

# International Health Law

JILL D. RHODES, EDMUND G. HOWE, MARK E. WOJCIC, JULIE GREENBERG,  
AND EZIO E. BORCHINI\*

## I. Update from the ABA Subcommittee on Biological Terrorism

After the anthrax attacks in 2001, when five people died and many others became ill, the United States started taking a closer look at biological terrorism and the possibilities of an attack. While biological terrorism had been on the radar screen of many U.S. government leaders, the general population remained oblivious to the dangers and possibilities.

In 2000, the Department of Defense brought together top level officials to conduct a mock exercise specifically related to a biological release in Denver. In this exercise, called TOPOFF, there was a hypothetical release of the plague in the Denver Performing Arts Center. By the time the release was discovered, people in the contaminated theatre had traveled as far as Japan, thereby producing an international crisis. The United States was not prepared to respond, and, in the end, the exercise was halted due to this overall lack of

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\*Jill D. Rhodes, author of Section I, Update from the Subcommittee on Biological Terrorism, is the Co-Chair of the ABA International Health Law Section Subcommittee on Bioterrorism. She has worked on National Security Issues for the last several years. Prior to this, Ms. Rhodes worked in International Democratic Development as a foreign service officer with the U.S. Agency for International Development. She is currently a Senior Advisor for Homeland Security Programs with SRA International. Edmund G. Howe III, M.D., J.D., author of Section II, Legal Developments related to (A) human cloning; (B) the rights of unborn children and of parents to sue when children are born with medical problems; and (C) physician assisted suicide, is Co-Chair of the International Health Law Committee of the ABA Section of International Law and Practice, and is currently Professor of Psychiatry, and Director, Ethical, Legal, and Social Issues in Medicine at USUHS. Mark E. Wojcik, author of Section III, Legal Issues Related to HIV and AIDS, is an Associate Professor of Law at The John Marshall Law School in Chicago. Professor Wojcik is also a Vice-Chair of the International Health Law Committee and Co-Chair of the International Human Rights Committee of the ABA Section of International Law and Practice. Julie Greenberg, author of Section IV, Informed Consent for Surgery on Intersex Children in Colombia, is the current Chair of the ABA Subcommittee on International Issues Relating to Gender, Sex, and Sexual Orientation, and a member of the Board of Directors of the Harry Benjamin International Dysphoria Association Legal Committee. Professor Greenberg writes, lectures, and teaches in areas related to gender and sexuality; she has taught at Thomas Jefferson School of Law since 1990 and is the Associate Dean of Faculty Development at the school. Jill D. Rhodes and Ezio E. Borchini, a Vice-Chair of the International Health Law Committee, edited this article.

preparedness. Estimates ranged from 3,700 sick people to more than 4,000 and between 950 and 2,000 dead.

In 2002, the ABA Subcommittee on Biological Terrorism combined efforts with members of the medical community to begin looking at the legal implications of biological terrorism. The subcommittee was initiated in April 2002 when Ezio Borchini, J.D., LL.M., and Dave Benedek, M.D., convened a meeting to bring together interested attorneys, physicians, and others to determine areas of potential intersection between the law, lawyers, and bioterrorism. The purpose of the meeting was to determine what role, if any, an ABA Subcommittee composed of interested lawyers and others could play in approaching these issues.

The initial meeting included presentations by a panel of speakers and the opportunity for questions and discussion. Speaker Aileen Marty, M.D., is a clinical expert in emerging infections and pathology, and teaches "Scientific, Domestic and International Policy Challenges of Weapons of Mass Destruction and Terror" at the Uniformed Services University of the Health Sciences. She discussed policy challenges facing the nation regarding bioterrorism. Coleen E. Klasmeier, Esq., an FDA lawyer and formerly an attorney with Covington & Burling, addressed the food security and other provisions of pending legislation<sup>1</sup> and provisions in the law that expressly or reasonably could be interpreted to address bioterrorism preparedness and response (e.g., selected Public Health Service Act provisions, the Federal Anti-Tampering Act and the Model State Health Emergency Powers Act). Jay Winchester, Esq., Senior Counsel at Ft. Detrick, discussed mechanisms for a long-term research and development of a military medical response to bioterrorism. Michael Scardaville, a policy analyst at the Heritage Foundation Kathryn and Shelby Cullom Davis Institute for International Studies, summarized recent Heritage Foundation reports related to the response to bioterrorism.

The first meeting of the ABA Subcommittee on Biological Terrorism developed significant interest in and led to the successful creation of a group focused on legal-related biological terrorism issues. After the initial meeting, Jill Rhodes and others formed a group of legal and medical experts to begin to develop a model that balances individual rights and state action before, during, and after a biological incident. This model was initially presented in August at the ABA Annual Meeting in Washington, D.C. Due to the lack of jurisprudence in this area, it is hoped that, as this model continues to develop, it will present a framework that may be used by lawyers and judges as cases arise.

There are many issues and facets of law that could be implicated as a result of a biological incident. A few of the most basic questions include:

- When can quarantine take place and who can authorize this?
- If someone breaks the quarantine, is there a right to use deadly force?
- At what point do citizens have a right to know about the detection of biological agents in the air?
- How much information can the government collect and disseminate about a patient without violating privacy rights?
- Can the government mandate vaccinations?
- In what order of priority does the government choose whom to vaccinate?

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1. Public Health Security and Bioterrorism Response Act of 2002, H.R. 3448, 107th Congress (2002) (incorporating S. 1765).

- If there is an incident, and there are not sufficient hospital beds for patients, can the government take a hotel and use this hotel as a hospital?

During this coming year, the committee will continue to look at these and many other issues. Members are also working with the University of the Pacific McGeorge School of Law to develop law school teaching materials focusing on these issues.

## II. Legal Developments related to: (A) human cloning; (B) the rights of unborn children and of parents to sue when children are born with medical problems; and (C) physician assisted suicide

Three areas addressed in the law over the past year were the legality of human cloning, the rights of unborn children and of parents to sue when children are born with problems, and physician assisted suicide.

### A. HUMAN CLONING

A major concern addressed in several countries over the past year was the legality of human cloning. This concern has come about largely because of new scientific developments that have made human cloning increasingly possible.

This increased possibility became known internationally when Dr. Severino Antinori, an Italian doctor, announced that he planned to carry out cloning in Britain. This decision followed a legal ruling in the United Kingdom that did not classify an organism obtained through cloning as an embryo. The British Parliament responded promptly by passing emergency legislation banning human reproductive cloning.<sup>2</sup> A committee of the United Kingdom House of Lords subsequently decided to allow research using human embryo clones, but only when it could be demonstrated that there was a need for these embryos that could not be met by in-vitro fertilization.<sup>3</sup>

A committee of the United Nations General Assembly concurrently proposed an international resolution to ban human cloning. This resolution was introduced by France and Germany.<sup>4</sup> The French Parliament approved a law that would ban human cloning altogether, but would permit embryo research.<sup>5</sup> German lawmakers allowed research to continue on 40,000 existing embryos, but forbade the importation of embryonic stem cells for the purpose of research.<sup>6</sup>

In Canada, regulations were proposed that would allow research using stem cells, but forbid the cloning of embryos for research purposes alone. The Canadian government later prohibited human cloning altogether.<sup>7</sup>

2. G. Hurst, *MPs Pass Bill to Ban Cloning*, *TIMES* (London), Nov. 30, 2001.

3. The House of Lords, *Stem Cell Research Report* (Feb. 27, 2002), available at <http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm>.

4. Press Release GA/9998, United Nations, *Assembly Backs Effort towards Global Law Against Reproductive Cloning of Human Beings, Study Group to Be Established* (Dec. 12, 2001), available at <http://www.un.org/news/press/docs/2001/ga9998.doc.htm>.

5. Reuters, *French Bioethics Law Passes First Reading* (Jan. 22, 2002), available at <http://www.multiple-sclerosis.org/news/Jan2002/FranceESCEthicsLaw.html>.

6. Carol J. Williams, *Lawmakers Ban Stem Cell Imports in German Vote*, *L.A. TIMES*, Jan. 31, 2002, at 3.

7. Editorial, *Reforming Health Care*, *BANGOR DAILY NEWS*, Apr. 25, 2002, at A10.

Legal developments remain controversial in this area because, while there are immense medical gains that can be made from cloning human cells, allowing cloning in any context raises the fear that this could result in cloning of human beings, which to many people is considered unconscionable. Further, while the line can be drawn legally at cloning for other purposes only, embryonic cells already existing may become less effective and are in extremely short supply.

#### B. THE RIGHTS OF UNBORN CHILDREN AND OF PARENTS TO SUE WHEN CHILDREN ARE BORN WITH MEDICAL PROBLEMS

A second area, not wholly unrelated to human cloning, in which there is much ongoing international legal activity, is the rights of unborn children and of parents to sue when children are born with problems. In the United Kingdom, a mother successfully sued for over a million pounds when one of the four children she delivered died and the other three survived with serious problems. She had been given hormones to stimulate her production of eggs and sued on the ground that she had not been offered ultrasound to determine the number of eggs which had been fertilized. Thus, she was not given the opportunity to reduce the number of fetuses. If this had been done, it would have resulted in her carrying fewer fetuses, such as twins, which, most likely, would have done well.<sup>8</sup>

This area remains controversial, in part, because the use of hormones to enhance reproduction not only brings about fetal lives, but also leads to ending the lives of successfully implanted fetuses when there are "too many." This latter procedure is referred to as "selective termination," which some view as the equivalent of an abortion. If fewer fetuses are present they are much more likely to do well, but as the number increases, the risk of fetal death or birth defects also increases. Some argue, therefore, that the use of hormones and the right to selective termination should be paired. This was not, of course, done in this case.

In another United Kingdom case a sterilization procedure failed on a woman who was nearly blind and she gave birth to a healthy baby. She sued on the ground of wrongful birth. The court, noting that this was the first case involving a claim being made by a disabled parent raising a healthy child, awarded money to pay for this disabled mother bringing up her child. The court reasoned that although it is usually presumed that a child will be a benefit, since the mother in this case had requested sterilization, the opposite conclusion is warranted, and that holding the surgeon responsible is not unreasonable.<sup>9</sup>

In France, on the other hand, legislators adopted a bill prohibiting actions for damages based solely on a child being born. This legislation followed a high court ruling granting a mother monetary compensation after she was mistakenly exposed to German measles during pregnancy. The legislation also was spurred by French obstetricians and gynecologists who were collectively starting to refuse to perform ultrasonography on pregnant women because they feared they would be sued if the women's babies were born with medical problems.<sup>10</sup>

8. Richard Alleyne, *£1m for Family Blighted by Fertility Treatment* (Nov. 13, 2001), available at <http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2001/11/13/nquad13.xml>.

9. Frances Gibb, *Payout Victory for Blind Woman Who Did Not Want Baby*, *TIMES* (London), Feb. 15, 2002.

10. Suzanne Daley, *France Bans Damages for 'Wrongful Births'*, *N.Y. TIMES*, Jan. 11, 2002.

In Canada, the Supreme Court allowed parents to recover when an obstetrician failed to inform them that the mother could abort a fetus who had Down's syndrome. The court awarded damages to provide for the expenses of the child until he reached age 19. This was based on the assumption that at that time he could live in a publicly funded home.<sup>11</sup>

It is generally held by U.S. courts that a life with medical problems is better than no life at all, and thus, awards on the basis that a mother would have had an abortion are not allowed. The disparity among different Western countries speaks to an absence of shared underlying value assumptions regarding an infant's life with and without serious birth defects. This highlights the question as to whether shared assumptions in this area will be made in the future.

### C. PHYSICIAN ASSISTED SUICIDE

Physician assisted suicide is a question confronting other countries as well as this one. In Australia, a doctor was acquitted after intentionally hastening a patient's death.<sup>12</sup> A study subsequently showed that a third of the general surgeons surveyed engage in this same practice, some even in the absence of patients making an explicit request.<sup>13</sup> Thus, this case and report have generated considerable debate.

In the few countries that have permitted physician assisted suicide, the patient's request has to be explicit and repeated over time. A potential problem with this requirement, however, is that it treats patients unequally if their mental functioning is impaired. Patients with early dementia, for example, may be unable to make this request. Whether physician assisted suicide becomes legally permissible for patients who are mentally impaired in Australia and other countries remains to be seen.

## III. Legal Issues Related to HIV and AIDS

### A. GLOBAL IMPACT

More than five million persons are believed to have been newly infected with HIV in 2002, and more than three million persons lost their lives to AIDS.<sup>14</sup> As the AIDS pandemic enters its third decade, it is estimated that more than forty-two million people are now living with HIV, including 19.2 million women and 3.2 million children under the age of fifteen.<sup>15</sup> In another sign of the global crisis, India is poised to overtake South Africa as the nation with the most reported number of HIV cases.<sup>16</sup>

HIV continues to deprive countries of the "resources and capacities on which human security and development depend."<sup>17</sup> Men, women, and children around the world face ever-increasing threats from HIV.<sup>18</sup> But many governments still lack the will and resources

11. *Krangle v. Brisco*, [2002] S.C. 9.

12. John Shaw, *Australian Doctors Admit Helping Patients Die*, N.Y. TIMES, Dec. 3, 2001, at A10.

13. Charles D. Douglas et al., *The Intention to Hasten Death: A Survey of Attitudes and Practices of Surgeons in Australia*, 2001 MED. J. OF AUSTRALIA 175, 511-15. Some of this review relied on *Legal Trends in Bioethics*, a quarterly piece written by Anne L. Flamm for *The Journal of Clinical Ethics*.

14. UNAIDS, AIDS EPIDEMIC UPDATE 3 (2002), available at [www.unaids.org](http://www.unaids.org).

15. *Id.*

16. *In Brief: International*, 17 AIDS POL'Y & L. 12 (May 24, 2002).

17. *UNAIDS Indicates Progress on Global HIV/AIDS Status in 2002*, 17 AIDS POL'Y & L. 5 (Dec. 20, 2002).

18. See, e.g., UNICEF, THE STATE OF THE WORLD'S CHILDREN 2003, at 112-13 (2003); UNICEF Report: *HIV/AIDS an Increasing Threat to World's Children*, 18 AIDS POL'Y & L. 5 (Jan. 17, 2003); *Crisis Approaching*

to prevent further infections and to provide treatment for those living with the disease.<sup>19</sup> These costs are not insubstantial; the annual global cost of treating and containing HIV may reach \$10.5 billion by 2005.<sup>20</sup> It is also estimated that more than sixty-eight million people may die of AIDS in the next two decades without vast intervention efforts.<sup>21</sup>

## B. DRUG ACCESS

Persons living with HIV continue to press legal claims for access to drugs. Legal claims, in Colombia, jumped by 400 percent over the last two years, due to citizens demands that the social security system provide free access to pharmaceutical drugs and viral testing.<sup>22</sup> The Constitutional Court of South Africa ruled that under the South African Constitution, the government must provide certain AIDS drugs to pregnant women, and that it must "within its available resources" provide a program to protect "the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV."<sup>23</sup>

Some pharmaceutical companies are making cheaper drugs available in developing countries in Africa and other regions of the world, but some of these companies' drug shipments are being diverted to developed nations in Europe and North America.<sup>24</sup>

Pharmaceutical companies have eighty-three new treatments in various stages of production, including fourteen new vaccines and thirty-three antiretroviral drugs.<sup>25</sup> At least one vaccine developer, however, has warned of possible bankruptcy.<sup>26</sup> The Supreme Court

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*From Orphans Created by HIV*, 17 AIDS Pol'y & L. 5 (Aug. 2, 2002); *AIDS Undermines International Education, Says World Bank*, 17 AIDS Pol'y & L. 1 (May 24, 2002); *UNAIDS Urges More Effort to Fight AIDS Among Children*, 17 AIDS Pol'y & L. 7 (May 24, 2002).

19. See, e.g., *Report: Most Nations Still Lack Necessary Will to Fight AIDS*, 17 AIDS Pol'y & L. 2 (Oct. 25, 2002); *World Leaders Square Off on HIV/AIDS Policies at Summit*, 17 AIDS Pol'y & L. 2 (Sept. 27, 2002); *U.N. Says World Leaders Too Slow in Fighting AIDS, Poverty*, 17 AIDS Pol'y & L. 2 (Sept. 13, 2002). There are important exceptions that show some governments do have a willingness to fight AIDS. See, e.g., *Brazil Shares Blueprint of Successful Battle Against HIV/AIDS*, 17 AIDS Pol'y & L. 7 (Aug. 30, 2002); *AIDS Infection Rate Falls Among Brazil's Injection Drug Users*, 17 AIDS Pol'y & L. 6 (June 7, 2002). And in an important early development of 2003, U.S. President George W. Bush surprised many with his call for the U.S. Congress "to commit \$15 billion over the next five years, including nearly \$10 billion in new money, to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean." *President's State of the Union Message to Congress and the Nation*, N.Y. TIMES, Jan. 29, 2003, at A12; Sheryl Gay Stolberg & Richard W. Stevenson, *Bush AIDS Plan Surprises Many, but Advisers Call It Long Planned*, N.Y. TIMES, Jan. 30, 2003, at A1. During 2002, the Bush administration decided it would not pay \$34 million it had set aside for the U.N. family planning programs that serve poor women overseas. See *U.S. to Withhold \$34 Million in Funds for U.N. AIDS, Population Control*, 17 AIDS Pol'y & L. 5 (Aug. 16, 2002).

20. *In Brief: International*, 17 AIDS Pol'y & L. 12 (Oct. 25, 2002); see also *HIV/AIDS a Global Economic Threat, UN Official Warns*, 17 AIDS Pol'y & L. 9 (May 24, 2002).

21. *UN Says AIDS Fight Has Barely Begun, Amplifies Efforts to Push Testing*, 17 AIDS Pol'y & L. 1 (July 19, 2002).

22. *Claims for HIV/AIDS Treatment in Colombia Jump by More than 400 Percent*, 18 AIDS Pol'y & L. 8 (Jan. 17, 2003).

23. *Minister of Health v. Treatment Action Campaign*, 2002 10 BCLR 1033 (CC). In another development, activists in South Africa gave the government a four-month ultimatum to provide drugs or face a civil disobedience campaign. *Activists Give South African Government AIDS Plan Ultimatum*, 17 AIDS Pol'y & L. 5 (Nov. 22, 2002). See also *South African Foreign Minister Defends AIDS Policies*, 17 AIDS Pol'y & L. 3 (Sept. 13, 2002).

24. See, e.g., *Europeans Investigate Resale of AIDS Drugs*, 17 AIDS Pol'y & L. 2 (Nov. 22, 2002).

25. See, e.g., *Treatment*, 17 AIDS Pol'y & L. 10 (Dec. 20, 2002).

26. *HIV Vaccine Development Company Faces Bankruptcy*, 17 AIDS Pol'y & L. 8 (Dec. 20, 2002).

of Canada upheld the Canadian patent on AZT held by Glaxo Wellcome.<sup>27</sup> And in Thailand, production began on a treatment that combines three separate antiretroviral drugs into a single pill.<sup>28</sup>

At the end of 2002, the United States reportedly thwarted World Trade Organization negotiations that would have increased access by poor countries to inexpensive pharmaceutical drugs.<sup>29</sup>

### C. TESTING AND TREATMENT

The Food and Drug Administration reportedly approved a twenty-minute test for HIV-1 using fingertip blood samples.<sup>30</sup> Positive tests must be confirmed by further screening tests.<sup>31</sup> The development of tests, which initially take less time, have benefits in hospitals and other health care settings, but they are subject to abuse if used in inappropriate contexts and without confirmatory tests.

The World Health Organization announced a new set of treatment guidelines for fighting AIDS in poor areas, adding antiretroviral drugs to its Essential Medicines List.<sup>32</sup> The Centers for Disease Control and Prevention recommended that sexually active men who have sex with other men be tested annually for HIV and other sexually transmitted diseases.<sup>33</sup>

### D. SUMMARY

There is no solution in sight for the AIDS pandemic. Further attention and commitment is needed around the world to halt the further spread of the disease and to care for those who are affected by it, whether directly or indirectly. Lawyers and advocates for human rights will continue to have a necessary role in providing the human rights framework that must accompany any solution.<sup>34</sup>

## IV. Informed Consent for Surgery on Intersex Children in Colombia

The Constitutional Court of Colombia issued two opinions that dramatically alter informed consent practices in Colombia in cases involving surgical genital alteration. These decisions impose significant restrictions on a doctor's ability to perform such surgeries on intersex children and on parents' ability to consent to such surgery. Specifically, the court created a new standard for informed consent that requires "qualified, persistent informed consent."<sup>35</sup>

27. *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] S.C.R. 77.

28. *Thailand Markets Low-Cost, 3-in-1 Antiretroviral Medication*, 17 AIDS POL'Y & L. 8 (Apr. 26, 2002).

29. *U.S. is Lone Holdout on Drug Access Vote*, 18 AIDS POL'Y & L. 1 (Jan. 17, 2003).

30. *See Approval of a New Rapid Test for HIV Antibody*, 51 MORBIDITY & MORTALITY WEEKLY REP. 1051 (Nov. 22, 2002).

31. *FDA Approves New Rapid HIV Test*, 17 AIDS POL'Y & L. 1 (Nov. 22, 2002).

32. *WHO Issues Treatment Guidelines for HIV/AIDS*, 17 AIDS POL'Y & L. 1 (May 10, 2002).

33. *Sexually Transmitted Diseases—Treatment Guidelines 2002*, 51 MORBIDITY & MORTALITY WEEKLY REP., at 7–10 (May 10, 2002); *see also CDC Suggests Annual HIV Tests for Gay, Bisexual Men*, 17 AIDS POL'Y & L. 2 (May 24, 2002).

34. *See, e.g., U.N. Entrenches Human Rights Principles in AIDS Guidelines*, 17 AIDS POL'Y & L. 2 (Oct. 11, 2002).

35. Julie A. Greenberg & Cheryl Chase, *Colombia High Court Limits Surgery on Intersexed Infants*, Intersex Society of North America, at <http://www.isna.org/colombia/background.html> (last visited May 15, 2003).

Although infant surgical alteration has been the international norm for over forty years, the court acknowledged that parental consent to such procedures under current international practices does not protect the child's fundamental human rights. The court ruled that intersex people constitute a minority group entitled to state protection from discriminatory practices even though the intersex child's parents are consenting to the treatment.<sup>36</sup>

The court balanced the state's interest in protecting children with the parents' interest in preserving family privacy and autonomy. Although the court agreed that parents typically should determine whether a particular medical procedure is in their children's best interests, the court believed that parents of intersex infants are likely to make decisions based upon their own concerns rather than what is best for their children.<sup>37</sup>

The court ruled that the state must impose limitations on a parent's ability to consent to genital modification surgery on their children. Specifically, the court held that: (1) before consenting, parents must be given accurate information about the risks of such procedures and the existence of treatment paradigms other than early surgery; (2) the consent must be in writing; and (3) the consent must be given on more than one occasion over an extended time period.<sup>38</sup> Finally, the court held that parents cannot consent to such surgery for children over five years old because by the time children reach this age they have achieved an autonomy that must be protected.<sup>39</sup>

This decision is groundbreaking because it is the only high court decision in the world that calls into question international medical practices that have been well accepted for over forty years. The Colombia Constitutional Court has thus progressed farther than courts in any other country in protecting the basic rights of intersex infants.

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36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*