safely, and that industry does not pollute the water, air, or soil.[65] It also requires legislation or other action to prevent third parties from limiting access to care, such as family planning and pre- and post-natal care, and accurate health information.

The obligation to *fulfill* requires the States to ensure that adequate healthcare is provided to the entire population, whether by public or private programs, or a mixture of the two.[66] Recognizing the social determinants of health, it also requires that everyone have equal access to safe food and water, basic sanitation, and adequate housing and living conditions. Ensuring care includes providing for appropriate training for medical professionals and ensuring a sufficient supply of hospitals and other health facilities accessible to everyone in the country. Assisting individuals to enjoy the right to health includes fostering research and disseminating information to the public. Satisfying these duties entails enacting legislation, adopting regulatory measures, or providing funding to develop affirmative programs.[67]

These three obligations parallel the three categories of laws affecting health in the U. S., as illustrated in Table 2 (see next page). The vast majority of public health activities and expenditures falls into categories 2 (Protection) and 3 (Fulfillment). Protection laws creating safety and health standards, such as occupational and business licensure, as well as standards for manufacturing and marketing products and operating businesses were the first and by far largest collection of public health laws in the United States.[68] The number and type of laws creating government programs in the Fulfillment category has risen dramatically since the mid-twentieth century. During the same period, environmental measures and medical advances that prevented contagious diseases eliminated much of the need for category 1 measures to control individuals, such as isolation and quarantine, in order to control the spread of disease.

Table 2: Parallels in Human Rights and United States Laws

HUMAN RIGHT TO HEALTH	U. S. HEALTH LAWS
1. Respect personal freedoms e.g., liberty, privacy Equal access to care Equal access to information Nondiscrimination	Individual rights & dutiese.g., liberty, privacy, confidentiality, nondiscrimination Criminal and civil prohibitions e.g., illicit drug laws, quarantine
2. Protect from harm by third parties Safety and quality standards for food, products, health professionals and facilities Pollution controls Equal access to care Equal access to information	Safety and health standardse.g., for workplace, environment, food, products, professional services and facilities Marketing standards e.g. anti-monopoly, anti-fraud, disclosure laws
3. Fulfill health needs Ensure provision of care Ensure health living conditions Promote education and research	Service benefit programs, e.g., medical/benefits insurance; direct service programs; environmental protection; professional and public information; research

It is somewhat surprising that public debate about public health laws today centers primarily on the first category — Respect. These include laws prohibiting discrimination in access to care, authorizing isolation and quarantine, mandatory testing or treatment, access to personal medical information, and prohibitions on smoking cigarettes and using marijuana and other illicit drugs. The trend toward conflating public health with bioterrorism and epidemics of contagious disease may have encouraged an overly narrow focus on controlling individuals. The controversy typically centers on a perceived conflict between the common good and individual autonomy,[69] although instances of meaningful conflict are remarkably rare.[70]

No one argues that limitations on liberty are never justified. Rather, controversy centers on why, when, and how — the sub-

stance of the justification and its compatibility with preserving the core freedoms protected by both the Constitution and the International Bill of Rights. The ICESCR recognizes, in Article 4, that in order to protect people in the enjoyment of the right to health, some limits may be required, but in the same sentence prohibits overreaching:

> *[T]he State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.*[71]

This caveat is intended to warn countries against using the right to health as a pretext for depriving people of other human rights. In General Comment No. 14, the ECOSOC Committee stated:

> *Issues of public health are sometimes used by States as grounds for limiting the exercise of other fundamental rights. The Committee wishes to emphasize that the Covenant's limitation clause, article 4, is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States. Consequently, a State party which, for example, restricts the movement of, or incarcerates, persons with transmissible diseases... has the burden of justifying such serious measures in relation to each of the elements identified in article 4. Such restrictions must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant [ICESCR], in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society.*[72]

Any limitations on freedom must be justified by its genuine contribution to preserving other freedoms and entitlements.

Much of the controversy over sacrificing individual liberty to achieve the common good of public health has ignored human

rights of entitlement — programs that provide the protections and services that make controlling individuals unnecessary. From the perspective of public health practitioners, law is one of many tools available to protect or promote health. Because there are many kinds of law, there are many legal tools. The human right to health framework lays out the entire spectrum of legal tools at our disposal. It not only parallels the types of health laws in the United States and many other countries, but also reminds us that human rights include *both* freedoms and entitlements. For this reason, it offers a valuable conceptual framework for the entire field of health law. Indeed, I would argue that it describes the current paradigm of the field of health law in most of the world and the future, if not the current, paradigm in the United States. Moreover, it gives lawyers a common language to communicate with their colleagues all over the world.

IV. Lessons from Contagious Disease Outbraks

The human rights framework can be used to evaluate the role of law in controlling contagious diseases.[73] Three examples from the recent past illustrate the advantages and disadvantages of relying on laws that control individuals and laws that create a public health infrastructure. They also demonstrate that the choice of law can be powerfully influenced by economics, politics, fear and prejudice.

Contagious diseases are not all the same. Some, like influenza, appear to be transmitted easily and efficiently from person to person. A person can inhale droplets containing the virus from another person's sneeze or cough or touch something with the virus on it and then transmit the virus by touching one's own mouth or nose, for example. Most healthy people who get influenza experience unpleasant symptoms that go away after several

days and are not at risk of death.[74] In contrast, the risk of death from contracting other diseases transmitted in the same way can be very high. Thus, the appropriate response to a contagious disease depends importantly on the disease itself. The following factors indicate how dangerous the disease is to the population at large:

- What kind of symptoms it causes (mild, severe, death)
- Whether those symptoms are distinctive and can be easily diagnosed or similar to other milder diseases
- How long after infection do symptoms of illness appear
- What proportion of those infected die or experience severe symptoms
- How the disease is transmitted (e.g., airborne; bloodborne; vector transmission)
- How efficiently the disease is transmitted (what proportion of exposures to the virus or bacillus result in actual infection)
- Whether there is an effective vaccine to prevent illness from infection or medicine to cure the illness
- How long the period of contagion lasts (when one person can infect others)

Answers to these questions allow the response to be carefully tailored to the type of risk the disease presents.

A. Tuberculosis

The World Health Organization estimates that one third of the world's population is infected with the tuberculosis bacillus (TB).[75] About five to ten percent of those infected experience symptoms of illness and become contagious, that is, capable of infecting

others by coughing or sneezing. Tuberculosis is contagious — capable of being transmitted to and infecting other people — only when the disease is in its active stage.[76] Relatively inexpensive medications developed after 1940 can end the active stage within perhaps two to four weeks if taken regularly and can cure the disease in about 90 percent of cases when continued for several months.[77] Left untreated, however, TB has been estimated to have a case fatality rate of 55 percent.[78]

In the United States and most developed countries where treatment is widely available, TB is rare today.[79] However, several states in the U. S. experienced a resurgence of TB between about 1988 and 1992. The response to rising TB rates varied across the country. Some states tried to rebuild tuberculosis treatment programs that had lost financial support in preceding years.[80] A few others, like New York, which experienced an especially large rise in TB, relied heavily on involuntary isolation and directly observed therapy (DOT).[81] Massachusetts managed to bring tuberculosis under control more rapidly than New York, largely by providing more personal services, including persuading people to receive DOT voluntarily. Public health nurses took medications to patients, at their home or work, instead of forcing patients to come to a clinic during the hours the clinic was open. The incidence of tuberculosis began to decline again in 1993, with most states claiming that their approach succeeded, even when the approaches were quite different.[82] Knowledgeable observers argued that the increase in cases was the result of mistakes in economic and public health policy in the preceding decade, which reduced services and increased the proportion of the population living in poverty, in prisons or in homeless shelters, all conditions that facilitated the spread of TB.[83] The rising incidence of HIV infection, which increased susceptibility to TB, coupled with immigration from countries where TB was prevalent, exacerbated the problem, especially in New York City.[84]

Most cases of involuntary confinement targeted recent immigrants, and people who were homeless or living in shelters, jail or prison, where tuberculosis can easily spread among people living in close quarters.[85] This population, however, comprised only a small fraction of all TB cases nationwide.[86] Some also suffered from mental illness that impeded their ability to follow treatment regimens. Others also had HIV, which increases the likelihood of active TB and complicates treatment. Others spoke little English and found the health care system difficult to navigate. Most were poor.

Hongkham Souvannarath became a visible example of a modern American tuberculosis patient when she was involuntarily jailed in California, allegedly for failing to comply with a TB treatment regimen. The Fresno County government paid $1.2 million to settle her 1999 federal lawsuit, which claimed violation of her rights under the U. S. constitution and California state law.[87] She also brought a state action, in which a California appeals court ordered the county to cease using the jail to detain patients with TB.[88] While the reported decision focuses on a state statute forbidding using the jail as a place to detain recalcitrant dangerous patients, the federal lawsuit and the events leading to her confinement suggest that confinement may not be necessary (and patients need not become either recalcitrant or dangerous) if appropriate services are made available to patients in need.[89]

Ms. Souvannarath, a refugee from Laos who came to the United States in 1984, was diagnosed with MDR-TB in California in 1998.[90] She obtained TB treatment from a county clinic for several months, but experienced side effects and understood little of either the disease or its treatment. She spoke very little English and the clinic's translator spoke little Laotian. Ultimately, Souvannarath decided to live with a son in Ohio who could better care for her, but he was delayed in picking her up for the move. The clinic gave Souvannarath a small supply of medications to

last until she could enter a pre-arranged Ohio clinic's program, but she ran out of medications before her son arrived. Feeling fine without taking medications, Souvannarath did not seek more.[91] The clinic discovered she had not arrived in Ohio and had her served with an order in English to appear at the clinic. When she did not appear, the county health officer issued a detention order. She was arrested at gun point by two police officers and a communicable disease specialist and confined in the country jail. When she cried that she was afraid of dying, a non-Laotian translator thought she was threatening suicide, so she was confined in a safety cell for 3 days. She remained in jail, where only one guard could attempt translation, for ten months, until she was given an attorney and a hearing. The court released her subject to electronic monitoring in May 1999. At a review hearing in July 1999, she was released unconditionally.

Ms. Souvannarath's case suggests several points at which the clinic could have ensured continued treatment and prevented incarceration. Initially, a translator who could explain the disease, treatment, its length, benefits and side effects might have persuaded Ms. Souvannarath to seek additional medications when she ran out, even though the drugs made her feel worse. If clinic staff had developed a more trusting relationship with Ms. Souvannarath, she might have been more receptive to their requests that she continue taking the medication. Even if all that failed, an order authorizing clinic staff to come to her house and help her take her medications would have avoided incarcerating her. The clinic, perhaps the entire TB program, may have had insufficient funds to accomplish these tasks.[92] However, patients should not be punished simply because their clinic is underfunded.[93] Ms. Souvannarath might never have been considered uncooperative, much less a danger, had the clinic had enough staff and funding to continue the care she willingly accepted originally.[94] Ironically, it may have cost the government more to pursue incarceration

than to create an effective clinic system. Both alternatives required legislation, but the different types of legislation can produce strikingly different results.

B. HIV

The HIV epidemic in the United States has brought out the best and worst in people.[95] Many physicians have organized compassionate treatment groups, despite some physicians' early fears of treating people with HIV infection.[96] The development of reasonably effective highly active antiretroviral therapy (HAART) has transformed HIV into a chronic disease of reasonably manageable proportions.[97] Nonetheless, in the absence of an effective vaccine to prevent HIV infection, public health efforts continue to emphasize preventing transmission. Both federal and state legislatures were slow to authorize programs to provide public education about HIV prevention and to create medical services to treat people with HIV. They have generally responded more favorably on proposals to protect newborn babies from HIV infection.[98]

The Centers for Disease Control and Prevention (CDC)[99] sought to eliminate or reduce the transmission of HIV from pregnant women to their babies in the United States. Treatment during pregnancy, and even just at delivery, substantially reduces the risk that the baby will become infected.[100] It has recommended testing all pregnant women for HIV as part of routine prenatal care unless a woman specifically refuses the test.[101] There is evidence that some patients agree to tests that physicians call "routine" without considering each one specifically, even though they might refuse a particular test if it were offered separately.[102] As a practical matter, physicians offering such routine testing physicians may merely ask the patient to allow "routine" blood tests to

be performed, without emphasizing that an HIV test is included. In the United States, however, state laws typically forbid HIV testing without the informed consent of the patient and also forbid disclosing the results of an HIV test without the patient's consent.[103] The CDC also encourages states to change such laws to permit HIV testing without the patient's specific or separate consent.

This type of recommendation raises several questions. The first is whether it is necessary to change the law to reduce the incidence of newborns with HIV infection. In 2000, CDC estimated that between 280 and 370 babies were born with HIV infection in the United States, with 80 to 110 of these born to women who were not aware of their HIV status.[104] The rate of HIV infections in newborns had already been reduced dramatically because most physicians encourage their patients with HIV infection to take medication, both for themselves and to prevent HIV transmission to their babies.[105] In Massachusetts, for example, the number of HIV infected babies dropped from 32 in 1992 to zero in 2001.[106] Massachusetts law still requires an individual's informed consent for testing, as well as treatment. Presumably, physicians were able to convince their patients of the benefits of HIV testing and treatment, because pregnant women are getting treatment.[107] It is important to recognize that HIV testing simply detects HIV infection. Testing is not treatment. Emphasis on testing alone cannot prevent infection. The woman must agree to treatment and must have other resources, such as health insurance, to pay for treatment, in order to prevent transmitting infection to her newborn. Often, the major barrier to preventing infection is the woman's inability to afford prenatal care.[108]

Another question is whether HIV transmission to newborns is a public health or a medical issue. HIV is certainly a public health concern. At the same time, prenatal care for pregnant women is part of medical practice. The public health goal cannot be

achieved without physicians. If testing and treatment are part of medical practice, then the doctrine of informed consent should apply. Even if the public health model applied, it is difficult to argue that the public health risk justifies overriding the patient's right to decide whether to be tested or treated, especially where there is little evidence that people are refusing testing or treatment.[109]

This example demonstrates the different approaches to preventing disease traditionally used in medicine and public health. Physicians have been quietly persuading their individual patients to voluntarily find out whether they have HIV and, if so, to take appropriate therapy to protect themselves and to prevent transmission to their children. They did so while respecting their patient's rights to make their own decisions about medical care. It appears that the public health goal is to eliminate all cases of HIV infection in newborns, which is an undeniably worthy goal.[110] The question is whether it is necessary to violate human rights in order to attain that goal. To succeed in reducing the remaining number of HIV infections, public health professionals must either persuade enough people to change their behavior through public education or take some other action to achieve the same result. If not everyone voluntarily changes behavior, then public health professionals are likely to seek new laws that force people to do so.

Public health risks rarely justify coercive laws that violate individual liberty, and almost never the right to bodily integrity and self-determination.[111] The fact that something poses a public health risk, by itself, does not determine the type of law, if any, needed to reduce that risk.[112] If any public health risk could justify eliminating basic patient rights, such as the right to refuse treatment, individuals would have few rights left.

The potential for eroding individual rights may be encouraged by public health's growing attention to health promotion.[113] As

chronic diseases overtook infectious diseases as the leading causes of death among Americans, the public health field shifted its attention to conditions like heart disease, cancer, and diabetes.[114] Both diabetes and obesity have been declared "epidemics", giving new meaning to the term.[115] Given the complex causes of many chronic diseases, one might expect public health programs to direct renewed attention to the full range of social determinants of health.[116] So far, however, most U. S. public health campaigns, from education to advocacy for new laws, have highlighted the risks to health that arise from personal behaviors, such as a high fat diet, lack of physical exercise, and smoking cigarettes.[117] Public awareness of how to improve one's health is usually a good thing.[118] Yet, this emphasis on personal risk behaviors also lends support to those who wish to characterize the primary problems in public health as the personal responsibility of individuals themselves, rather than as problems that require societal solutions.[119] The result may be proposals for laws to force people to comply with health recommendations, rather than laws creating the health infrastructure that makes it possible for people to live a healthy life.[120]

C. SARS

SARS (severe acute respiratory syndrome) illustrates the type of infectious disease that can create a global epidemic and strike fear into the hearts of people all over the world.[121] When SARS appeared, there was no rapid diagnostic test to distinguish it from other respiratory illnesses, no vaccine and no effective specific therapy. The first known case of SARS occurred in Foshan City, Guangdong Province, China, on November 16, 2002.[122] The virus appears to have passed from animals (exactly which remains uncertain) to food handlers, and then from a patient to perhaps 200

others when the patient was transferred among three hospitals.[123] A physician caring for patients in Guanghzhou became infected and traveled to Hong Kong to attend a wedding, staying at the Metropole Hotel. Twelve guests at the hotel became infected without their knowledge and carried the virus to their home countries of Canada, Ireland, Singapore, Vietnam, and the United States.[124] More than 8,000 probable cases of SARS developed in four months.[125]

Fortunately, SARS proved to be less long-lasting and less lethal than feared. The World Health Organization declared the epidemic over by early July, 2003. The total number of deaths worldwide was 774 (9.6% of cases).[126] Most people with SARS did not infect other people. Most infections arose from close personal contact (within 3 meters) and took place in the home or hospital.[127] The likelihood of transmitting infection appears to have been highest after symptoms appeared, during the second week of illness.[128] People with severe symptoms are not likely to feel like socializing or traveling; many were already hospitalized. This may explain the high proportion of infections that took place in the hospital. In addition, the coronavirus that causes SARS was identified and described within weeks after it appeared, enabling more precise diagnostic testing in the later months of the epidemic.[129]

Some reports have concluded that old-fashioned public approaches like case reporting and quarantine were important defenses against a major epidemic like SARS. The reality is more complicated. Countries used a combination of approaches to contain SARS — contact tracing, closing public gatherings, recommending or requiring quarantine, implementing emergency surge capacity plans and enhancing infection controls in health care facilities, providing public education about SARS, wearing masks and disinfecting the home.[130] The evidence of their effectiveness is mixed and, in some cases, it proved difficult to disentangle the independent effect of a single intervention with certainty.

Many observers concluded that rapid case reporting helped to slow the epidemic.[131] Rapid identification of a person with SARS enabled physicians and public health workers to ask the person where he had been and who he had been in close contact with. This made it possible to trace the route (chain) of transmission. The median incubation period (the time between infection and symptoms) was long enough (4 to 5 days) to permit calling or visiting the contacts to advise them to stay away from other people and monitor their own health for the week or two in which symptoms might appear or to provide medical treatment to those who were actually infected. However, it was not always easy to find all the cases or contacts.

Although the first case of SARS arose in China in November 2002, news of the unidentified illness did not come from formal reporting mechanisms for several months.[132] Dr. Carlos Urbani, a WHO official, feared that a patient he was treating in Hanoi had avian influenza and contacted the WHO Pacific Regional Office.[133] WHO asked China for information and was told on 14 February 2003 that an outbreak consistent with atypical pneumonia was coming under control.[134] As with earlier epidemics, the most accurate, timely and valuable information came not from official reporting systems, but from alert physicians caring for patients.[135]

Nonetheless, WHO has recently drafted revised International Health Regulations to allow it to obtain information about new contagious diseases quickly from countries where they emerge.[136] This appears to be in response to the delay in formal reporting from China. China formally requested technical assistance from WHO to investigate the outbreak in March 2003.[137] WHO issued a global alert of the appearance of appearance of a severe respiratory illness of undetermined cause on 12 March 2003, more than three months after SARS (as it was later called) appeared.

After SARS entered a country, transmission occurred predominantly in hospitals and clinics, where people sought treatment. Having hospitals that were prepared to respond quickly to the influx of patients in an emergency (surge capacity) conferred a critical advantage in controlling the epidemic.[138] Infection control procedures prevented the spread of disease among patients, physicians, nurses, other hospital staff and visitors. The best evidence of this comes from Canada.[139] Ontario had in place an Emergency Management Act, which gave the government the authority to regulate local governments and facilities to ensure that essential services are provided. The provincial government declared an emergency on 26 March 2004, and ordered hospitals to activate their emergency plans. These called for hospitals to keep all nonessential employees and visitors (except parents of sick children) away from the hospital and to temporarily suspend all elective and outpatient services. In addition, the hospitals created isolation wards for SARS patients, required all staff to use protective gloves, gowns, eyewear and respirators when seeing patients, and screened all staff, patients and visitors for SARS symptoms. A report of the epidemic in Toronto concludes that "SARS in Toronto was primarily a nosocomial illness, largely restricted to persons who were exposed in affected hospitals and their household contacts".[140]

A key lesson from Toronto is that heightened infection control measures brought the epidemic under control.[141] Once the controls were put in place, transmission stopped. Ontario lifted the emergency on 17 May 2003, after WHO declared the province free from SARS. Hospitals then discontinued the use of special precautions for most patients without respiratory symptoms, and a new outbreak occurred. Infection control measures were reinstituted, and the second phase of the epidemic finally abated by 2 July 2003.[142]

Basic medical standards dictate that each SARS patient should be treated in isolation to prevent infecting others. Reviews of the

SARS epidemic contain mixed opinions about whether quarantine was necessary outside the hospital setting.[143] Some concluded that quarantine helped to prevent the spread of SARS,[144] while others found it unnecessary or even counterproductive.[145]

There is some ambiguity in the literature about the extent to which law was needed or used to authorize or enforce isolation or quarantine. Few reports the medical or policy literature distinguish between voluntary and involuntary (court-ordered) quarantine and isolation, but instead describe all instances in which a person stayed apart from others generically as an example of "quarantine".[146] It appears that court orders for isolation were issued in only a tiny percentage of cases. Most cases of "quarantine" were in the person's own home. Exceptions included travelers and homeless people who could not go home, people who did not wish to stay at home for fear of infecting their families, and a handful of people who refused for other reasons.[147] People in "quarantine" were sometimes permitted to leave, with instructions to wear a mask and avoid crowded places.[148] Hospitals in Toronto created a "work quarantine" in which essential staff were told to stay at home when they were not at the hospital, but did not forcibly restrict workers.[149] While it undoubtedly helped prevent the spread of disease, this "quarantine" was primarily a matter public health education, encouraging people to voluntarily protect themselves and others, and not the exercise of legal authority.[150]

China used involuntary quarantine more widely than any other country. In late March, Hong Kong's health authorities issues an unprecedented quarantine order in late March 2003, requiring some residents of the Amoy Gardens apartment towers, a hotspot of the infection, to remain in their units for 10 days.[151] Nonetheless, only a small fraction of people who were quarantined, mostly family members of someone diagnosed with SARS, actually were infected.[152] Defiance of quarantine orders was rare. However, in Beijing, more than 250,000 people fled the city after a future

quarantine was announced. In April 2003, residents of a rural Chinese town ransacked a school building that was being converted into a quarantine facility for urban SARS patients or those at risk for SARS.[153]

Quarantine, whether voluntary or involuntary, may be the first line of defense against a new disease that is highly efficiently transmitted, especially one for which there is no vaccine or treatment. Even those enthusiastic about the value of quarantine appear to believe that quarantine would have value only for the short time — until a vaccine could be produced — or in poor countries unable to afford drugs or vaccines.[154]

Public education also had mixed results. One technique that appears to have worked reasonably well without significantly disturbing the population was "social distancing", a term encompassing canceling programs and events that attract large crowds. These included closing schools, canceling public concerts, theater performances, and sports events. It is difficult to determine whether this distancing actually prevented any illness, since it is not known whether anyone with SARS would have attended any particular event. Similarly, the use of face masks may have helped to prevent infection, although it is difficult to assess the precise effect.[155] Campaigns to have the general public measure their temperatures may have speeded recognition of symptoms and getting to medical care. On the other hand, because there are so many other causes of fever, most of which do not prompt people to seek medical care, this technique has the potential to overwhelm hospitals and clinics with patients who have nothing more than a common cold.

Screening travelers by questionnaires or temperature monitors appears to have had little value in identifying SARS cases. Some locations used thermal scanning in public places to try to identify individuals with a high fever. This proved ineffective in Beijing.[156] More than 35 million people were subjected to thermal scanning

in Canada, China (including Hong Kong), Taiwan, and Singapore upon entering the country, and at least 7 million more were scanned when leaving the country, but no SARS cases were detected using that method.[157] Chinese officials took the temperature of almost 14 million travelers coming to or leaving Beijing. No international travelers had SARS. Twelve domestic travelers had probable SARS. About 45.4 million people filled out health questionnaires when leaving China (including Hong Kong), Taiwan, and Singapore. A total of 13,000 people had reported symptoms and 500 had reported contact with SARS. However, only four cases of SARS were identified by answers to these questionnaires, two among those who reported that they had had contact with someone with SARS and two among people who reported symptoms. In countries with limited resources, the cost of screening such large numbers of people may have wasted substantial resources. Yet the presence of these interventions may have discouraged people at risk from traveling.[158]

New diseases may or may not succumb to interventions like those used for SARS.[159] Influenza, for example, has characteristics that make it more difficult to control. It has a short incubation period (2 to 4 days), is contagious 24 hours before the onset of symptoms and therefore has a short period in which it can be transmitted to others. People are less likely to seek medical care, where the illness could be detected. It rarely leads to hospitalization, except among those at high risk for respiratory illnesses, and transmission in the hospital is not common. This suggests that hospital precautions may not be sufficient, by themselves, to contain an epidemic of a new lethal form of influenza. For example, if the avian influenza virus (H5N1), which has ravaged poultry stocks in Southeast Asia and killed forty-six people, became efficiently transmissible to humans and from person to person, it might cause a global pandemic affecting millions.[160] Although no one knows whether such a viral shift will occur, it would be pru-

dent to pursue not simply an early warning system, but public education about contact with animals, research on possible vaccines, and organizing services to care for people who become ill.[161] Perhaps the most effective preventive measure would be to create new job opportunities that make it unnecessary for people to live with chickens and ducks to survive.

V. Conclusion

In the twenty-first century, contagious diseases can be frightening even when they are rare. Scientific advances have produced vaccines and medicines to prevent or control many of the diseases that decimated populations in the past. In developed countries, chronic diseases have become the major cause of death. Still, much of the world's population still suffers from infectious diseases like tuberculosis, HIV and malaria, and new diseases like SARS can emerge without warning. With today's global travel, a highly contagious disease can spread around the world.

Fortunately, countries have better tools to respond to disease outbreaks than in the past. One essential tool is law. Although laws cannot not vaccinate or treat a patient, they make it possible for countries to build social institutions that can prevent or respond to an outbreak. Laws lay the foundation for medical and public health institutions, regulate their capacity to provide appropriate care, and ensure everyone access to care. Laws create lines of authority and communication networks that allow rapid responses to disease outbreaks, as well as guarding the privacy of personal information. Laws protect people from health risks that may arise from the environment, workplace, food and consumer products by setting standards for safety and health. In rare and extreme cases, laws can authorize involuntary quarantine or punish dangerous activity. Laws also protect individuals from the ar-

bitrary or discriminatory exercise of power, even in the name of medicine and public health.

The role of law in controlling epidemics is foundational and wide-ranging. The different historical perspectives of public health and medicine on the relative value of individual liberty and health outcomes, however, sometimes produce quite different recommendations for laws to control disease outbreaks, as seen in the different responses to outbreaks of tuberculosis, HIV and SARS. Similarly, the United States government's concern with terrorism has shaped its response to naturally occurring diseases. Its concern for security has too often encouraged unnecessary sacrifices of liberty and inappropriately placed responsibility for disease prevention on individuals rather than social institutions.

The human right to health framework can help lawyers and policy makers avoid such errors. It captures the broad range of laws that can be used to create an effective response to epidemics without imposing unnecessary restraints on human rights. It offers a reminder that health often depends on positive government actions and that individual human rights must not and need not be violated in order to safeguard an entire population. The human right to health framework recognizes that laws can and should seek health though justice.

Notes

[1] Chase, Marilyn. The Barbary Plague: the Black Death in Victorian San Francisco, 2003.

[2] In addition to fearing plague, those living in the Chinese quarter worried that if a fire broke out they would burn to death because they could not escape and no rescue personnel would enter, as had happened under similar circumstances in Hawaii. *Id.* at 18-19.

[3] *Id.* at 62-63,

[4] Wong Wai v. Williamson, 103 F. 1, 9-10 (C.C.D. Cal. 1900); Jew Ho v. Williamson, 103 F. 10, 24 (C. C. D. Cal. 1900).

[5] *Jew Ho*, 103 F. at 22.

[6] Chase, *supra* note 1, at 71-72, 85-90.

[7] Rats often had fleas infected with *yersinia pestis,* or bubonic plague. Fleas transmitted the plague by biting human beings. Rats were not discovered to be a host source of plague-carrying fleas until about 1900. *Id.* at 105-106. Dr. Blue first had to assure residents that he would not put them in quarantine, then convince them that rats, not people, were the source of disease and that it was even worth tearing down rat-infested buildings to destroy the rats. *Id.* at 108.

[8] Plague did return to San Francisco and remains endemic in southwestern states today. See William H. McNeill, Plagues and Peoples 154 (1976).

[9] Off. of Surgeon General, Dep't of Health & Human Services (HHS), Rupert Blue (1912-1919), *at* www.surgeongeneral.gov/library/history/bioblue.htm (last visited Mar. 26, 2005).

[10] Mariner, Wendy K., Annas, George J., Glantz, Leonard H., "Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law". *Am. J. Pub. Health* 2005; 95 : 581-582.

[11] Preliminary data for 2003 indicate that the leading causes of death in the United States were:

CAUSE OF DEATH	TOTAL NUMBER OF DEATHS
All causes	2,443,930
1. Heart disease	684,462
2. Malignant neoplasms (cancers)	554,643
3. Cerebrovascular diseases (stroke etc.)	157,803
4. Chronic lower respiratory disease	126,128
5. Accidents (unintentional injuries)	105,695
6. Diabetes mellitus	73,965
7. Influenza and pneumonia	64,847
8. Alzheimer's disease	63,343
9. Nephritis, nephritic syndrome and nephrosis	42,536
10. Septicemia	34,243
11. Suicide	30,642
12. Chronic liver disease	27,201
13. Essential (primary) hypertension and hypertensive renal disease	21,841
14. Parkinson's disease	17,898
15. Pneumonitis due to solids and liquids	17,457

Hoyert, Donna L. *et al.,* Deaths: Preliminary Data for 2003, 2005; 53 *Nat. Vital Stat. Rep.* 1, 4 tbl. B. Available at www.cdc.gov/nchs/data/nvsr/nvsr53/nvsr53_15.pdf (last visited Mar. 25, 2005). These causes are in the same order as in 2002, except that homicide deaths dropped from 17,638 to 17,096, placing homicide out of the first fifteen causes in 2003, and Parkinson's moved into 14th place. *Id.* at 3-4.

[12] See *generally* Anne Nadakavukaren, *Our Global Environment: a Health Perspective.* 5th ed (2000).

[13] Leichter, Howard M. "Evil Habits" and "Personal Choices": Assigning Responsibility for Health in the 20th Century. *Milbank Q.* 2003; 81 603, 611; see Parmet, Wendy E. *et al.,* "Individual Rights Versus the Public's Health : 100 Years After Jacobson v. Massachusetts" *New Eng. J. Med.* 2005; 352 : 652, 654.

[14] See Monto, Arnold S. "The Threat of Avian Influenza Pandemic"., 352 *New Eng. J. Med.* 323 (2005); Kumnuan Ungchusak *et al.,* "Probable Person-to-Person Transmission of Avian Influenza A (H5N1)", 352 *New Eng. J. Med.* 333 (2005); Klaus Stöhr, "Avian Influenza and Pandemics : Research Needs and Opportunities", 352 *New Eng. J. Med.* 405 (2005).

[15] The International Bill of Human Rights is comprised of the Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. United Nations (UN), Universal Declaration of Human Rights (1948). Available at www.un.org/Overview/rights.html (last visited Mar. 25, 2005) [hereinafter UDHR]; Off. High Comm'r Human Rights (HCHR), UN, International Covenant on Civil and Political Rights (1966). Available at www.unhchr.ch/html/menu3/b/a_ccpr.htm (last visited Mar. 25, 2005); HCHR, UN, International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) [hereinafter ICESCR]. Available at www.unhchr.ch/html/menu3/b/a_cescr.htm (last visited Mar. 25, 2005). Related international human rights covenants, treaties, and other instruments are available from the UN *at* www.un.org/rights/# (last visited Mar. 25, 2005) and the UN HCHR *at* www.ohchr.org/english/ (last visited Mar. 25, 2005).

[16] A short definition by the Institute of Medicine (IOM) is commonly used by public health professionals: "what we, as a society, do collectively to assure the conditions for people to be healthy". Comm. for the Study of Future of Public Health, IOM, The Future of Public Health 19 (1988) [hereinafter The Future of Public Health]. Available at www.nap.edu/books/0309038308/html/index.html

(last visited Mar. 31, 2005). Even more succinct is "Collective action for sustained population-wide health improvement". Beaglehole, Robert *et al.,* "Public Health in the New Era : Improving Health Through Collective Action", *Lancet*. 2004; 363 : 2084. "Population health" is sometimes used as a synonym for public health, but is a distinct specialty that grew out of demography. See, e.g., "Mechanic, David Who Shall Lead: Is There a Future for Population Health? ", *J. Health Pol., Pol'y & L.* 2003; 28 : 421.

[17] Winslow, Charles E. A. "The Untilled Fields of Public Health", *Science* 1920; 51 23, 30.

[18] See Afifi, Abdelmonem A., Breslow, Lester, "The Maturing Paradigm of Public Health", *Ann. Rev. Pub. Health* 1994; 15 : 223, 232. "Public health practice embraces all those actions that are directed to the assessment of health and disease problems in the population; the formulation of policies dealing with such problems; and the assurance of environmental, behavioral, and medical services designed to accelerate favorable health trends and reduce the unfavorable". *Id.*; see also *Oxford Textbook of Public Health* (Roger Detels *et al.,* eds., 4th ed. 2002); Bernard J. Turnock, *Public Health: What It is and How It Works* (3rd ed. 2003).

[19] See *New Ethics for the Public's Health* (Dan Beauchamp & Bonnie Steinbock (eds.), 1999) (noting that public health is, in part, "a species of public policy"); Parmet, Wendy E. "From Slaughter-House to Lochner: the Rise and Fall of the Constitutionalization of Public Health", *Am. J. Legal Hist.* 1996; 40 : 476, 477.

[20] For an excellent concise history of the field of public health, see Fee, Elizabeth *The Origins and Development of Public Health in the United States.* In: Detels, Roger *et al.,* 1 *Oxford Textbook of Public Health*. 3, 3-34 (Walter W. Holland *et al., (*eds.), 2nd ed. 1991).

[21] See Duffy, John *The Sanitarians: a History of American Public Health* (1990); Rosenkrantz, Barbara *Public Health and the State: Changing Views in Massachusetts, 1842-1936*, at 69-71 (1972).

[22] Arias, Elizabeth "United States Life Tables". *Nat'l Vital Stat. Rep. 2002;* 56 : 1 33-34 tbl. 12, available at www.cdc.gov/nchs/data/nvsr/nvsr53/nvsr53_06.pdf (last visited Mar. 25, 2005). See George Rosen, A History of Public Health (expanded ed., 1993) (1958).

[23] See generally, Jordan, Edwin O., *et al., A Pioneer of Public Health : William Thompson Sedgwick* (1924). This period also saw the rise of movements for women's suffrage, birth control, temperance, and the abolition of child labor. Morone, James A. Hellfire Nation : The Politics of Sin in American History (2003).

[24] See, e.g., Social Determinants of Health (Marmot, Michael, Wilkinson, Richard G. (eds.), 1996); Social Epidemiology (Berkman, Lisa F., Kawachi, Ichiro (eds.), 2000); The Society and Population Health Reader: Income Inequality and Health 1 (Ichiro, Kawachi *et al.,* (eds.), 1999); Why Are Some People Healthy and Others Not? The Determinants of Health of Populations (. Evans, Robert G *et al.,* (eds.), 1994); Wilkinson, Richard G. Unhealthy Societies: The Afflictions of Inequality (1996); Adler, Nancy E. *et al.,* "Socioeconomic Status and Health : The Challenge of the Gradient", 49 *Am. Psychologist* 15 (1994); Wagstaff, Adam, van Doorslaer, "Eddy Income Inequality and Health: What Does the Literature Tell Us? ", 21 *Ann. Rev. Pub. Health* 543 (2000).

[25] See Starr, Paul *The Social Transformation of American Medicine.* 338-351 (1982); Fuchs, Victor R. *Who Shall Live? Health, Economics, and Social Choice.* 144 (1974) (arguing that genetic, environmental, and behavioral factors had more influence on health than costly medical care). But see Cutler, David M. "Declining Disability Among the Elderly", *Health Affs.* Nov.-Dec. 2001; 20 : 11 (arguing that physicians and medical researchers played a greater role in increasing life expectancy than is generally acknowledged).

[26] Comm. on Elimination of Tuberculosis in the U. S., Institute of Medicine, Ending Neglect: The Elimination of Tuberculosis in the United States (Geiter, Lawrence (ed.), 2000) available at www.nap.edu/books/0309070287/html (last visited Mar. 25, 2005) [hereinafter Ending Neglect]; Frank Ryan, *The Forgotten Plague: How the Battle Against Tuberculosis was Won : and Lost.* 397 (1992). The rising prison population also contributed to transmission. Skolnick, Andrew A. "Some Experts Suggest the Nation's 'War on Drugs' is Helping Tuberculosis Stage a Deadly Comeback", *JAMA* 1992; 268 3177.

[27] See, e.g., Hugh Gravelle, "How Much of the Relation Between Population Mortality and Unequal Distribution of Income is a Statistical Artifact?", *Brit. Med. J.* 1998; 316 : 382. Social conservatives are the most critical of research addressing the social determinants of health, probably because the remedies would require some income redistribution, such as taxation, increased public spending, and regulation of business and property. Bloom, Samuel W. *The Word as Scalpel: a History of Medical Sociology.* 104 (2002) (recounting objections to terms like social determinants because they could be construed as socialism). However, many public health officials also embrace the view that public health does not include social policies not directly involving individuals at risk of disease. In particular, advocates of certification of a profession of

public health seek to narrow the boundaries in order to be able to prescribe specific skills or "competencies", which would be almost impossible were all the factors that affect health included. See Council on Educ. for Pub. Health (CEPH), About CEPH, *at* www.ceph.org/i4a/pages/index.cfm?pageid=3274 (last visited Apr. 11, 2005).

[28] Lupton, D.. *The Imperative of Health: Public Health and the Regulated Body* (1995); Barsky, Arthur, J. *Worried : Sick Our Troubled Quest for Wellness* (1988).

[29] Board on International Health, IOM, America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests 11 (1997). Available at www.nap.edu/openbook/0309058341/html/index.html (last visited Mar. 25, 2005); Annas, George J. "Bioterrorism, Public Health and Human Rights". *Health Affs*. Nov.-Dec. 2002; 21 : 94; Beaglehole, Robert *et al., supra* note 16 (arguing for a definition of public health that includes attention to major global health challenges); Lee Phillip, Paxman, Dalton "Reinventing Public Health". *Ann. Rev. Pub. Health* 1997; 181 : 2 (noting globalization as growing factor); Farmer, Paul Gastineau, Nicole "Rethinking Health and Human Rights : Time for a Paradigm Shift" In: Gruskin, Sofia *et al.,* (eds.) *Perspectives on Health and Human Rights*, 2005. 73-92 (arguing for a new level of cooperation between medicine, public health, and human rights in both academic scholarship and service programs).

[30] See generally Ohmae, Kenichi. The Next Global Stage: The Challenges and Opportunities in Our Borderless World (2005).

[31] War and Public Health. Updated ed. (Levy, Barry S., Sidel, Victor W. (eds.), 2000).

[32] Health and Human Rights: a Reader 14 (Jonathan Mann *et al.,* eds., 1999); Gruskin, Sofia, Tarantola, Daniel, *Health and Human Rights*. In: Oxford Textbook of Public Health, *supra* note 18, at 311.

[33] See Laurie Garrett, *The Coming Plague: Newly Emerging Diseases in a World Out of Balance*. 620 (1994); Fidler, David P. "The Globalization of Public Health: Emerging Infectious Diseases and International Relations", *Ind. J. Global Legal Stud.* 1997; 5 : 11. 21-22.

[34] Knobler, Stacey *et al.,* Learning from SARS: Preparing for the Next Disease Outbreak, Workshop Summary 63 (2004). Available at http://books.nap.edu/htm/SARS/0309091543.pdf. See *also* Part IV.B. *infra*.

[35] The United States already has some experience with what today would be called bioterrorists — from United States residents who used vi-

ruses or bacteria to frighten and make people sick. Miller, Judith *et al.,* Germs: Biological Weapons And America's Secret War (2001) (describing 1984 salmonella contamination of salad bars in Oregon); W. S. Carus, *The Rajneeshees* In: Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons (J. B. Tucker, (ed.) 2000) (same; the fact that the contamination was part of a deliberate attempt to keep people from voting in a local election was not accepted by public health officials until the perpetrators' colleagues revealed the incident a year later).

[36] Shane, Scott "Anthrax Scare is Attributed to a Testing Error"*, New York Times.* 2005 Mar. 16, at A16 (stating that five people died from inhalation anthrax); see James, George "Homeland Security; Disaster Plan Less Disastrous"*, New York Times,* 2002 Nov. 3, at 14NJ; Kolata, Gina "A Nation Challenged: the Response; Many Lessons to be Learned With Anthrax"*, New York Times,* 2001 Oct. 28, at B1 (stating the Secretary of Health and Human Services, Tommy Thompson, opined that the first victim might have become infected while hunting in Florida and commenting that the CDC was not aware that anthrax could be aerosolized small enough to escape through envelopes, thereby leaving postal employees at risk, while the better known letter recipients received special attention).

[37] See Fidler, David P. "Caught Between Paradise and Power: Public Health, Pathogenic Threats, and the Axis of Illness", *McGeorge L. Rev.* 2004; 35 : 45 (arguing that international diplomacy has shifted between considering contagious disease as a threat to national power and as an opportunity for global cooperation).

[38] Congress appropriated funds to help states pay for "emergency preparedness". 42 U. S. C. § 5195 (2005); see *also* 42 U. S. C. § 5196b (2005). See, e.g., Bryan Jacalyn L, Fields, Helen F. "An Ounce of Prevention is Worth a Pound of Cure : Shoring Up the Public Health Infrastructure to Respond to Bioterrorist Attacks"*, Am. J. Infection Control* 1999; 27 : 465-467 (noting the need for resources to improve public health programs to respond to attacks if they occur); Kellman, Barry "Biological Terrorism: Legal Measures for Preventing Catastrophe", *Harv. J. L. & Pub. Pol'y* 2001; 24 : 417. 449-467 (outlining regulatory measures to restrict the availability of pathogens, materials, and equipment that can be used to make biological agents and to restrict access to weaponization technology). Kellman also argues in favor of better counterterrorism intelligence and against the need to invade liberty or privacy rights and notes that non-legal measures, such as better planning and communication among officials, are also necessary. *Id.* at 463-465. See

generally Alibek, Ken Biohazard (1999) (telling the story of the largest covert biological weapons program in the world).

[39] See Annas, George J. "Puppy Love: Bioterrorism, Civil Rights, and Public Health", *Fla. L. Rev.* 2003; 55 : 1171, 1173 (hereinafter *Puppy Love*). The federal government has given about $1 billion in grants to state and local health departments for bioterrorism or emergency preparedness. There are mixed reviews about whether this funding has helped build infrastructure or diverted resources from necessary public programs. Smith, Stephen "Anthrax vs. The Flu as State Governments Slash Their Public Health Budgets, Federal Money is Pouring in for Bioterror Preparedness", *Boston Globe,* 2003, July 29, at C1 (quoting the American Public Health Association Executive Director as worried that the focus on bioterrorism, anthrax, and SARS has crowded out concern for problems that kill many more people and left public health programs without funding to maintain basic services.) In contrast, from 1990 to 1999, approximately 36,000 Americans died from influenza related deaths each year, with the elderly and people with chronic diseases most at risk. Harper, Scott A. *et al.,* "Prevention and Control of Influenza: Reccomendations of the Advisory Committee on Immunization Practices", *Morbidity & Mortality Wkly. Rep., Recommendations & Rep. 2004*; 53 : 1, 3 [hereafter *Prevention and Control of Influenza*]. Available at www.cdc.gov/mmwr/PDF/rr/rr5306.pdf (last visited Apr. 1, 2005). The U. S. had a shortage of flu vaccines in the fall of 2004 when Britain discovered contamination at a Chiron plant and suspended its license. Henderson, Diedtra "U. S. Flu Vaccine's Shortage Ends in an Oversupply", *Boston Globe*, 2005, Feb. 9, at A1. Chiron was to supply about half the U. S. supply of vaccines. *Id.* The shortage exposed the absence of an effective plan for assuring an adequate supply of vaccines. *Id.* After the CDC and most states recommended limiting the short supply to the elderly and some other groups supposedly at high risk, the shortage turned into an oversupply. *Id.* Some critics then questioned whether the right groups were targeted for priority vaccination. Simonsen, Lone *et al.,* "The Impact of Influenza Vaccination on Seasonal Mortality in the US Elderly Population", *Arch. Int. Med.* 2005; 165: 265 (As of June 2005, the U. S. government still had not developed a plan to assure an adequate annual supply of influenza vaccine.

[40] The Future of Public Health, *supra* note 16.

[41] Mariner, Wendy K. "The Search for Public Health Ethics", *Leadership Pub. Health* 2000; 5 : 3 (noting that professions typically are identified by

a common, if complex, methodology and knowledge base).

[42] In the United States, the Council on Education in Public Health, which accredits schools of public health, attempts to establish a common knowledge base for students in Master of Public Health (M. P. H.) degree programs. See CEPH, ABOUT CEPH, *at* www.ceph.org/i4a/pages/index.cfm?pageid=3274 (last visited Apr.11, 2005). It also supports "credentialing" public health practitioners, presumably as a means of establishing public health as an identifiable profession. *Id.* The curriculum for schools of public health demonstrates the interdisciplinary nature of the M. P. H. by requiring the following: courses in epidemiology, biostatistics, health services, behavioral sciences, and environmental health; and elective courses in maternal and child health, international health, management, economics, and health law. Boston University School of Public Health requires a health law course for its M. P. H. graduates. See CEPH, ACCREDITATION CRITERION V.A, *at* www.ceph.org/i4a/pages/Index.cfm?pageid=3320#Instructional_Programs (last visited Apr. 11, 2005). Most of the "core" and elective subjects are themselves applied fields.

[43] See Annas, George J. *The Rights of Patients* (3rd 2004) [hereinafter *The Rights of Patients*].

[44] See Beauchamp, Tom L., Childress, James, F. Principles of Biomedical Ethics. 5th ed. (2001); Grodin, Michael A. (ed.), Meta Medical Ethics: the Philosophical Foundations of Bioethics (1995); President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions. Vols. 1, 3 (1982); National Commission for the Protection of Human Subjects of Biomedical Research and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. DHEW Pub. No. (OS) 78-0012 (1978).

[45] See Annas, George J. *The Rights of Patients*, *supra* note 43; Faden Ruth R., Beauchamp, Tom L. *A History and Theory of Informed Consent* (1986); Katz, Jay *The Silent World of Doctor and Patient* (1984).

[46] See Annas, George J. *The Rights of Patients*, *supra* note 43; Rotenberg, Marc *The Privacy Law Sourcebook* (1999); Rothstein, Mark A. (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997); Bennett, Colin J. *Regulating Privacy: Data Protection and Public Policy in Europe and the United States* (1992).

[47] Annas, George J. "Human Rights and Health : the Universal Declaration of Human Rights at 50", 339 *New Engl. J. Med.* 1778 (1998).

[48] Comm. on Emerging Microbial Threats to Health, Institute of Medi-

cine, Emerging Infections: Microbial Threats to Health in the United States 151-153 (Joshua Lederberg *et al.,* eds., 1992). Available at www.nap.edu/books/0309047412/html/index.html (last visited Mar. 31, 2005) [hereinafter IOM, Emerging Infections].

[49] See generally Institute of Medicine, Mobilizing Against AIDS : The Unfinished Story of a Virus (1986); Joint United Nations Programme on HIV/AIDS, Partners in Prevention: International Case Studies of Effective Health Promotion Practices in HIV/AIDS (1998).

[50] In the United States, a significant proportion of public health expenditures are for individual healthcare services in publicly funded programs, such as programs for family planning, mental health facilities, substance abuse treatment, and community health clinics. See The Future of Public Health, *supra* note 16, at 182; Institute of Medicine, No Time to Lose : Getting More from HIV Prevention (Ruiz, M. S., Gable, A.R, Kaplan, E.H. *et al.,* (eds.) 2001). About 1.6% of the federal health budget is estimated to be spent on population-based prevention, the traditional definition of public health programs. Mullan, Fitzhugh "Interview: David Satcher Takes Stock", *Health Affairs.* Nov.-Dec. 2002; 21 : 6 154, 157. Expenditures for public health in the U. S. are notoriously difficult to estimate because they are spread among so many different public and private programs and depend on what is counted as "public health". See Allin, Sara *et al.,* Making Decisions on Public Health: a Review of Eight Countries 23 (2004); Christopher, Atchison, *et al.,* "The Quest for an Accurate Accounting of Public Health Expenditures" *J. Pub. Health Mgmt. Prac.* 2000; 6 : 93, 99 (estimating state spending on personal health services as between 53 and 77% of total state public health expenditures).

[51] Lasker, Roz D. *Comm. on Med. & Public Health,* Medicine and Public Health: The Power of Collaboration 9 (1997).

[52] One might even include bankruptcy, civil procedure, conflict of laws, contracts, and criminal procedure. As Clark Havighurst noted, there is no "discrete body of legal doctrine" for health law. See Havighurst, Clark C. "Health Care as a Laboratory for the Study of Law and Policy", *J. Legal Educ.* 1988; 38 : 499-500. The same can be said of what is called public health law. See Mariner, Wendy K. "Public Health and Law: Past and Future Visions", *J. Health Politics, Pol'y & L.* 2003; 28 : 535, 542.

[53] In the United States, the federal law and regulations, together with state common law duties of employers generally govern safety standards in the workplace. See Occupational Safety and Health Act, 29 U. S. C. §

651 (2005); 2 Am. Jur. 2d *Failure to Provide a Safe Place to Work* § 517 (1974); Environmental Protection Agency, Occupational Health, *at* www.epa.gov/ebtpages/humaoccupationalhealth.html (last visited Apr. 1, 2005).

[54] Novak, William J. The People's Welfare: Law and Regulation in Nineteenth-Century America 14-15 (1996); Parmet, *supra* note 19, at 483.

[55] See, e.g., Wing, Kenneth R. The Law and the Public's Health. 6th ed., 2003. 175-177. (describing and analyzing the types of laws governing public health matters).

[56] UDHR, *supra* note 15:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Id. at art. 25 (1). Other articles specify related rights and the universality of all the rights described in the Declaration. For example, Article 1 states: "All human beings are born free and equal in dignity and rights". *Id.* at art. 1. Article 2 states: "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status". *Id.* at art. 2. Article 5 states: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment". *Id.* at art. 5. Article 9 states: "No one shall be subjected to arbitrary arrest, detention or exile". *Id.* at art. 9. Article 12 states "No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation". *Id.* at art. 12. see *also*

[57] ICESCR, *supra* note 15.

[58] *Comm. on Econ., Soc. & Cultural Rights*, UN, General Comment No. 14, *The Right to the Highest Attainable Standard of Health* (Article 12) § 33 (2000). Available at www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument (last visited Apr. 2, 2005) [hereinafter GENERAL COMMENT]. The most authoritative interpretation of the right to health is *General Comment No. 14* of the Committee on Economic, Social and Cultural Rights of the United Nations Economic and Social Council (ECOSOC), which summarizes the generally accepted principles embodied in ICESCR Article 12. ICESCR, *supra* note 15. The ICESCR did not adopt the World Health Organization's broader definition of health: "Health is a state of complete physical, mental, and social well-being

and not merely the absence of disease or infirmity". WHO, Const. of the WHO, pmbl., *available at* w3.whosea.org/aboutsearo/pdf/const.pdf (last visited Mar. 24, 2005). The ICESCR imposes duties on States Parties but limits the duties according to what is feasible. ICESCR, *supra* note 15, art. 2.

[59] The precise contours of the States Parties' obligations remain subject to some interpretation, of course, and are implemented to varying degrees in different countries. See Kinney, Eleanor D. "The International Human Right to Health: What Does This Mean for Our Nation and World? ". *Ind. L. Rev.* 2001; 34 : 1457, 1470.

[60] An excellent concise description of the development of international human rights and their application to health is Gruskin Sofia, Tarantola, Daniel *Health and Human Rights*. In: Gruskin, Sofia *et al.,* (eds.) Perspectives on Health and Human Rights, 2005. 3-57.

[61] GENERAL COMMENT, *supra* note 91, § 8.

[62] *Id.* § 33

[63] *Id.*

[64] *Id.*

[65] *Id.* §§ 35, 51. *General Comment No. 14* also mentions the obligation to refrain from marketing unsafe drugs and polluting the environment as part of the duty to respect. *Id.* § 34.

[66] *Id.* § 36.

[67] *Id.* § 37.

[68] See ROSEN, *supra* note 22, at 69-72, 171-172.

[69] See Epstein, Richard A. "Let the Shoemaker Stick to His Last, A Defense of the 'Old' Public Health", 46 *Perspectives in Biol. & Med.* (Supp) 2003; 46 : S138-S159 (arguing that individual liberty can be sacrificed to protect the population from bioterrorism and contagious diseases); Gostin, Lawrence O. "When Terrorism Threatens Health: How Far Are Limitations on Personal and Economic Liberties Justified?" *Fla. L. Rev.* 2003; 55 : 1105 (same); Rehnquist, William H. All the Laws But One: Civil Liberties in Wartime (1998) (arguing that war can justify significant restrictions on civil liberties).

[70] See Annas, George J. Bioterrorism, Public Health and Human Rights, supra note 29, at 96 (noting that "human rights and health are not inherently conflicting goals"); Mann, Jonathan M. "Medicine and Public Health, Ethics and Human Rights", *Hastings Ctr. Rep.* 6 (May-June 1997) (arguing that human rights sustain health); Annas, George J. "Puppy Love", supra note 39 (arguing that restrictions on civil liberties typically undermine public health efforts and violate more basic principles of law); Parmet, Wendy E. "Liberalism, Communitarianism and Public

Health", *Fla. L. Rev.* 2003; 55 : 1221 (critiquing arguments in favor of restricting civil liberties on the ground that they are based on inaccurate premises); Cole, David "Enemy Aliens", *Stan. L. Rev.* 2002; 54 : 953, 955 (critiquing government actions as ineffective and unjustified, and noting that in times of crisis we are likely to "overestimate our security needs and discount the value of liberty").

[71] ICESCR, *supra* note 15, at art. 4.

[72] GENERAL COMMENT, *supra* note 91, § 28.

[73] This Article uses the term "contagious disease" to mean an infectious disease that can be transmitted from one person to another person. Contagious diseases form a subgroup within the category of infectious diseases. An infectious disease is any disease in which a virus, bacterium or parasite invades (infects) a human being; the virus, bacterium or parasite may come from an animal, an environmental source, or another human being. For example, anthrax is infectious but not contagious, because a person infected with anthrax cannot transmit the infection to other people. Small pox can be transmitted from an infected person to another person if the uninfected person touches the virus on the infected person. Small pox can also survive on certain surfaces, such as bed linens, and infect a person who touches those linens within a limited period of days — the infectious period. Airborne infections are transmitted though the air, often from a cough or sneeze. Bloodborne infections (e.g., HIV, hepatitis B) are transmitted from blood source to blood source, where the infected blood contacts the blood of another person.

[74] Persons with compromised immune systems are at a higher risk of death from influenza. See Harper, *et al.,* Prevention and Control of Influenza, supra note 39.

[75] See World Health Organization, Global Tuberculosis Control : Surveillance, Planning, Financing (2005). Available at http://www.who.int/tb/publications/global_report/en/index.html (last visited July 12, 2005); World Health Organization, *Tuberculosis,* available at http://www.who.int/mediacentre/factsheets/fs104/en/ (last visited July 12, 2005).

[76] Tuberculosis is a bacterial disease caused by mycobacterium tuberculosis (TB). TB is transmitted by droplets through the air, most often by coughing or sneezing. See Toman's Tuberculosis: Case Detection, Treatment and Monitoring (Frieden, T. (ed.). 2nd ed. (2004) (hereafter Toman's Tuberculosis).

[77] Medications currently recommended include isoniazid, rifampicin, pyrazinamide, and ethambutol. Persons who receive improper treatment regimens or who do not take the medication for the recommended pe-

riod of time, usually 6 to 8 months, are at risk for developing resistance to the drug and for relapsing with active TB in the future. *Id.;* American Thoracic Society, Centers for Disease Control and Prevention, Infectious Diseases Society of America, "Treatment of Tuberculosis", *Am. J. Respir., Crit. Care Med.* 2003; 167: 603 (official joint statement of the 3 organizations approved October 2002), available at http://www.thoracic.org/adobe/statements/treattb.pdf (last visited 3-7-05). If a person develops resistance to at least 2 drugs (multidrug-resistant tuberculosis or MDR-TB), a combination of drugs taken for up to 24 months are usually needed for effective treatment. Mukherjee, Joia S. *et al.,* "Programmes and Principles in Treatment of Multidrug-resistant Tuberculosis", *The Lancet* Feb. 7, 2004; 363 : 474. MDR-TB is a particular public health concern because of the possibility that a person could become resistant to all possible treatments and spread drug-resistant TB to others. WHO estimates the percentage of people with TB that is resistant to at least one drug ranges from 0% in Western Europe to 57% in Kazakhstan, with a global median of 10%. World Health Organization, Anti-Tuberculosis Drug Resistance in the World 15-16 (2004).

[78] See Dolin, P. J., Raviglione, M.C., Kochi, A. "Estimates of Future Global Tuberculosis Morbidity and Mortality", *Morbidity & Mortality Wkly Rep.* 17 Dec. 1993; 42 : 49 961.

[79] Before TB's cause was discovered, the disease was popularly known as "consumption", for its wasting effect on the body, or "white plague". See Dormandy, Thomas *The White Death : A History of Tuberculosis* (2000); and Rene Dubos, Dubos, Jean *The White Plague: Tuberculosis, Man and Society* (1952). Consumption was a romanticized euphemism associated with nineteenth century artists like Chopin and Shelley. Discovery of the bacterium in 1882 forced a closer look at how the disease was transmitted, and it became associated with the squalor of crowded, nineteenth century urban tenements. As Rene and Jean Dubos note, tuberculosis was symbolically transformed from the delicate condition of creative genius to the mark of social outcasts. *Id.* at 66. See *also* Feldberg, Georgina, D. Disease and Class: Tuberculosis and the Shaping of Modern North American Society (1995); Rothman, Sheila M. Living in the Shadow of Death: Tuberculosis and the Social Experience of Illness in America (1994); Rosenkranz, Barbara Gutmann (ed.), From Consumption to Tuberculosis: A Documentary History (1994).

[80] See Institute of Medicine, Ending Neglect, *supra* note 26 at 2 (noting that the federal government had ended its categorical financing of TB

treatment and concluding that "without question the major reason for the resurgence of tuberculosis was the deterioration of the public health infrastructure essential for the control of tuberculosis".).

[81] See World Health Organization, DOTS, available at http://www.who.int/tb/dots/whatisdots/en/index.html (last visited July 12, 2005).

[82] See Institute of Medicine, Ending Neglect, *supra* note 26 at 2.

[83] See Ryan, Frank The Forgotten Plague: How the Battle Against Tuberculosis Was Won : and Lost (1993); Annas, George J. "Control of Tuberculosis : the Law and the Public's Health", *New Eng. J. Med.* 1993; 328 :585; Andrew A. Skolnick, "Some Experts Suggest the Nation's 'War on Drugs' Is Helping Tuberculosis State a Deadly Comeback", *JAMA* 1992; 268 : 3177; Reichman, Lee B. "The U-Shaped Curve of Concern", *Am. Rev. Respir. Dis.* 1991; 144 : 741; Brudney, Karen, Dobkin, Jay "Resurgent Tuberculosis in New York City: Human Immunodeficiency Virus, Homelessness, and the Decline of Tuberculosis Control Programs", *Am. Rev. Respir. Dis.* 1991; 144: 745; Brudney, Karen, Dobkin, Jay "A Tale of Two Cities: Tuberculosis Control in Nicaragua and New York City", *Seminars Resp. Infect.* 1991; 6 : 261; Snider, Dixie E. Jr., Hutton, Mary D. "Tuberculosis in Correctional Institutions", *JAMA* 1989; 261 : 436. See *also* note 79 *supra*.

[84] See Daniel, Thomas M. Captain of Death: The Story of Tuberculosis (1997). 50

[85] See, e.g., CDC, "Public Health Dispatch: Tuberculosis Outbreak Among Homeless Persons : King County, Washington, 2002-2003", *Morbidity & Mortality Wkly Rep.* 2003 Dec. 12; 52 : 49 1209-1210. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5249a4.htm (TB cases among homeless population in the Seattle area increased from an annual average of 13 in 1999-2001 to 44 cases from May 2002 through September 2003) (for surveillance, note that only 20 of the 44 were reported, and 11 of those were found by the outbreak investigation screening program initiated); and CDC, "Public Health Dispatch: Tuberculosis Outbreak In a Homeless Population : Portland, Maine, 2002-2003", *Morbidity & Mortality Wkly Rep.* 2003 Dec. 5; 52 : 48. 1184-1185. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5248a5.htm (5 of 7 TB cases in the year ending July 2003 had resided in the same homeless shelter and 6 of the 7 cases had been incarcerated in the same jail).

[86] See National Center for Health Statistics, *Table 23. Tuberculosis Cases in Residents of Correctional Facilities* (3.3% of TB cases in 1999 were residents of correctional facilities); *Table 24.*

Tuberculosis Cases by Homeless Status (6.3% of tuberculosis cases in 1999 were homeless), *Table 32. Tuberculosis Cases by Occupation* (58.2% of TB cases in 1999 were unemployed in past 24 months, 1.1% were migrant workers). Individuals able to stay in their own homes, avoid contact with others, and obtain treatment paid for by health insurance or their own funds are not ordinarily subjected to involuntary confinement in the U. S.

[87] Public Health Institute, TB and the Law Project, *Souvannarath Case Study* (2003) [hereafter *Souvannarath Case Study*], available at www.phlaw.org. See also Roemer, John "Reclaiming a Soul", *Daily Journal* (Apr. 30, 2001).

[88] Souvannarath v. Hadden, 95 Cal. App. 4th 1115, 116 Cal. Rptr. 2d 7 (5th Dist. CA 2002) (treatment and detention could take up to 2 years).

[89] The California Appellate Court noted that fewer than 20 people had been detained in Fresno County for TB since 1995. *Id.,* 95 Cal. App. 4th at 1118.

[90] These facts are drawn from Public Health Institute, *Souvannarath Case Study, supra* note 85 and the sources cited therein.

[91] Anti-tuberculosis medications can cause unpleasant side effects. See Toman's Tuberculosis, *supra* note 76.

[92] The state health department reportedly had opposed the law prohibiting housing TB patients in jails in order to gain "flexibility in placing TB patients in the event jail beds are the only available beds for the [TB] program". See Souvannarath v. Hadden, 95 Cal. App. 4th 1115, 1127 (2002)

[93] See Institute of Medicine, Ending Neglect, *supra* note 26 at 4 ("The key to achieving tuberculosis elimination will be through social mobilization and maintaining the public interest and commitment necessary to provide sufficient resources for the effort".).

[94] See *generally,* World Health Organization, Addressing Poverty in TB Control : Options for National TB Control Programmes, 2005. Available at http://whqlibdoc.who.int/hq/2005/WHO_HTM_TB_2005.352.pdf (last visited July 12, 2005)

[95] See generally, Ronald Bayer, Private Acts, Social Consequences: AIDS and the Politics of Public Health, 1991. In the 1980's, fear of people with HIV, especially gay men, encouraged proposals for laws to criminalize HIV transmission. See. Sullivan, Kathleen M, Field, Martha, A "AIDS and the Coercive Power of the State", *Harv. Civil Rights & Civil Lib. L. Rev.* 1988; 23 : 139.

[96] See Glantz, Leonard H., Annas, George J., Mariner, Wendy K. "Risky Business: Setting Public Health Policy for HIV-infected Health Care Professionals", *Milbank Quarterly* 1992; 70 : 43.

[97] HAART is a multidrug regimen typically consisting of a nucleoside

analog, a protease inhibitor, and a non-nucleoside reverse transcription inhibitor (NNRTI) or a second nucleoside analog. Panel on Clinical Practices for Treatment of HIV Infection, U. S. Dept. of Health and Human Services, *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (7 April 2005). Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf (last visited July 12, 2005). Adverse reactions and side effects caution against the use of certain drugs for prophylaxis in the absence of infection. See e.g., Smith, D. K.*et al.,* "Antiretroviral Post-exposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States". *Morbidity & Mortality Wkly Rep.* 21 Jan. 2005; 54 : 1 (RR02). Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm.

[98] See Institute of Medicine, Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States (1999).

[99] The CDC is an agency of the United Stated Department for Health and Human Services and is responsible for collecting information and making recommendations for reducing public health risks. It has no authority to require states to pass laws. See http://www.cdc.gov.

[100] See Public Health Service Task Force, *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States* (24 Feb. 2005), available at http://www.aidsinfo.nih.gov/guidelines/perinatal/PER_022405.pdf (last visited July 12, 2005) [hereinafter *PHSTF Recommendations*].

[101] See CDC, "Revised Recommendations for HIV Screening of Pregnant Women", *Morbidity & Mortality Wkly Rep.* 2001; 50 (RR-19) : 59; CDC, *Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status: a Practical Guide and Model Protocol* (2004), available at http://www.cdc.gov/hiv/rapid_testing/materials/Labor&DeliveryRapidTesting.pdf (last visited 10 May 2005) [hereinafter *Rapid HIV Testing During Labor*]. The different options for offering diagnostic tests to patients include (1) a specific request for a specific test, with all the elements of informed consent (sometimes called "opt-in"); (2) a request for a battery of tests, with or without information about each test, but telling the patient that she can refuse any test (often called "opt-out"); and (3) a request for a series of tests without specifying or providing specific information about each one. The likelihood that a patient will consent to a test is highest with the third option, presumably because the patient had little informa-

tion on which to base a refusal. The more ordinary or "routine" the test is characterized, the less likely a patient will refuse it.

[102] CDC, *Rapid HIV Testing During Labor*, *id.* ("the available data indicate that both 'opt-out' prenatal screening and mandatory newborn screening achieve higher maternal screening rates than 'opt-in' prenatal screening. Accordingly, CDC recommends that clinicians routinely screen all pregnant women for HIV infection, using an 'opt-out' approach, and that jurisdictions with statutory barriers to such routine prenatal screening consider revising them".)

[103] These laws were enacted to protect people against discrimination in housing, employment and health insurance. Although discrimination against people with HIV has diminished in the United States, it has not disappeared.

[104] See Office of the Inspector General, Reducing Obstetric Barriers to Offering HIV Testing (April 2002), available at http://oig.hhs.gov/oei/reports/oei-05-01-00260.pdf (last visited 10 May 2005) [hereinafter OIG, Reducing Barriers].

[105] *Id.* (finding that 93% of obstetricians surveyed did routinely offer HIV testing to their pregnant patients as part of standard prenatal care). Barriers to doing so included language, late entry into prenatal care, and a perception that patients were at low risk for HIV. *Id.* During labor and delivery, almost half of the obstetricians surveyed reported having too little time for counseling and testing. *Id.*

[106] See Massachusetts Dept. of Public Health, Massachusetts HIV/AIDS Data Fact Sheet 2 (Oct. 2004), available at www.mass.gov/dph/aids (last visited 10 May 2005). In 2003, one baby was born with HIV infection, and none in 2002. Personal communication from Samuel Jenness, Policy Analyst, HIV/AIDS Bureau, Massachusetts Dept. of Public Health (17 May 2005).

[107] *Id.* ("Of women who knew their HIV positive status before giving birth in Massachusetts in 2001, 100% received antiretroviral therapy during pregnancy and/or during labor and delivery".). Ninety-eight percent of HIV positive women in Massachusetts knew their HIV status before giving birth. *Id.*

[108] See OIG, Reducing Barriers, *supra* note 104.

[109] Significantly, the Office of the Inspector General and the Public Health Service Task Force both emphasized retaining the patient's right to consent or refuse testing. Id.; *PHSTF Recommendations, supra* note 100.

[110] The CDC estimated that if all pregnant women were tested for HIV during pregnancy and given treatment, 70-90 fewer babies would be

born with HIV, but not all births with HIV infection would be prevented. See OIG, Reducing Barriers, *supra* note 104. If a reduction in fewer than 100 cases of disease justifies testing without consent, one may ask what would *not* justify overriding consent to medical testing or treatment.

[111] S*ee* text accompanying note 72 *supra*. The type of coercive law that is sometimes justified in the case of contagious disease is involuntary confinement to prevent a person from spreading a contagious disease to others, but involuntary treatment is not ordinarily permitted. See Annas, *The Rights of Patients*, *supra* note 43; Mariner, *et al., Jacobson v. Massachusetts*, *supra* note 10, at 586-587.

[112] See Andrews, Lori B. "A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models", *Wash. U. L.Q.* 2001; 79 : 221, 271 (noting the growing use of the term "public health threat" to encompass genetic conditions and chronic diseases, and finding that "the mere fact that a disease affects numerous people, and is thus a major social concern, does not mean that it is a public health threat" for purposes of determining applicable law).

[113] The shift to health promotion may date from 1974, when Canada published the landmark Lalonde Report. Marc Lalonde, Minister of Nat'l Health & Welfare, A New Perspective on the Health of Canadians: a Working Document (1974). United States Surgeon General Julius Richmond published the first United States version, *Healthy People,* in 1979, which inspired the ongoing periodic review of Americans' overall health status and goal setting for improvement (analogous to 5- and 10-year plans), currently in the *Healthy People 2020* stage. See Off. of Disease Prevention & Health Promotion, HHS, Healthy People 2010. 2nd ed. (2000), available at www.health.gov/healthypeople/document/ (last visited 25 Mar. 2005).

[114] See Detels Roger, Breslow, Lester *Current Scope and Concerns in Public Health*. In: Oxford Textbook of Public Health, *supra* note 18, at 49; J. Michael McGinnis, "The Case for More Active Policy Attention to Health Promotion", *Health Affs.* Mar.-Apr. 2002; 21-78. 78-93.

[115] See Hedley, Alison A. *et al.,* "Prevalence of Overweight and Obesity Among US Children, Adolescents, and Adults, 1999-2000", *JAMA* 2004; 291: 2847. But see Flegal Katherine M., *et al.,* "Excess Deaths Associated with Underweight, Overweight, and Obesity", *JAMA* 2005; 293 : 1861 (finding overweight not associated with excess mortality).

[116] There have been some attempts to educate the public about hazardous working conditions or housing. For example, the "right to know" move-

ment was an effort to inform employees about hazardous chemicals or working conditions. Emergency Planning and Community Right-to-Know, 42 U. S. C. §§ 11001-11050 (2005). The mapping of the humane genome increased awareness of genetic predispositions to certain diseases. See generally National Human Genome Research Institute, National Institutes of Health, *at* www.genome.gov (last visited Mar. 25, 2005).

[117] Programs to discourage smoking have had some success, as evidenced by the declining rates of smoking the United States. See. Davis, Ronald M "Healthy People 2010: Objectives for the United States: Impressive, But Unwieldy", *Brit. Med. J.* 2000; 320 : 818, available at http://bmj.bmjjournals.com/cgi/reprint/320/7238/818 (last visited Mar. 31, 2005).

[118] But see Knowles, John H. "Doing Better and Feeling Worse: Health in the United States", *Daedalus xx.* 1977; 106 (classic issue devoted to the paradox that as population health improves, public opinion focuses more fixedly on health problems); Barsky, Arthur J. Worried: Sick Our Troubled Quest for Wellness (1988).

[119] See Mariner, Wendy K. *The Merger Between Public Health and Health Law : the US Situation*, 2001 European Health Forum Gastein Congress Rep. 173, 175-176 ("Public health efforts succeeded primarily by making the *world* safer for *people* — by cleaning up the water, food, sewage, and housing in the nineteenth century and also the workplace and environment in the twentieth century... Promoting health [today] means making *people* safer for the *world*".). See also Rabin, Robert L., Sugarman, Stephen D., (eds.) *Smoking Policy: Law, Policy & Culture,* 1993. 3-21 (describing how policy approaches to risks vary with public perceptions of personal responsibility for risk creation).

[120] The trend in the United States toward changing personal behavior coincides with renewed concern about the rising cost of healthcare and a political climate that emphasizes personal responsibility and discourages reliance on public benefit programs. If people change their behavior in ways that improve their health, they are less likely to need expensive medical care. See Tesh, Sylvia N. Hidden Arguments: Political Ideology and Disease Prevention Policy 46 (1988) (arguing that state laws increasingly targeted individual conduct to reduce healthcare costs or population mortality rates); Green, Lawrence W. "Health Education's Contributions to Public Health in the Twentieth Century: a Glimpse Through Health Promotion's Rear-View Mirror", *Ann. Rev. Pub. Health* 1999; 20 : 67, 69 (arguing that health promotion replaced traditional health

education when public policy and funding for research began seeking ways to reduce healthcare expenditures). For example, employers have adopted policies forbidding their employees from smoking or drinking at home as well as on the job. Gunn, Eileen "No Ifs, Ands or Butts: Smokers Need Not Apply", *Career J.,* Dec. 14, 2004, at www.careerjournal.com/hrcenter/articles/20041214-gunn.html?hrcenter_whatsnew (last visited Mar. 25, 2005); Peters, Jeremy W., "Company's Smoking Ban Means Off-Hours Too", *New York Times,* Feb. 8, 2005, at C5; Marc Kaufman, "Surgeon General Favors Tobacco Ban", *Wash. Post,* June 4, 2003, at A1. Maryland state legislators introduced legislation requiring employees to take a Breathalyzer test and possibly be fired if their blood-alcohol level was 0.02% or more; laws prohibiting driving while intoxicated typically use 0.08%. David E. Leiva, "Bill Would Let Your Boss Test Your Breath", *Capital,* Feb. 18, 2005, available at www.hometownannapolis.com/vault/cgi-bin/trial/search (last visited Mar. 25, 2005).

[121] SARS is a viral respiratory illness caused by a coronavirus — SARS-associated coronavirus (SARS-CoV). World Health Organization, *Severe Acute Respiratory Syndrome (SARS) : Status of the Outbreak and Lessons for the Immediate Future* 1 (20 May 2003), available at http://www.who.int/csr/media/sars_wha.pdf (last visited 24 June 2005). SARS-CoV is believed to be an animal virus. Evidence of a related coronavirus has been identified in several species that are served as food delicacies in southern China, although the exact source of transmission to humans has not been identified. Transmission from animal to human (crossing the species barrier) may have become possible with changes in ecology or human behavior. The virus may have adapted to its human host to permit human-to-human transmission. World Health Organization, *WHO SARS Risk Assessment and Preparedness Framework* 4 (Oct. 2004), available at http://www.who.int/csr/resources/publications/CDS_CSR_ARO_2004_2.pdf.

[122] World Health Organization, *Update 95 — SARS : Chronology of a Serial Killer*, (July 4, 2003), available at http://www.who.int/csr/don/2003_07_04/en/.

[123] Institute of Medicine, *Learning from SARS: Preparing for the Next Disease Outbreak* 6 (MA Stoto, DA Almario, MC McCormick, (eds.) 27 Jan. 2004), available at http://books.nap.edu/html/SARS/0309091543.pdf (last visited 24 June 2005) [hereinafter IOM, *Learning from SARS*].

[124] *Id.*

[125] Data on the number of cases of a new disease can be difficult to

interpret. Reports of "SARS cases" often include "potential", "suspected", or "probable" cases, without indicating final diagnosis. Final data on the number of actual diagnosed cases of SARS are limited. For example, WHO reported a total of 251 "probable" cases of SARS in Canada, with 109 of these among hospital workers, and 43 deaths. WHO SARS data chart (December 2003). Toronto Public Health identified 2,132 "potential" SARS cases and found that 1,907 did not fit the diagnostic criteria for a case of SARS, leaving 225 probable SARS cases. See Svoboda, Tomislav, Henry, Bonnie, Shulman, Leslie, Kennedy, Erin, Rea, Elizabeth, Ng, Wil, *et al.,* "Public Health Measures to Control the Spread of the Severe Acute Respiratory Syndrome in Toronto". *New Engl. J. Med.* 2004; 350 : 2352, 2358 [hereinafter *Public Health Measures*] Investigators sought to conduct serologic tests on these 225 cases. Ninety-six people refused testing, died or could not be contacted, so definitive results are not available for 43 percent of probable cases. The remaining 129 cases were tested. Five tests had negative results and 124 cases had positive tests for SARS. Nonetheless, all 225 cases are described as cases of SARS. *Id.*

[126] In Toronto, 16.9 percent (38 out of 225) of probable SARS cases died. Most other countries had a lower death rate, perhaps because the majority of people who died in Toronto (21 out of 38, 55l.3% of deaths) had been infected in the hospital, where multiple or more active infections might have occurred. *Id.* at 2358.

[127] Important exceptions include cases in Metropole Hotel and the Amoy Gardens apartments in Hong Kong.

[128] See Poutanen, S. M., Low, D. E., Henry, B. *et al.,* "Identification of Severe Acute Respiratory Syndrome in Canada", *New Engl. J. Med.* 2003; 348 : 1995 [hereinafter "Identification of SARS"]; Booth, C. M., Matukas, L. M., Tomlinson, G. A., *et al.,* "Clinical Features and Short-term Outcomes of 144 Patients with SARS in the Greater Toronto Area"*, JAMA* 2003; 289 : 2801-2809) (Erratum, *JAMA* 2003; 290 : 334.

[129] See Dyer, O. "Two Strains of SARS Virus Sequenced". *B.M.J.* 2003; 326 : 999. The virus is described in Marra, M. A., Jojnes, S. J., Astell, C. R *et al.,* "The Genome Sequence of the SARS-Associated Coronavirus". *Science* 2003; 300 : 1399; Rota, P. A., Oberste, M. S., Monroe, S. S. *et al.,* "Characterization of a Novel Coronavirus Associated with Severe Acute Respiratory Syndrome". *Science* 2003; 300 : 1394; Poutanen, *et al.,* "Identification of SARS"*, supra* note 128. Continuing research has possibly discovered how SARS affected people so severely, which may permit

development of therapy. Rosenthal, Elisabeth "With New Clue to How SARS Kills, Scientists Work on Treatment". *New York Times* (14 July 2005).

[130] Although masks were used during epidemics in earlier centuries, they were characterized as "novel interventions" by a CDC infectious disease official. M. Bell, David, World Health Organization Working Group, "Public Health Intervention and SARS Spread", 2003. *Emerg. Infect. Dis.* 2004; 10 : 11. 1900, 1902 [hereinafter "Public Health Intervention and SARS Spread"].

[131] See *id.* Robert A. Weinstein, "Planning for Epidemics : the Lessons of SARS". *New Engl. J. Med.* 2004; 350 : 23 [hereinafter "Planning for Epidemics"].

[132] A Chinese team reported an outbreak of atypical pneumonia to provincial hospitals in late January 2003, during the Chinese New Year Holiday. This was an unhappy coincidence, because many officials were on vacation and could not attend to the report, and holiday travel probably exacerbated the spread of disease. IOM, Learning from SARS*, supra* note 123, at 4. Outside China, news of the outbreak was first received by e-mail, internet chat rooms and local media.

[133] The patient had stayed at the Metropole Hotel in Hong Kong. *Id.* at 7.

[134] Kamps, Bernd Sebastian, Hoffman, Christian. SARS Timeline (Oct. 2003), available at http://www.sarsreference.com/sarsref/timeline.htm.

[135] See Weinstein, Planning for Epidemics*, supra* note 131, at 24 ("The recent high-profile epidemics (e.g., those of SARS, West Nile virus, anthrax, and monkeypox) were all first identified by alert clinicians".).

[136] Fifty-Eighth World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (23 May 2005), available at http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf (last visited 12 July 2005).

[137] See IOM, Learning from SARS*, supra* note 123, at 7.

[138] See National Advisory Committee on SARS and Public Health, Health Canada, Learning from SARS: Renewal of Public Health in Canada (2003).

[139] See Svoboda *et al.,* Public Health Measures, *supra* note 125, at 2353.

[140] *Id.* at 2359.

[141] Weinstein, Planning for Epidemics*, supra* note 131, at 2332.

[142] Since July 2003, SARS has reappeared on four confirmed occasions, three of which resulted from laboratory accidents or breaches of safety procedures (in Singapore, Taipei, and Beijing), while animal or environmental exposures were blamed for a fourth outbreak in Guangzhou, China. *WHO SARS Risk*

Assessment and Preparedness Framework 4 (October 2004), available at http://www.who.int/csr/resources/publications/CDS_CSR_ARO_2004_2.pdf.

[143] The term "isolation" generally refers to keeping a person with a contagious disease by himself. The term "quarantine" generally refers to preventing people from leaving a geographic area.

[144] See Bell, Public Health Intervention and SARS Spread, 2003*, supra* note 130. The conclusions of this group were based on a review of the existing literature and the opinions of members of an informal working group, but did not address preventing transmission in healthcare settings.

[145] See Institute for Bioethics, Health Policy and Law, University of Louisville School of Medicine, Mark A. Rothstein, Director, *Quarantine and Isolation: Lessons Learned from SARS: A Report to the Centers for Disease Control and Prevention* (Nov. 2003), available at www.louisville.edu/medschool/ibhpl/publications/SARS%20REPORT.pdf.

[146] See Bell, Public Health Intervention and SARS Spread, *supra* note 130, at 1901; Svoboda, *et al.,* Public Health Measures*, supra* note 123; M. I. L. Lee, C. J. Chen, I. J. Su, K. T. Chen, C. C. Yeh, C. C. King, *et al.,* "Use of Quarantine to Prevent Transmission of Severe Acute Respiratory Syndrome-Taiwan, 2003". *Morbidity & Mortality Wkly Rep*. 2003; 53 : 680; J. Ou, Q. Li, G. Zeng, Z. Dun, A. Qin, F. E. Fontaine, "Efficiency of Quarantine During an Epidemic of Severe Acute Respiratory Syndrome in Beijing, 2003". *Morbidity & Mortality Wkly Rep*. 2003; 52 : 1037.

[147] Germany may have avoided any cases of SARS by hospitalizing the only identifiable possible cases to arrive in the country. A physician who had treated patients with what turned out to be SARS in Singapore and two family members were returning to Singapore from New York. The physician had called a colleague in Singapore and mentioned that he had symptoms similar to his patients. The colleague contacted health authorities and WHO alerted the airline. The family was removed from the flight during a stopover in Frankfurt and placed in isolation in the hospital. World Health Organization, *Severe Acute Respiratory Syndrome (SARS) : Status of the Outbreak and Lessons for the Immediate Future* 3-4 (May 20, 2003), available at http://www.who.int/csr/media/sars_wha.pdf. Here again, an alert physician initiated protective action.

[148] In Toronto, few people were forcibly quarantined, and some health officials worried that they acted too hastily in imposing involuntary isolation in many cases. In the vast majority of "quarantine" cases, health officials telephoned contacts of people with SARS (or suspected of having

SARS) and simply advised the contacts to stay at home for 10 days after their last exposure to a person that might have SARS. Public health workers periodically called or visited the contacts to see whether they developed SARS symptoms. See Svoboda *et al., Public Health Measures, supra* note 123, at 2354.

[149] *Id.* at 2354-2355.

[150] Despite widespread voluntary compliance, even voluntary quarantine caused stress and other problems. See World Health Organization. Conference on Severe Acute Respiratory Syndrome (SARS), June 17-18, 2004, available at http://www.who.int/csr/sars/conference/june_2003/en/; Hawryluck, L., Gold, W.L., Robinson, S., Pogorski, S., Galea, S., Styra, R.., *et al.,* "SARS Control and Psychological Effects of Quarantine, Toronto, Canada". *Emerg. Infect. Dis.* 2004; 7 : 1206; Blendon, Robert J., Benson, J. M., DesRoches, D. M., Raleigh, E., Taylor-Clark, K. "The Public's Reaction to Severe Acute Respiratory Syndrome in Toronto and the United States"*, Clin. Infect. Dis.* 2004; 38 : 925.

[151] See IOM, *Learning from SARS, supra* note 123, at 6.

[152] One summary concludes that published reports "indicate that SARS was diagnosed in 0.22% of quarantined contacts in China-Taiwan, 2.7% in China-Hong Kong., and 3.9%-6.3% in China-Beijing". Bell, *Public Health Intervention and SARS Spread*, *supra* note 130, at 1901. Variations appear to have resulted from different criteria for quarantine. *Id.*

[153] Eckholm, Erik "Thousand Riot in Rural Chinese Town Over SARS". *New York Times* (April 28, 2003).

[154] See Bell, *Public Health Intervention and SARS Spread, supra* note 130, at 1905 ("For more readily transmissible infections [e.g., an emerging pandemic strain of influenza], they would not completely halt transmission but might 'buy time' during a narrow window of opportunity during which an effective vaccine could be produced and other preparations made. For countries lacking specific countermeasures, such as drugs and vaccines, nonmedical public health interventions may be the only measures available to combat epidemics. See World Health Organization, WHO Consultation on Priority Public Health Interventions Before and During an Influenza Pandemic, Available at http://www.who.int/csr/disease/avian_influenza/consultation/en/.

[155] Face masks were used by patients and exposed contacts in "quarantine" and by the general public when going out.

[156] X. Pang, F. Xu, J. Guo, X. Gong, D. Liu, *et al.,* "Evaluation of control Measures Implemented in the Severe Acute Respiratory Syndrome

Outbreak in Beijing". *JAMA* 2003; 290 : 3215.

[157] Bell, *Public Health Intervention and SARS Spread, supra* note 130, at 1903.

[158] Data on airline passengers proved elusive, because it proved difficult to trace the passengers and their contacts. Reports of SARS transmission to airline passengers in flight are somewhat puzzling, with passengers seated away from a person with SARS becoming infected. See Olsen, S. J., Chang, H. L., Cheung, T. Y. Y., Tang, A. F. Y., Fisk, T. L, Ooi, S. P. L. *et al.,* "Transmission of the Severe Acute Respiratory Syndrome on Aircraft". *New Engl. J. Med.* 2004; 349 : 2416; Wilder-Smith, A., Paton, N. I., Goh, K. T. "Low Risk of Transmission of Severe Acute Respiratory Syndrome on Airplanes: the Singapore Experience", *Trop. Med. Int'l Health.* 2003; 810 : 35; Breugelmans, J. G., Zucs, P., Porten, K, Broll S., Niedrig, M., Ammon, A, *et al.,* "SARS Transmission and Commercial Aircraft". *Emerg. Infect. Dis.* 2004; 10 : 1502; Flint, J., Burton, S., Macey, J. F., Deeks, S. L., Tam, T. W. S., King, A. *et al.,* "Assessment of In-flight Transmission of SARS : Results of Contact Tracing". *Can. Commun. Dis. Rep.* 2003; 29 : 105; Desenclos, J. C., Van der Werf, S., Bonmarin, I., Levy-Bruhl, D., Yazdanpanah, Y., Hoen, B. *et al.,* "Introduction of SARS in France, March-April, 2003". *Emerg. Infect. Dis.* 2004; 10 : 195. Indeed, the transmission rate was far lower than for ordinary influenza or tuberculosis among airline passengers. See Moser, M. R., Bender, T. R., Margolis, H. S, Noble, G. R., Kendal, A. P., Ritter, G. "An Outbreak of Influenza Aboard a Commercial Airliner", *Am. J. Epidemiol.* 1979; 110 : 1; Kenyon, T. A., Valway, S. E., Ihle, W. W., Onorato, I. M., Castro, D. G. "Transmission of Multidrug-resistant Mycobacterium tuberculosis during a Long Airplane Flight", NEW ENGL. J. MED. 1996; 334 : 933.

[159] See IOM, *Emerging Infections*, *supra* note 48.

[160] See Spector, Michael "Nature's Bioterrorist" *The New Yorker* 50 (Feb. 28, 2005).

[161] The World Health Organization, which offers guidance to most countries in the world, encourages all these measures, but has only a fraction of the funding it would need to develop an adequate mechanism for coordinating information and responses to major disasters. See Garrett, Laurie *Betrayal of Trust: The Collapse of Global Public Health* 6, 2000; Frenk, Julio, Gómez-Dantés, Octavio "Globalization and the Challenges to Health Systems", *Health Affs.* May-June 2002; 21 : 160-162.