International Health Law

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This article on recent events in international health law is divided into three parts: (1) international research; (2) complementary and alternative medicine; and (3) other recent developments.

I. International Research

In 2000, there were two major initiatives to revise the current thinking about international human subjects research. First, the 52nd General Assembly of the World Medical Association (WMA) voted to revise the Declaration of Helsinki for the fifth time since its adoption in 1964.[1] The Declaration of Helsinki consists of guidelines for biomedical research involving human subjects. It has no legal force in the United States, but the guidelines do influence investigators, institutional review boards, and policy makers. Furthermore, in the new document the WMA asserts a change in the Declaration's status and authority. The Declaration announces that it no longer serves as just "recommendations" to physicians, and instead claims priority over national laws and regulations. The new Declaration states "No national ethical, legal, or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration."[2] The practical meaning of this asserted supremacy is unclear.

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1. WORLD MEDICAL ASSOCIATION, DECLARATION OF HELSINKI (2000), *available at* http://www.wma.net/e/policy/17-c_e.html (last visited Mar. 1, 2001).

2. *Id.* at provision 9.

The Declaration was revised because of controversy over ambiguities in the language used in its provisions. The WMA claims to have altered the document, in part, to make clear that it is morally wrong to use placebos in studies in poorer countries if their use in the same studies in wealthy countries would be considered unethical. Provision 29 states that researchers must use the standard of "the best current prophylactic, diagnostic, and therapeutic methods"[3] for all subjects when conducting research. Under this change, placebo use is considered unethical when treatments are available for the disease or condition under study.[4] The use of placebos is only considered acceptable when no proven treatment exists. If the new language were applied, many trials in the United States and abroad would be considered "unethical." In response to the revisions, Greg Koski, director of the U.S. Office for Human Research Protections stated, "I believe that it would be a mistake to rule out the use of placebos in well-designed research. . . . I don't believe we would literally take the declaration as the . . . basis for new regulations."[5] Many researchers claim that the use of placebos is scientifically necessary to effectively evaluate new drugs. Depending on the study design and responsiveness to the host community, researchers also claim that the use of placebos can be considered ethical. In addition, the Declaration addresses several important issues on which it was previously silent and revises its position on others. There are new provisions guiding the obligations for monitoring and oversight of clinical research, disclosure of financial conflicts of interest, and access to study drugs at the completion of research.[6]

The second initiative to alter the conduct of international research came from the U.S. National Bioethics Advisory Commission (NBAC). In 2000, NBAC released a draft of its report titled *Ethical and Policy Issues in International Research*.[7] The NBAC asserts that the "purpose of th[e] report is to consider the ethical, legal, and policy issues that arise when research that is subject to U.S. regulations, is sponsored or conducted in other countries."[8] In the report, NBAC discusses issues such as recruitment of subjects, informed consent, the risks and benefits of conducting multinational collaborative research, and obligations of research sponsors to participants in research, host communities, and countries. NBAC also investigates how and to what extent cultural and other factors influence these issues, analyzes national and international guidelines and statements, and makes recommendations about ways to enhance multinational collaborative research.

NBAC recommends: (1) limiting clinical trails in developing countries to those that are responsive to the health needs of the host country; (2) designing trials that provide the control group with an established, effective treatment; (3) involving community representatives in trial design and implementation of research; and (4) arranging to make successful interventions available to participants at the conclusion of trials. In addition, NBAC includes recommendations about voluntary informed consent.

3. *Id.* at provision 29.

4. Liz McMillen, *A World Medical Group Opposes Use of Placebos in Drug Experiments*, THE CHRONICLE OF HIGHER EDUC., Oct. 9, 2000.

5. David Brown, *Medical Research Group Revises Guidelines on Placebos*, WASH. POST, Oct. 8, 2000, at A2.

6. For a more detailed analysis of the revisions, see Forster et al., *The 2000 Revision of the Declaration of Helsinki: A Step Forward or More Confusion?* (on file with author).

7. NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH (2000), *available at* http://bioethics.gov/toc.html. A copy may also be obtained by calling (301) 402-4242.

8. NATIONAL BIOETHICS ADVISORY COMMISSION, DRAFT REPORT: ETHICAL AND POLICY ISSUES IN INTERNATIONAL RESEARCH PUBLIC COMMENT, *available at* http://bioethics.gov/report.html.

II. Complementary and Alternative Medicine[9]

A. United States

By Executive Order 13,147 issued on March 7, 2000, President Clinton authorized the establishment of the White House Commission on Complementary and Alternative Medicine Policy.[10] The Commission is to report on legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine. In particular, the Commission is to address education and training, research coordination, information delivery to the general public and the professions, and access and delivery. Proceedings at the Commission can be followed through their website at http://www.whccamp.hhs.gov.

B. France and the United Kingdom

A French national statute[11] permits the practice of *specialites ancienne* described as medicinal plants, whether indigenous or farmed, mixed or not. These may not be sold to the public, except from pharmacies or herb stores (*herbortisteries*). In France there is also national regulation of the profession of the *herboriste*.[12]

The practice of acupuncture, in France and the United Kingdom, is not regulated.[13] In the United Kingdom, chiropractors and osteopaths have been regulated under a regime very similar to the regulation of physicians.[14] In contrast, acupuncturists and homeopaths must comply with local laws that render such practices unlawful if practiced without a premises permit obtained from a local council. If an acupuncturist wanted to set up in London for example, the London Local Authorities Act of 1991 requires a health practitioner to establish that the particular practice specialty has an umbrella organization with a code of conduct, insurance requirements, and disciplinary procedures in order to obtain the permit.[15]

Most countries regulate complementary and alternative medicine practices (CAM) to some extent but space in this publication does not permit further discussion. In addition to existing regulation, along the lines of the White House Commission, the UK Parliament's Select Committee on Science and Technology issued its sixth report[16] on CAM on Novem-

9. For the purpose of Section II, complementary and alternative medicine and traditional medicine are intended to mean the same activities.

10. Exec. Order No. 13,147, 65 Fed. Reg. 13,233 (Mar. 7, 2000).

11. Art. L. 659, C. Santé Publique (1998) (Fr.).

12. *Id.* at n.1.

13. Medicine Act, 1983 (Eng.).

14. Osteopath Act, 1993, c. 21 (Eng.). Earliest complementary modality to be licensed and most widely used in the United Kingdom. Elements copied into Chiropractor Act, 1994 (Eng.), include: registrar of chiropractors, educational committee, standards of proficiency, code of practice, disciplinary procedures, appeals process, indemnity insurance requirements, and provisions that comply with EU rules, such as anti-competition, data protection, and access to personal health information.

15. London Local Authorities Act, 1991, c. xiii (Eng.). It is unlawful to use a premises without a permit from borough council. There are certain exceptions for medical practitioners or members of a body of health practitioners where the body has codes of conduct, insurance requirements, and disciplinary procedures. This rule applies to acupuncturists, massage therapists, and other healers.

16. Select Committee on Science and Technology Sixth Report on Complementary and Alternative Medicine (Nov. 21, 2000), *available at* http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12302.htm.

ber 28, 2000. The report calls for further regulation and research, noting among other items, the need for standardized training and accreditation. The report further notes that acupuncture, herbal medicine, and homeopathy have developed significant evidence to moves towards statutory regulation.

C. The European Economic Commission

The European Economic Community (EEC) began to address the policy and regulatory aspects of CAM much earlier than the United States and the United Kingdom. In 1995, the European Council called for a study on generic medicinal products in the EEC Member States and OECD countries including the United States, Canada, and Japan.[17] In 1996, a report emerged[18] covering diverse subjects such as the environment, marketing, animal testing, genetic experimentation, biotechnology, mergers in the pharmaceutical industry and more topics related to medicinals, including their impact on international trade. The resolution embraces one of the directions established by the World Health Organization (WHO) in its current strategic agenda,[19] which is to look at the links between health and improved economic performance.

The report also urged the establishment of the Traditional Medicines Evaluation Agency with an agenda to assess the worth of phytomedicines, to develop a responsible policy on exports of medicinals, to draft a code of conduct for producers of medicinals for export to the third world, to expend effort towards achieving harmonization of pharmaceutical registration under the framework of international conferences on harmonization (such as the Hague Conference, UNIDROIT, and the UN), and that current intellectual property safeguards be maintained in line with TRIPS.[20]

On the issue of education and training, the EEC has established rules for the recognition of diplomas and professional qualifications when the activity in question is not restricted to a physician.[21] Thus, a CAM practitioner can seek the acceptance of his or her credentials in another state of the EEC based on a set of European-wide set of rules for recognition of an educational background.

D. International Treaties and Non-Governmental Organizations

In the field of health, there are essentially no treaties directly on the subject of health and there are certainly none on the subject of complementary and alternative medicine.

17. Council Resolution of 20 December 1995 on Medicinal Plant Preparations, 95/C 350/05.

18. Resolution on the communication to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community 1996 O.J. (C 141) 63. The Office of the Delegation of the European Economic Commission to the United Nations in New York assisted in this query.

19. World Health Organization Strategic Agenda Statement at the 105th Session of the Executive Board that launched the Commission on Macroeconomics and Health under Dr. Jeffrey Sachs, http://www.who.int/wha-1998/eb105/PDF/ee2.pdf.

20. Trade Related Aspects of Intellectual Property Agreement (TRIPS), Dec. 15, 1993, 33 I.L.M. 81, is one of the agreements of the General Agreement on Tariffs and Trade (GATT), Dec. 15, 1993, 33 I.L.M. 28.

21. Written Question E-2932/98; Council Directive 89/48/EEC of 21 December 1988 on a General System for the Recognition of Higher-education Diplomas Awarded on Completion of Professional Education and Training of at Least Three years' Duration, 1989 O.J. (L019) 16; Council Directive 92/51/EEC of 18 June 1992 on a Second General System for the Recognition of Professional Education and Training to Supplement Directive 89/48/EEC, 1992 O.J. (L209) 25.

Rather, health, and consequently CAM, is treated within a number of other treaties with substantive import on such diverse topics as intellectual property law, the environment, human rights, and biological diversity.

In 1993, the United States joined 158 other countries in signing the UN Convention on Biological Diversity.[22] The Convention seeks to achieve a fair and equitable sharing of the benefits derived from the utilization of genetic resources that include plants and tropicals. These are very much a component of the array of items considered traditional.

Most recently, the United Nations Committee on Economic, Social and Political Rights reaffirmed[23] pursuant to Article 12(1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR),[24] that every human being is entitled to the highest attainable standard of health conducive to living a life in dignity, rather than simply living in the absence of disease or infirmity. In this light, the Committee commented that availability, accessibility, acceptability, and quality were the essential terms to achieve health. Regarding accessibility, the Committee noted the following sub-elements: (1) non-discrimination, physical accessibility or services within safe physical reach of all parts of the population; (2) economic accessibility or affordability with payment to be based on the principle of equity; and (3) information accessibility with its corresponding components of privacy and confidentiality.

E. World Health Organization

The World Health Organization (WHO), through the office of Traditional Medicine, is undertaking a study of all member states to answer the questions that follow on the use of traditional medicine. Traditional medicine is defined by the WHO as the ways of protecting and restoring health that existed before modern medicine, using approaches that belong to the cultural traditions of each country. The term can include acupuncture, traditional birth attendants, mental healers, and herbal medicine. The questions included in the WHO country study are: What is the extent of complementary medicine? What education and training is available? What does the license to practice medicine include? What complementary medicines are covered under public and private insurance?

While the full report is not yet available, a sample report on Belgium[25] demonstrates the information the report will contain and how useful it will be. Assuming the data collected for all countries is of similar quality, the report will be extremely useful to advance international and comparative research in this area.

III. Other Recent Developments in International Health

A. Reproductive Issues

The Japanese Health Ministry's Central Pharmaceutical Affairs Council has recommended that the government permit women to use the birth control pill. Manufacturing,

22. Convention on Biological Diversity, Dec. 29, 1993, *available at* http://www.unep.ch/bio/conv-e.html.

23. 22nd session, April 25-May 12, 2000.

24. *International Covenant on Economic, Social and Cultural Rights*, G.A. Res. 2200A (XXI), U.N. GAOR Supp. No. 16, U.N. Doc. A/6316 (1966). art. 12(1).

25. World Health Organization, Office of Traditional Medicine Draft Document, not available to the public as of the date of this article. The author was given a copy of the section related to Belgium.

importing, and marketing will be conducted by nine specially designated pharmaceutical companies.[26]

B. Genetics

Insurers in Britain can now use the results of genetic tests for Huntington's Disease to refuse insurance coverage or increase premiums for beneficiaries who test positive. This new legislation contravenes the advice of the Human Genetics Advisory Commission. Britain will be the first nation in which insurers can request genetic tests of people with family histories of genetic disorders and demand to see the results of tests people have taken.[27]

Conversely, a recent court case in Hong Kong led to increased protection against genetic discrimination. Three men were discriminated against for having a parent with schizophrenia, which their employers argued put them at increased risk of developing the disease. The judge ruled against the employers and found no threat to safety in the workplace. Incidentally, the men have only a 4 percent chance of developing schizophrenia.[28]

C. Informed Consent

A British court found undergoing surgical sterilization to be in the best interests of a thirty-one-year-old woman with severe learning disabilities, though she was unable to consent to the procedure. Evidence of sexual activity, concern about the risk of pregnancy, and the potential harm of taking a child away from the woman motivated the decision.[29]

A lower court ruling (affirmed by Britain's Court of Appeals) resulted in the surgical separation of conjoined twin girls against their parents' wishes. Physicians contended that both girls would have died without the surgery, but with the surgery the stronger twin would have an increased chance of survival. The weaker twin passed away after the operation and though the stronger twin faces many more surgeries, she is expected to lead a relatively normal life.[30]

Over fifty South African physicians have been accused of testing people for HIV without their consent at the request of their employer. The University of Witwatersrand AIDS Law Project has brought suit on behalf of the people tested against the Health Practitioners Association of South Africa. No one who was tested was offered counseling regarding the results and the people who tested positive may be in danger of losing their jobs.[31]

D. Intellectual Property Rights

A bureaucratic error led to the University of Edinburgh being granted a patent that covers techniques of preparing transgenic humans. The European Patent Office issued a patent

26. Associated Press, *Japan: Pill Makers Approved*, N.Y. Times, June 17, 1999.

27. *See* Roger Highfield, *Insurers get approval to use genetic tests*, Daily Telegraph (U.K.), Oct. 13, 2000, *available at* http://www.telegraph.co.uk.

28. *See* Robin McKie, *China is Thwarted by Jobs Ruling*, Guardian (UK), Oct. 1, 2000, *available at* http://www.guardian.co.uk/Archive/Article/0,4273,4070400,00.html.

29. *In Re* X, 2 F.L.R. 1124 (Fam. 1998), *available at* 1998 WL 1042916.

30. *See* Russell Jenkins, *Siamese Twin Jodie is Bright and Flourishing*, Times (London) Dec. 16, 2000, *at* http://www.thetimes.co.uk/article/0,,2-52463,00.html; T.R. Reid, *Life for One Twin, or Death for Both?* Wash. Post, Sept. 7, 2000, at A1.

31. *See Secret HIV Tests Alleged in S. Africa*, A.P., Aug. 26, 2000.

for, among other things, a procedure to create a "transgenic animal" from purified stem cells. As critics have noted, humans are animals, so this patent violates European guidelines that prohibit the patenting of methods of genetic manipulation in humans. In February 2000, a rally was held in Munich to protest the granting of this patent. Though the error has been officially admitted, there are administrative barriers that will prolong the resolution of the mishap.[32]

E. Global Inequities

Two recent studies have shown that the cost of prescription drugs in Africa is much higher than in the developed world. A drug that prevents transmission of HIV from a pregnant woman to her fetus, Nevirapine, costs $874 in Kenya, almost twice what it costs in Norway. Measuring the relative cost of medicine in terms of hourly wages, a resident of Tanzania would have to work 500 hours to afford a tuberculosis treatment while someone in Switzerland would have to work for an hour to purchase the same treatment.[33]

F. End of Life

After British clinicians decided to withdraw care from David Glass, a severely disabled twelve-year-old, his mother brought suit to ensure he would continue to be treated. The High Court of Britain cited the difficulty of decision-making in life and death situations and deferred to the judgment of the clinicians to let David die peacefully.[34]

The Dutch lower house of Parliament passed a bill that legalizes physician-assisted suicide. Though the bill has yet to be reviewed by the upper chamber, approval is viewed as a mere formality. Euthanasia is a crime in the Netherlands, but in 1993, Parliament approved guidelines for the practice of euthanasia that physicians could follow without fear of prosecution (such as first determining that the patient's suffering is "unbearable"). The new bill would reverse the presumption that currently exists—physicians who euthanize patients will no longer be committing a crime for which they may be exempt from prosecution. Instead, euthanasia that is consistent with the guidelines will be a legal act. When there is doubt that the guidelines have been followed, a physician's actions would be examined by a regional review committee composed of doctors.[35]

G. Sexuality

Among the most important of international legal issues is, of course, human rights. These rights include protecting persons not only from discrimination because of race, religion, and gender, but discrimination based on sexual preference, as well. Furthering rights in this area will be an important task in the United States and throughout the world in the decades to come. The court case described here concerns persons whose rights have just, however, begun to be addressed: persons who are transsexual. In this country, there have been just a few such cases, and only a handful of foreign countries have even considered this issue.

32. *See* Michael Hagmann, *Protest Leads Europeans to Confess Patent Error*, 287 Sci. 1567 (2000).

33. Donald G. McNeil, Jr., *Prices for Medicine Are Exorbitant in Africa, Study Says*, N.Y. Times, June 17, 2000.

34. *See* Ian Murray, *A Gray Legal Area*, Times (London), Apr. 22–23, 1999.

35. *See* Keith B. Richburg, *Netherlands Moves to Legalize Assisted Suicide*, Wash. Post, Nov. 29, 2000, at A32.

A few introductory comments about persons who are transsexual are in order. Transsexual persons are those who for some reason or experience themselves as being in "the wrong body" or as being of the "wrong" sex. Their emotional pain often exists from early infancy and is, all too frequently, excruciating. They usually keep these painful feelings "in the closet" during their youth and, unless they are fortunate enough to be able to obtain medical help, as some can in this country, they may stay in this closet throughout their lifetime. Those who can pursue a change in their body to "become a person of the opposite sex" do this through surgery and taking hormones. They also receive counseling.

Yet, there are often large gaps in their acquiring these medical interventions. Their lives during these gaps, again, can be excruciating. They may, for example, receive hormone treatments initially but, then, have to wait several more years to acquire the funds to undergo surgery. And in some cases, the success of these interventions remains inherently, irreversibly limited. Men who have reached maturity may, for example, already have experienced a deepening in their voice brought about by male hormones that have changed their larynx. As a result, their voices may never become softer or higher, even as a result of surgical intervention and hormones. Consequently, though they can appear female in other respects, they may not to the extent that they retain a deeper voice.

In light of a transexual's needs and situation, an appellate case of first impression recently decided in the United States is highly significant. In *Littonton v. Prange*,[36] a transsexual woman who had been born a man sued a doctor as a "surviving spouse." This court's summary statement of the question before it was on point: "The deeper philosophic (and now legal) question is: can a physical change the gender of a person with a scalpel, drugs and counseling, or is a person's gender immutably fixed by our Creator at birth."[37]

The Plaintiff had been born with normal male genitalia but from the age of three or four years old she felt, inside, "like a girl." After years of difficulties such as feeling embarrassed changing in front of boys, she underwent hormonal treatments, sexual reassignment surgery, and psychiatric counseling. Her doctors testified that psychologically she was a female "before and after" surgery and that she "functioned" sexually after surgery "as a female."[38]

She married a man in 1989 who died in 1996. She subsequently filed a medical malpractice suit as her husband's surviving spouse under the Texas Wrongful Death and Survival Statute. The doctor defended by challenging her claim as a wrongful death beneficiary, asserting she was a man.

The trial court agreed with the doctor on the basis that despite her and her husband having had a ceremonial marriage, Texas statutory law did not permit marriage between persons of the same sex. The Texas Court of Appeals, believed, however, that statutory law did not resolve this question. Rather the question they believed critical was "Is Christie a man or a woman?"[39]

The court recited the relevant history of law regarding transsexual persons. In the first such case, an English court decided that, legally, gender was determined at birth.[40] The

36. Littleton v. Prange, 9 S.W.3d 223 (Tex. App. 1999).
37. *Id.* at 223.
38. *Id.* at 224.
39. *Id.*
40. Corbett v. Corbett, 2 All E.R. 33 (1970), *available in* 1970 WL 29661.

court also cited an unreported New Zealand case in which, unlike the case in England, the court ruled "for the transsexual" because "the alternative would be more disturbing."[41]

The court also discussed the only U.S. case that had gone the other way.[42] The trial court's opinion in this case is remarkable: "[I]f the psychological choice . . . is . . . not a mere whim, and irreversible sex reassignment surgery has been performed, society has no right to prohibit the transsexual for leading a normal life. Are we to look upon this person as an exhibit in a circus sideshow?"[43] The appellate court affirmed this lower court's ruling, stating that it perceived "no legal barrier, cognizable social taboo, or reason grounded in public policy" to rule otherwise.[44]

The appellate court in the Littleton case concluded that although Christie had made "every conceivable effort to make herself a female, . . . [t]here are some things we cannot will into being. They just are."[45] Thus, Christie was deemed a male, as a matter of law.

41. *Id.* at 229 (citing Mary Coombs, *Sexual Dis-Orientation: Transgendered People and Same-sex marriage*, 8 U.C.L.A. WOMEN'S L.J. 219, 250 n.137 (1998).

42. *See* M.T. v. J.T., 140 N.J. Super. 77, 355 A.2d 204 (1976).

43. *Id.* at 207.

44. *Id.* at 210–11.

45. *Littleton*, 9 S.W.3d at 230–31.