International Health Law

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The past year will be seen as extraordinary in the history of international health law as news events have placed its principles and status in the headlines. Terrorist threats to public health altered the legal landscape, requiring nations to reexamine and reformulate their health regulations. The process of revising the WHO International Health Regulations has been activated. Medical research and the provision of vital drugs in poor countries drew other countries and organizations into intense debate. Scientific advances in mapping the human genome and in reproductive technology posed ethical and legal difficulties regarding the possible and proper use of this knowledge. Organ transplantation posed questions regarding the informed consent of donors. The prevention and mitigation of terminal illness challenged national and international laws and policies in 2001. Finally, the work of the White House Commission on Complementary and Alternative Medicine Policy nears completion.

I. Bioterrorism and Public Health

Following the September 11th terrorist attacks in the United States, bioterrorism again terrified the world. An unknown assailant mailed highly virulent anthrax spores to several prominent U.S. politicians and media outlets. This terrorism via the post resulted in twenty-two cases of anthrax, consisting of ten confirmed cases of inhalational anthrax and twelve

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(seven confirmed and five suspected) cases of cutaneous anthrax. Geographically, these cases occurred in Delaware, District of Columbia, Florida, Maryland, New Jersey, New York City, Pennsylvania, and Virginia. The anthrax contamination even spread abroad, via diplomatic mail pouches to U.S. embassies in Peru and Lithuania, and to Pakistan and Argentina, through unidentified means. These anthrax attacks resulted in five deaths over three months and demonstrated the legal and public health systems’ difficulty in preventing or addressing bioterrorism.

The U.S. Congress provided $20 billion for bioterrorism recovery and preparation efforts. The House and Senate also each passed comprehensive legislation (H.R. 3448 and S. 1765, respectively) to bolster bioterrorism vigilance and response, including public communications planning, restrictions on the possession of selected agents that could be used for bioterrorism, and provisions for the safety of drugs, devices, food, and water. The U.S. Government also made an extraordinary effort to guarantee an inexpensive antibiotic stockpile to treat widespread anthrax exposure. After threatening, in the interest of national security, to invalidate Bayer Pharmaceutical’s patent on the antibiotic Cipro, the government agreed to Bayer’s reduced price of ninety-five cents per Cipro tablet for 100 million tablets.

Bioterrorism’s seriousness seems to dwarf public health concerns paramount in the spring and summer of 2001. Earlier in the year, highly contagious foot and mouth disease infected United Kingdom livestock, necessitating the destruction of thousands of cattle. Amid fears that the epidemic would spread to animals worldwide, other countries banned imports of European animals and animal products and implemented strict controls on people traveling from foot and mouth-contaminated areas.

II. WHO International Health Regulations (IHR)

Though the World Health Assembly voted in 1995 to revise the International Health Regulations, public comment began in earnest this past year. Approved in 1969, and amended twice since then, the Regulations provide a legal framework for infectious disease control and surveillance for cholera, yellow fever, and the plague.

The revision process will continue through 2002 with a revised draft circulated for comments during 2003 and a final to be presented to the WHA in 2004. Anticipated changes include, among others, an expansion of the definition of what diseases will be subject to the

IHR and the addition of provisions addressing the intentional introduction of an infectious agent, or bioterrorism.  

III. Research

The Council for International Organizations of Medical Services (CIOMS)\(^8\) and national organizational revision to international medical research guidelines triggered this year’s intensified debates surrounding standards for international research.\(^9\) In the United States, the National Bioethics Advisory Commission issued its final recommendations on this topic to President Bush in April 2001.\(^10\) The U.S. House of Representatives also considered requiring U.S. researchers to submit their foreign research plans to federal regulators.\(^11\) The core question regarding international research is what country’s standards should be used. For example, testing lower doses of drugs than are required in the United States would fail to meet United States standard of care; thus, this research would be precluded in the United States. Yet medication doses used in the United States might be too expensive to be feasible in poorer countries, necessitating examination of the efficacy of lower doses. Testing of low doses of medication is risky, however, as this may result in the transmission of terminal diseases, such as HIV.

Another recent standard-setting question is whether companies researching in other countries must supply the host country with drugs at a cheaper price if these drugs prove successful. While imposing this requirement would benefit people suffering from disease, drug companies allege that decreased price margins would limit incentives to research and develop new medications.

The struggle to obtain a supply of sleeping sickness medication exemplifies this quandary. In 1995, the pharmaceutical company Aventis ended production of eflornithine, the “resurrection drug” having spectacular effect on comatose patients in late stage Gambiense Sleeping Sickness. The drug, used to treat patients in Africa, was not profitable for Aventis.\(^12\) Only discovery of an alternative use for the drug restarted production of eflornithine. In 2001, Bristol-Myers Squibb (BMS) began marketing Vaniqa, an eflornithine-based product intended to remove women’s facial hair. Their profits assured from Vaniqa (and due to


intense lobbying by the World Health Organization and Doctors without Borders), Aventis and BMS agreed to make and donate 60,000 doses of eflornithine to satisfy the global five-year need for sleeping sickness treatment.\textsuperscript{14}

Placebo use has been another highly controversial international research issue over this past year. Placebos help researchers discern whether a new treatment is safe and effective, yet other means may determine a new treatment’s safety and efficacy. In October 2001, the World Medical Association (WMA) clarified its prior position that placebos be used only in the absence of an existing treatment. The WMA Council, without a full assembly vote, stated that a placebo could be given if necessary to determine a medication or technique’s safety or harm, if the patient’s illness is minor, or if the use of a placebo would not cause serious harm.\textsuperscript{15} The United States Food and Drug Administration opposed WMA’s position and did not incorporate it into U.S. regulations.\textsuperscript{16}

\textbf{IV. HIV Infection}

Illustrating the research standard-setting debate in the HIV context, the South African government announced in 1999 that costs prohibited it from giving HIV-infected pregnant women AZT, the standard anti-retroviral medication used to prevent maternal-child transmission of HIV at birth.\textsuperscript{17} In March 2001, the government changed its position to provide HIV-positive pregnant women with a medication called Nevirapine.\textsuperscript{18} Although significantly less expensive than AZT, Nevirapine is also less efficacious than AZT in preventing mother to child transmission of HIV. The right to the highest possible standard of health was thus pitted against cost control measures.

The struggle between profit and developing countries’ needs is exemplified by the past year’s AIDS drugs controversy in South Africa. Thirty-nine pharmaceutical companies opposed South Africa’s importing or manufacturing generic versions of HIV treatment medication.\textsuperscript{19} These multinational companies sued the South African government to protect their patent rights to their medication. Due to public pressure, the companies dropped their suit and decreased the prices on HIV medication.\textsuperscript{20}

Other new legal questions relate to reducing the spread of AIDS. One city in China adopted regulations requiring health care workers to persuade pregnant women with HIV to abort their fetuses.\textsuperscript{21} The Chinese regulations contrast with views giving greater respect to pregnant women’s decision-making autonomy and recognizing that not all children of HIV-positive mothers will be born infected and that available treatments may enable in-


\textsuperscript{18} See id.


fected children to survive. This same Chinese city also has banned HIV-infected persons from some professions, such as teaching kindergarten. This too contrasts with standard knowledge about HIV transmission and the right of people living with HIV and AIDS to work and to choose their professions.

The United Nations, in an unprecedented action, devoted three days to arriving at a consensus regarding the HIV global crisis. The U.N. established the Global AIDS Fund to further open discussion, prevention, and care. The link between racism, stigma, human rights, and AIDS was also much discussed at the 2001 World Conference on Racism, held in Durban, South Africa.

V. Tobacco

During 2001, extensive negotiation and drafting occurred on the Framework Convention on Tobacco Control (FCTC), the first treaty developed under the auspices of the WHO. Formal talks on the treaty commenced in 2000 with the first session of the FCTC Intergovernmental Negotiating Body (INB). The INB is responsible for negotiating the text of the Convention and possible related protocols. The WHO FCTC Secretariat compiled State FCTC textual submissions from the first INB. To facilitate and streamline negotiations, in January 2001, the FCTC Chairman submitted for Member States’ review a draft FCTC based on the textual submissions. Member States debated and refined this text during the second INB Session from April 30 to May 5, 2001 and the third INB Session in November 2001.

Following the third INB, the draft FCTC text specifies a range of public health and economic measures to reduce tobacco-related death and disease. These measures include eliminating or restricting tobacco advertising, promotion and sponsorship; reducing tobacco smuggling and illicit trade; banning misleading tobacco descriptors such as “light” and “low tar;” protecting people from second-hand smoke; requiring prominent health warnings to occupy a significant portion of tobacco packaging and to contain pictures or pictograms; and eliminating duty-free tobacco sales. Countries negotiating the treaty have yet to reach consensus on many of these issues. Nevertheless, the third INB Session was

22. See id.
a great success, resulting in the participation of almost 170 countries and organizations; a cleaner, more readable draft FCTC text; and preliminary discussions on advertising and illicit trade protocols.

VI. Genetics

Recent advances in mapping human genes have also raised new legal quandaries as to the conditions under which companies can gain DNA material from isolated populations to conduct research. Iceland sold to deCode Genetics, a U.S. company, its citizens' DNA samples, presuming agreement unless a citizen affirmatively declined to participate in genetic research.30 In the past year, a biotechnology firm sought DNA samples from citizens in Tonga, a South Pacific island nation.31 Tongans participated in this research only if they gave prior informed consent. If new medical innovations are developed using this research, the Tongan government will share in the profits. The Tonga arrangement contrasts with other research arrangements that use citizens of developing countries as study subjects but do not provide subjects with rewards of resultant scientific advances.

VII. Reproduction

In his first act as U.S. President, George W. Bush signed an Executive Order prohibiting the use of U.S. funds in other countries to provide information about or advocacy for abortion.32 The U.S.-based Center of Reproductive Law and Policy (CRLP) challenged this order as an impermissible free speech restriction on Americans working abroad and sued Bush.33 The district court dismissed CRLP's suit on the ground that the plaintiff failed to allege concrete and immediate injuries resulting from the government's policy.34 CRLP has appealed this ruling.

New technology has brought about new legal questions related to infertility. A British woman sued her doctor for medical malpractice after her infertility treatments resulted in triplets instead of twins. While the court ruled in the woman's favor, the House of Lords subsequently decreed that care providers are not liable under similar circumstances if the National Health Service provided the fertility treatment.35 Two of the most controversial problems related to fertility are cloning and using stem cells taken from embryos not needed to treat infertility. Cloning involves duplicating a person's DNA. Experts in the United States and Italy planned to create embryos for infertile couples by placing DNA from a male into a female's enucleated egg.36

34. See id.
There is wide international consensus for governmental regulation of cloning: Australia and Britain oppose cloning, and in 2001, Canada drafted legislation to ban human cloning. Further, France and Germany asked the United Nations to ban cloning in human reproduction for twenty years. In an effort to halt or control cloning in America, the Food and Drug Administration determined that cloned tissue is a biological product regulated by the Food, Drug and Cosmetic Act.

A U.S. biotechnology company, Advanced Cell Technology (ACT), claimed in late 2001 that it would publish its successful results in human embryo cloning. ACT focuses on "therapeutic cloning," where a cloned embryo is made using the DNA of a patient who could benefit from a stem cell transplant. The cloned embryo divides only a few times, after which the embryonic stem cells are collected and used to grow genetically matched tissues or specific cell types needed to treat the patient. While therapeutic cloning is different from reproductive cloning, in which an embryo grows into an identical copy of a human, the techniques used in both kinds of cloning are identical. For some, this implies that therapeutic cloning will lead to reproductive cloning. Others see therapeutic cloning as destructive of human life.

Although Canada opposes using stem cells from embryos, an eminent Canadian group, the Canadian Institutes of Health Research, recommended that stem cells be taken from fetal tissue and embryos if these are not used in fertility treatments. In Germany, the Deutsche Forschungsgemeinschaft (DFG) has issued similar guidelines, allowing researchers to derive stem cells from excess embryos.

A final issue with new legal developments in human reproduction is embryo freezing. The United Kingdom lifted a ban on freezing women's eggs in January 2001.

VIII. Organ Transplants

Greater success at transplanting organs has raised new legal and ethical dilemmas. Between 1988 and 1995, physicians in London took organs from thousands of deceased children without their parents' consent. The United Kingdom is now attempting to return these organs to these children's families. This event raises questions as to the kinds of protections due deceased persons and their families, and the requirements for obtaining pre- or post-mortem consent from individuals and families.

If consent for organ donation is required, the coercive nature of prison and impending execution call into doubt the voluntariness of prisoners' consent. In China, gov-

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43. See id.
ernment prison officials harvested organs from inmates immediately following execu-
tion; according to a witness, one prisoner's organs were removed even before he died.48
Organ harvesting occurred in spite of Chinese law requiring prisoners' prior consent
goingan donation.49

Finally, in yet another legal and ethical battle, the Indian Council of Medical Research
(ICMR) issued guidelines prohibiting xenotransplantation.50 Although there is not a legal
framework to implement them, the guidelines are convincing for Indian institutional ethics
panels. Among other questions, the guidelines examine when, if ever, non-human sentient
beings should be used in medicine.

IX. Euthanasia

The Netherlands became the first country to legalize voluntary euthanasia in December
2001. Patients consenting to euthanasia must have had a long-standing relationship with
the physician assisting their suicide and must consult with at least one other physician.51
Belgium has proposed similar legislation with more stringent requirements for non-
terminally ill patients.52 These laws raise questions of justice and equal protection. Holland's
law excludes from euthanasia those, such as children, who cannot speak for themselves or
those without a long-standing relationship to a physician.

Lastly, in another end-of-life decision, the Canadian government recently proposed rules
to allow terminally and chronically ill patients to use marijuana if they can show that this
is the only means by which they can gain relief of their suffering.53 In contrast, the U.S.
Supreme Court ruled that there is no medical necessity exception to the Controlled Sub-
stances Act's prohibitions on manufacturing and distributing marijuana.54 This ruling bars
state legislatures from permitting medical marijuana use despite marijuana's alleged benefits
to very sick patients.

X. Complementary and Alternative Medicine

The WHO released in 2001 Legal Status of Traditional Medicine and Complementary/
Alternative Medicine, a compilation of the relevant laws and regulations from its Member
States.55 It provides summaries of the policies enacted in different countries and of the
models of integration adopted by national policy makers.

48. See Subcommittee on International Operations and Human Rights, U.S. House of Representa-
visited June 26, 2002).
49. See Steven Mufson, Chinese Doctor Tells Of Organ Removals After Executions, WASH. POST, June 27, 2001,
at A01.
50. See Dinesh Sharma, India Publishes Comprehensive Ethical Guidelines For Biomedical Research, 356 LANCET
1502 (2000).
52. See Anne Marie Owens, Assisted Suicides for Non-Terminal Patients Proposed: Belgium Draft Legislation,
Nat'l Post (Canada), Jan. 15, 2001, at A02.
The White House Commission on Complementary and Alternative Medicine Policy released its Interim Progress Report in September 2001. Its final report and recommendations will be presented to the White House this year. The report recommends the coordination of federal regulation of the practices through the creation of a permanent centralized federal office.
