

# International Health Law

JONATHAN TODRES, LAUREL R. HYLE AND ELIZABETH SEPPER\*

## I. Introduction

In 2006, a number of important international health law issues continued to attract significant attention worldwide, including the threat of public health emergencies, HIV/AIDS, intellectual property issues, biomedical science developments, bioterrorism, and health and human rights concerns. At the same time, newly emerging public health concerns, such as obesity, found their way on to the agendas of governments and international organizations. These developments confirm the growing impact of public health issues in the international arena. In turn, international and regional efforts to respond to public health issues increased, reflecting recognition of the need for coordinated multilateral responses in this field.

## II. Public Health Emergencies, Infectious Diseases, and Immunization Programs

Infectious diseases and the threat of a global pandemic continue to concern public health officials throughout the world. Avian influenza remains a risk, but it is not the only disease that presents a threat.<sup>1</sup> The 2005 revision of the International Health Regulations

---

\* Jonathan Todres is an Acting Assistant Professor at New York University School of Law and Chair of the International Health Law Committee of the ABA Section of International Law. Laurel R. Hyle is an Associate Legal Officer at The University of Texas M. D. Anderson Cancer Center and a Vice Chair of the International Health Law Committee. Elizabeth Sepper is an Institute for International Law and Justice Scholar and LLM candidate in International Legal Studies at New York University School of Law. This article covers events and developments that occurred from January 1, 2006, to December 1, 2006. As in prior years, space limitations for this article do not allow for a discussion of all of the important developments in the field of international health law. The omission of an area of international health law or a particular development should not be construed as suggesting that such issue is not important.

1. See World Health Org., Epidemic and Pandemic Alert and Response (EPR), Avian Influenza—Situation in Indonesia—Update 37, Nov. 13, 2006, [http://www.who.int/csr/don/2006\\_11\\_13/en/index.html](http://www.who.int/csr/don/2006_11_13/en/index.html) (reporting two additional cases of human infection with the H5N1 avian influenza virus, bringing the total number of confirmed cases in Indonesia to seventy-four, fifty-six of which have been fatal); World Health Org., Epidemic and Pandemic Alert and Response (EPR), Disease Outbreaks by Year, <http://www.who.int/csr/don/archive/year/2006/en/index.html> (last visited Nov. 26, 2006) (reporting on such disease outbreaks as meningococcal disease in Sudan and suspected plague outbreak in the Democratic Republic of Congo).

(IHR)<sup>2</sup> marked a milestone achievement in developing an effective response to public health risks and emergencies.<sup>3</sup> The revision significantly broadens the scope of the regulations and requires countries to develop the capacity to detect, evaluate, and report certain public health events in a timely manner as well as respond promptly and effectively to public health risks and emergencies.<sup>4</sup> As the IHR does not enter into force until June 15, 2007, several interim steps were taken in 2006, evidencing agreement that public health preparedness must be accelerated to avert a devastating pandemic from avian influenza or any other disease.

In May 2006, the World Health Assembly adopted a resolution calling for early compliance by World Health Organization (WHO) Member States with the provisions of the IHR relevant to the risk posed by avian influenza and a potential pandemic of human influenza.<sup>5</sup> Provisions relating to "surveillance, reporting, information-sharing, transport of biological substances and public health measures for travelers were identified as important to ensure a strong and coordinated response by the international community to both the present situation and a possible pandemic."<sup>6</sup> Although early compliance is voluntary under the resolution, its adoption reflects the consensus view that health issues must be a top priority for all governments. In adopting the 2006 resolution, WHO Member States affirmed that "[e]ffective and transparent communications are crucial for the early detection and notification of human cases of influenza, rapid risk assessment and the immediate implementation of appropriate containment and response measures should a pandemic strain emerge."<sup>7</sup> The resolution also urges countries to collaborate to ensure adequate vaccine supplies.<sup>8</sup> Another interim step by the WHO was to appoint the WHO Influenza Pandemic Task Force as the entity temporarily responsible for coordinating responses to avian influenza outbreaks until the IHR enter into force.<sup>9</sup>

While avian influenza continues to garner most of the headlines related to public health emergencies, other diseases continue to present challenges for populations around the globe. Although great progress has been made in recent decades in combating infectious diseases, millions of children do not receive immunizations for such basic diseases as measles, diphtheria, tetanus, and pertussis.<sup>10</sup> An estimated three million people die each year from vaccine-preventable diseases.<sup>11</sup> In 2006, international organizations continued to

---

2. See Revision of the International Health Regulations, WHO Doc. A58/55 (May 23, 2005), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA58/A58\\_55-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/A58_55-en.pdf). [hereinafter IHR]. The IHR apply to all 192 WHO Member States.

3. For more on the IHR, see Jonathan Todres et al., *International Health Law*, 40 INT'L LAW. 453, 453-55 (2006).

4. See IHR, *supra* note 2, at arts. 5, 13.

5. See Application of the International Health Regulations (2005), WHO Doc. A59/VR/8 (May 26, 2006), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/WHA59\\_2-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/WHA59_2-en.pdf) [hereinafter IHR Early Compliance Resolution].

6. World Health Org., Epidemic and Pandemic Alert and Response (EPR), Summary Update on the IHR (2005), Sept. 2006, available at <http://www.who.int/csr/ihr/en> (follow "Summary Update on 1 HR (2005)").

7. *Id.*

8. See IHR Early Compliance Resolution, *supra* note 5, ¶ 4(5).

9. See *id.* ¶ 5(4).

10. David E. Bloom et al., *The Value of Vaccination*, 6 WORLD ECON. 15, 15 (July-Sept. 2005).

11. *Id.* at 16.

work with governments to ensure greater commitment to immunization programs.<sup>12</sup> The Global Immunization Vision and Strategy (GIVS) kicked off its first full year in 2006. The program, launched by WHO and UNICEF in late 2005, aims to achieve a 90 percent or greater national vaccination coverage in all countries and a two-thirds reduction in childhood morbidity and mortality due to vaccine-preventable diseases by 2015.<sup>13</sup> GIVS has adopted a four-pronged strategy for achieving these goals that includes: (1) ensuring protection of more people in a rapidly changing world; (2) introducing new vaccines and technologies; (3) integrating immunization, other health interventions, and surveillance in the health systems context; and (4) developing global partnerships to support and finance immunization programs.<sup>14</sup> Ensuring success of these programs will benefit not only the health of individuals but also the economies of developing countries.<sup>15</sup> Overall, the combination of successful immunization programs and effective response mechanisms to disease outbreaks and public health emergencies will benefit all countries in this increasingly interdependent world.

### III. HIV/AIDS

June 2006 marked twenty-five years since the first AIDS case was reported.<sup>16</sup> Many advances have been made in that time, but, as highlighted by the events of 2006, universal access to care and treatment remains an ambitious goal. The number of people living with HIV/AIDS increased in 2006, and currently there are an estimated 39.5 million people living with HIV/AIDS globally.<sup>17</sup> Of this number, approximately two million are children under fifteen years of age.<sup>18</sup> Additionally, there were over four million new HIV infections and almost three million deaths due to AIDS in 2006.<sup>19</sup> Approximately half a million of these new infections and over 300,000 of these deaths occurred in children under fifteen.<sup>20</sup>

While these numbers demonstrate that there is much progress yet to be made, there have been many positive steps forward. Expanded access to antiretroviral treatment is estimated to have resulted in a gain of approximately two million life years in low and

12. See, e.g., Press Release, Pan American Health Organization (PAHO), Health Ministers Approve Rubella Elimination, Increased Vaccination Coverage (Sept. 28, 2006), available at <http://www.paho.org/English/DD/PIN/pr060929.htm> (noting an agreement by health ministers on a new regional strategy to sustain immunization programs in the Americas); PATH, Cambodia Achieves Significant Boost in Immunization, Oct. 16, 2006, available at [http://www.who.int/immunization/newsroom/PR\\_Cambodia\\_16\\_10\\_2006.pdf](http://www.who.int/immunization/newsroom/PR_Cambodia_16_10_2006.pdf) (reporting a dramatic increase in immunizations in Cambodia as a result of a collaborative effort between the government, international organizations, and other entities).

13. WHO & UNICEF, GLOBAL IMMUNIZATION VISION AND STRATEGY 2006-2015 8 (2005), available at [http://www.who.int/vaccines-documents/DocsPDF05/GIVS\\_Final\\_EN.pdf](http://www.who.int/vaccines-documents/DocsPDF05/GIVS_Final_EN.pdf).

14. *Id.* at 7, 12-13

15. See Bloom, *supra* note 10, at 37 (reporting research that finds that “immunization does appear to be an important tool for improving survival and strengthening economies”).

16. See Kaiser Family Foundation, The Global HIV/AIDS Timeline, available at <http://www.kff.org/hiv/aids/timeline/hivtimeline.cfm> (last visited Feb. 15, 2007).

17. See UNAIDS, UNAIDS/WHO AIDS EPIDEMIC UPDATE: DECEMBER 2006 (2006), available at [http://www.unaids.org/en/HIV\\_data/epi2006/default.asp](http://www.unaids.org/en/HIV_data/epi2006/default.asp) (follow “Global Summary of the AIDS Epidemic” hyperlink).

18. See *id.* (follow “Global Summary of the AIDS Epidemic” hyperlink).

19. See *id.* (follow “Maps” hyperlink).

20. See *id.* (follow “Global Summary of the AIDS Epidemic” hyperlink).

middle income countries since 2002.<sup>21</sup> This progress supports the United Nations' endorsed goal of universal access to HIV prevention, care, and treatment by 2010 but also makes it clear that there is much to be accomplished in the next four years if this goal is to be reached.<sup>22</sup>

One significant step toward this goal in the United States was the endorsement of new recommendations by the Centers for Disease Control and Prevention, which support HIV screening as part of routine medical care for persons age thirteen to sixty-four.<sup>23</sup> These recommendations met a mixed response with certain groups, including the American Civil Liberties Union, expressing concern that routine testing might serve a discriminatory purpose.<sup>24</sup> Others, however, supported the new recommendations as a positive step toward decreasing stigma and increasing access to care and treatment.<sup>25</sup>

The past year also welcomed a once-a-day AIDS medication that combines three already existing drugs into one and simplifies a vitally important treatment regimen. The drug, Atripla, was approved by the U.S. Food and Drug Administration (FDA) in July 2006 and was the product of a cooperative effort between drug makers Gilead Sciences, Inc. and Bristol-Myers Squibb Co.<sup>26</sup> While introduction of this drug into the U.S. market represents significant progress, it is hoped that the new drug will also simplify treatment in resource-constrained settings. Toward this end, the FDA approved the drug for overseas patients receiving assistance through the President's Emergency Plan for AIDS Relief (PEPFAR).<sup>27</sup>

The once-a-day AIDS drug to be used in the PEPFAR distribution chain will be manufactured by the Indian generic drug manufacturing company Aurobindo Pharma.<sup>28</sup> This collaboration between the U.S. government and the Indian generic pharmaceutical market is not insignificant given concerns expressed over India's recent restructuring and strengthening of its intellectual property protections and the pressure that the United States has sometimes been thought to exert on developing markets to strengthen patent protection, especially those associated with the production of generic pharmaceuticals.<sup>29</sup>

Private organizations and public-private collaboratives continue to play a vital role in HIV/AIDS funding and access to treatment, as demonstrated by numerous efforts by

21. See *id.* (follow "Introduction" hyperlink).

22. See UNAIDS, SCALING UP ACCESS TO HIV PREVENTION, TREATMENT, CARE AND SUPPORT: THE NEXT STEPS (2006), available at <http://data.unaids.org/Publications> (follow "Publications" hyperlink; then "IRC-pub07"; then "jc1247-univac-the next steps en.pdf").

23. CENTERS FOR DISEASE CONTROL AND PREVENTION, REVISED RECOMMENDATIONS FOR HIV TESTING OF ADULTS, ADOLESCENTS, AND PREGNANT WOMEN IN HEALTH-CARE SETTINGS (2006), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>.

24. See Press Release, Am. Civil Liberties Union, ACLU Says New CDC HIV Testing Recommendations Raise Health and Civil Liberties Concerns (Sept. 21, 2006), available at <http://www.aclu.org/hiv/testing/26819prs20060921.html>.

25. See Donald G. McNeil, Jr., *U.S. Urges H.I.V. Tests for Adults and Teenagers*, N.Y. TIMES, Sept. 22, 2006, at A1.

26. See Marc Kaufman, *FDA Clears Once-a-Day AIDS Drug*, WASH. POST, July 13, 2006, at A1.

27. See Donald G. McNeil, Jr., *F.D.A. Approves New AIDS Pill to Treat People in Poor Countries*, N.Y. TIMES, July 6, 2006, at A7.

28. See *id.*

29. See Int'l Ctr. for Trade and Sustainable Dev., *Indian Parliament Approves Controversial Patent Bill*, BRIDGES, available at <http://www.ictsd.org/weekly/05-03-23/story1.htm>; Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005).

pharmaceutical companies, and non-governmental and other organizations, and highlighted by Warren Buffett's \$31 billion gift to the Bill and Melinda Gates Foundation.<sup>30</sup> Also, increasing focus is being given to the needs of women and children affected by HIV/AIDS, as reflected by both the May 2006 report *Saving Lives: Children's Right to HIV and AIDS Treatment* and efforts by the UNAIDS Global Coalition on Women and AIDS to increase efforts regarding prevention, care, and treatment for women.<sup>31</sup>

#### IV. Trade and Intellectual Property Law

The U.N. Commission on Intellectual Property Rights, Innovation, and Public Health, which collects and analyzes data regarding intellectual property rights and public health, released a major report in April 2006 detailing, among other things, ideas for how best to introduce medicines into developing countries fairly and expeditiously.<sup>32</sup> The report acknowledges the importance of intellectual property rights in stimulating innovation in developed countries but appears to question their value in developing nations.<sup>33</sup>

For example, the report questions the practice of protecting data from clinical trials after the term of a pharmaceutical patent has expired.<sup>34</sup> The Commission points out that this practice could lead to the unnecessary repetition of clinical trials to prove the safety and efficacy of a generic when this information is already available as a result of earlier clinical trials for a bio-equivalent drug in patented form. These unnecessary clinical trials would likely delay access to appropriate pharmaceuticals for patients in developing countries because many patients may only be able to afford much-needed drugs in generic form.<sup>35</sup>

International intellectual property protection continues to be a focus of the United States Trade Representative (USTR), and, in 2006, the USTR cited both Russia and China for lax enforcement of intellectual property rights.<sup>36</sup> For its part, China seems relatively unruffled by potential ramifications and, in response to a U.S. request for additional information regarding Chinese enforcement of intellectual property rights, provided the following statement: "China has noted that Article 63.3 of the TRIPs

30. See Donald G. McNeil, Jr. & Rick Lyman, *Buffett's Billions Will Aid Fight Against Disease*, N.Y. TIMES, June 27, 2006; Nathaniel Lipkus, *How to Understand Product Development: Public-Private Partnerships as Vehicles for Innovation in Combating Neglected Disease*, 10 MICH. ST. U. J. MED. & L. 385 (2006).

31. See THE GLOBAL MOVEMENT FOR CHILDREN, *SAVING LIVES: CHILDREN'S RIGHT TO HIV AND AIDS TREATMENT* (2006) available at [http://unicef.org/aids/files/Saving\\_Lives\\_English\\_final.pdf](http://unicef.org/aids/files/Saving_Lives_English_final.pdf) (comprised of UNICEF, Oxfam, Plan International, Save the Children, World Vision, ENDA Tiers Monde and the Latin American and Caribbean Network for Children); UNAIDS, *Global Coalition on Women and AIDS*, available at <http://www.unaids.org/en/MediaCentre/Newsletter/200601/060122-gcwa.asp> (last visited Feb. 15, 2007); Sharon LaFraniere, *Slowly, Africa Starts to Care for AIDS Children*, N.Y. TIMES, Mar. 8, 2006, available at <http://www.nytimes.com/2006/03/08/international/africa/08lesotho.html?pagewanted=1&ei=5070&en=c0f1962634e79695&ex=1164690000>.

32. See WORLD HEALTH ORG., *PUBLIC HEALTH INNOVATION AND INTELLECTUAL PROPERTY RIGHTS* (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

33. See *id.*

34. See *id.*

35. See *id.* See also R. Levin, *UN Commission on IP Issues Report*, 25 BIOTECHNOLOGY L. REP. 296 (2006) (providing a more detailed review of the Commission's Report).

36. See Christopher S. Rugaber, *USTR Cites Russia, China for IPR Violations, but Avoids Punitive Action*, 72 BNA PAT., TRADEMARK & COPYRIGHT J. 1768, 11 (2006).

Agreement only refers to a member's right to request information, but there is no mention of a corresponding obligation of the requested member to actually follow the request.<sup>37</sup> China, however, demonstrated some concern for intellectual property protection and, following an investigation of numerous web sites, shut down seventy-six that were distributing pirated materials and ordered 137 others to modify the content of their sites.<sup>38</sup> Whether this concern for intellectual property rights will extend beyond efforts to control distribution of pirated materials via the internet remains to be seen.

In addition to restructuring its intellectual property laws in 2005, India adopted new changes in 2006 intended to increase innovation by simplifying the patent application process.<sup>39</sup> Due to the number of recent changes to Indian patent law, it is unclear how courts will construe the new laws and what impact this will have on investors or consumers. For instance, two patients-rights groups brought suit against Gilead Sciences in an Indian court in May 2006 in an attempt to stop Gilead from patenting a generic HIV/AIDS pharmaceutical.<sup>40</sup> Subsequently, Gilead signed licensing agreements with several pharmaceutical companies in India for the manufacture and distribution of the drug at issue.<sup>41</sup>

There is continuing concern in some sectors around the issue of direct-to-consumer importation of Canadian pharmaceuticals into the United States. A recent report by the Fraser Institute found that the annual total value of cross-border internet sales from Canada into the United States is approximately CDN\$507 million (approximately US\$450 million) and that 47 percent of the value of these sales is accounted for by pharmaceuticals not available in generic form in the United States.<sup>42</sup> The report discussed this activity as a likely violation of U.S. patent law, but it is unclear whether or to what extent prosecution is being pursued in these cases.

The European Union and Council of Europe have also expressed concerns regarding online pharmaceutical sales and counterfeit drug sales.<sup>43</sup> Although the line separating public health concerns from financial and intellectual property concerns in the debate over internet sales of drugs remains unclear, both the European Union and the Council of Europe continue to investigate the issue and work toward a more comprehensive legal solution.<sup>44</sup>

37. See Christopher S. Rugaber, *China Resists U.S. Request at WTO For More Information on IPR Enforcement*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 1755, 362 (2006).

38. See Kathleen E. McLaughlin, *Government Shuts Down Web Sites in China That Distributed Pirated Materials*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 1758, 438 (2006).

39. See Vir Singh, *India Modifies Patent Rules to Boost Innovation and Attract Investment*, 72 BNA PAT., TRADEMARK & COPYRIGHT J. 1771, 89 (2006).

40. See Amelia Gentleman & Hari Kumar, *AIDS Groups in India Sue to Halt Patent for U.S. Drug*, N.Y. TIMES, May 12, 2006, available at <http://www.nytimes.com/2006/05/12/world/asia/12aids.html?ex=1164690000&en=2ced8337100161cc&ei=5070>.

41. Pharm. Bus. Review Online, *Gilead Licenses Viread to Eight Generic Companies*, Sept. 26, 2006, available at [http://www.pharmaceutical-business-review.com/article\\_news.asp?guid=E945A0FB-F9EF-46D3-9C4F-64552E1766B1&z=](http://www.pharmaceutical-business-review.com/article_news.asp?guid=E945A0FB-F9EF-46D3-9C4F-64552E1766B1&z=).

42. Brett J. Skinner, The Fraser Institute, *Price Controls, Patents, and Cross-Border Internet Pharmacies: Risks to Canada's Drug Supply and International Trading Relations*, Feb. 2006, available at <http://www.fraserinstitute.ca/admin/books/files/PriceControls&XborderPharmacies1.pdf>.

43. Arthur Rogers, *Council of Europe Weighs Accord on Curbing Counterfeit Drugs*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 1766, 700 (2006).

44. See *id.*

## V. Stem Cell Research and Funding

Developments in stem cell research and funding at the international, regional, and national levels continued in 2006. While ethical and moral issues relating to the legality and funding of embryonic stem cell research remained at the forefront of legislative and policy debates, other pressing issues emerged.

### A. INTERNATIONAL

Currently, no international laws regulate the funding and use of stem cells and embryos in research; at the international level, countries have been able to agree on only the non-binding United Nations Declaration on Human Cloning.<sup>45</sup> Nor is there an international consensus on proper regulatory restraints on stem cell research. At the end of 2005, this lacuna in regulatory and ethical guidelines was exposed when an international scandal broke forth over the revelation that a Korean scientist had fabricated stem cell experiments and the Korean Health Ministry had bought eggs from women, including researchers in labs, for use in these experiments.<sup>46</sup> A host of ethical and regulatory questions, including the development of informed consent principles, prevention of the commodification of human genetic material, and legislative protection of women's reproductive rights, became urgent.<sup>47</sup>

In response to this need for clear ethical standards, leading ethicists, scientists, and lawyers from around the world met at the beginning of 2006 to form the Hinxton Group, an international consortium on stem cell ethics and law. The group expressed concern that conflicting national regulations discourage international research collaboration and leave scientists unsure how to conduct themselves in an ethically responsible way. It, therefore, issued recommendations for the creation of an international ethical code for stem cell research and resolved to continue to develop guidelines as new ethical dilemmas materialize.<sup>48</sup>

### B. REGIONAL

Only the European Union has cooperated at the regional level to fund stem cell research. In 2006, the Council of the European Union agreed to continue funding human embryonic stem cell research within the twenty-five member states.<sup>49</sup> These research grants will come out of the European Union's six-year, \$65 billion research budget.<sup>50</sup> To achieve broader consensus among member states, the new EU rules prohibit funding the

45. See U.N. Declaration on Human Cloning, U.N. Doc. A/Res/59/280 (Mar. 23, 2005). See also Press Release, General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37 (Mar. 8, 2005), available at <http://www.un.org/News/Press/docs/2005/ga10333.doc.htm>.

46. *S. Korea Cloning Pioneer Disgraced*, BBC NEWS, Nov. 24, 2005, available at <http://news.bbc.co.uk/2/hi/asia-pacific/4465552.stm>.

47. See generally Ubaka Ogbogu, *A Review of Pressing Ethical Issues Relevant to Stem Cell Transnational Research*, 14 HEALTH L. REV. 39 (Mar. 22, 2006).

48. *Conflicting Laws Hinder Research*, BBC NEWS, Feb. 25, 2006, available at <http://news.bbc.co.uk/2/hi/science/nature/4748884.stm>.

49. Associated Press, *EU Will Fund Human Stem Cell Research Without Cloning, Killing Embryos*, BOSTON HERALD, Jul. 24, 2006.

50. *Id.*

destruction of human embryos necessary for stem cell harvesting, which must be funded from outside the EU budget.<sup>51</sup> Similarly, the European Union will not fund research for human cloning for reproductive purposes.<sup>52</sup>

### C. NATIONAL

National laws governing methods and funding of stem cell research vary widely worldwide. To date, some fifty countries have passed laws or issued regulations against human cloning.<sup>53</sup> Others, such as Iran and Singapore, have extremely liberal human embryonic stem cell laws and generous funding of research.<sup>54</sup> This year, for example, Singapore began building a nationally-funded stem cell bank and authorized the commercial production and sale of human embryonic stem cell lines.<sup>55</sup>

Several countries moved to liberalize their laws within the last year. In November 2006, the Australian Senate voted to overturn the ban on developing embryonic stem cell lines; the House of Representatives approved the bill in December 2006.<sup>56</sup> New Zealand similarly began considering relaxing laws on the use of human embryos for research but has not yet proposed any legislation.<sup>57</sup>

The United States also attempted to revise its laws on stem cell funding. Although there are no federal laws prohibiting stem cell research, federal funding has been restricted to research on embryonic stem cell lines created before August 9, 2001, which now number around twenty.<sup>58</sup> In July 2006, Congress passed a bill to remove this restriction and provide federal funding to research on newly created stem cells.<sup>59</sup> The bill failed, however, when President Bush used the first veto of his presidency to defeat it, and Congress subsequently failed to override his veto.<sup>60</sup>

In the past two years, more than 100 bills have been considered by dozens of state legislatures.<sup>61</sup> Some, including California, Connecticut, Illinois, Maryland, and New Jersey, have allocated state funds to research; South Dakota has banned it entirely; and other states fall somewhere in between.<sup>62</sup> In 2006, several U.S. states created programs to fund stem cell research and attract scientific research, some of which were a direct reaction to the President's veto. In 2006, the Maryland legislature created the Maryland Stem Cell Research Fund, which will provide grants for adult and embryonic stem cell research. California also announced the first grants under its funding program, which had been

---

51. *Id.*

52. *Id.*

53. Gregory M. Lamb, *How Cloning Stacks Up*, CHRISTIAN SCI. MONITOR, July 13, 2006, at 13.

54. Anne Barnard, *Iran Looks to Science as Source of Pride*, BOSTON GLOBE, Aug. 22, 2006, at A1.

55. Wayne Arnold, *Science Haven in Singapore: Luring Top Stem Cell Researchers with Financing and Freedom*, N.Y. TIMES, Aug. 17, 2006, at C1.

56. Michael Madigan, *Cure-all for Cloning: Bill Wins Backing in Senate*, COURIER MAIL (Aust.), Nov. 8, 2006, at 7; *Australia Relaxes Stem Cell Restrictions*, CHICAGO TRIB., Dec. 7, 2006, at 12.

57. Matthew Torbit, *Call for Embryo Freedom*, DOMINION POST (N.Z.), Aug. 5, 2006, at 5.

58. Erin Cline, *Questions & Answers/Stem Cell Research*, L.A. TIMES, July 30, 2006, at A2.

59. *Id.*

60. *Id.*

61. Jodi Rudoren, *Stem Cell Work Gets States' Aid after Bush Veto*, N.Y. TIMES, July 25, 2006, at A1.

62. Nat'l Conference of State Legislatures, *State Embryonic and Fetal Research Laws*, [www.ncsl.org/programs/health/genetics/embfet.htm](http://www.ncsl.org/programs/health/genetics/embfet.htm) (last visited Feb. 17, 2007).



approved by the state's voters in 2004 but delayed by legal challenges until 2006.<sup>63</sup> Most notably, in what some saw as a decisive victory for scientific progress, in November 2006, Missouri voters approved an amendment to protect all stem cell research not prohibited by federal law.<sup>64</sup>

## VI. Bioterrorism

In 2006, the potential dangers of the growing biotechnology industry, inadequacy of current legal regimes, and necessity of robust lab safety standards were the prominent issues in international and national efforts to counteract and prevent bioterrorism.

### A. INTERNATIONAL

Since 2001, many nations, including the United States, India, China, and Cuba, have pursued biochemical research using dangerous viruses and bacteria.<sup>65</sup> Although advances have been made (in 2006, for example, researchers created a vaccine against the deadly ricin poison),<sup>66</sup> this expansion of biological research increases the risk of harm caused by intentional or accidental release of these lethal agents.

Since the SARS virus outbreak was traced to lax safety standards at three different laboratories in Asia, the international community has worked to regulate and improve lab safety. In 2005 and 2006, states implemented the WHO's new Laboratory Biosafety Manual,<sup>67</sup> passing laws on the possession, import, transport, and disposal of biological agents and toxins.<sup>68</sup> In 2006, Interpol also launched a biocriminalization project to develop model legislation for countries that lack established legal frameworks to prepare for and respond to bioterrorism.<sup>69</sup> Interpol also issued a Bioterrorism Incident Pre-Planning and Response Guide, which provides states with tools for prevention and response efforts.<sup>70</sup>

Nonetheless, the global community has made little progress toward limiting and regulating the proliferation of potentially dangerous biotechnology. Countries still disagree over which pathogens should be regulated for export.<sup>71</sup> The existing international agreements on bioterrorism, the 1972 Biological and Toxin Weapons Convention and 1993 Chemical Weapons Convention, are relatively weak and do not address current problems.<sup>72</sup> Consequently, in May 2006, the Secretary General of the United Nations

63. *Stem Cell Research Funding Generates Controversy*, CLINICAL TRIALS ADVISOR, Vol. 11, No. 11, June 1, 2006.

64. Rachel Melcer, *Vote Clears Way for Research*, ST. LOUIS POST-DISPATCH, Nov. 9, 2006, at C1.

65. Joby Warrick, *The Secretive Fight Against Bioterror*, WASH. POST, July 30, 2006, at A1.

66. Associated Press, *Researchers Create Human Ricin Vaccine*, N.Y. TIMES, Jan. 31, 2006, at A17.

67. WORLD HEALTH ORG., LABORATORY BIOSAFETY MANUAL (3d ed. 2004), available at <http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>.

68. Chang Ai-Lien, *WHO Praises Lab Safety Culture Here*, STRAITS TIMES (Singapore), Mar. 10, 2006.

69. INTERPOL, Outcome Statement: Interpol Workshop on Preventing Bioterrorism, Nov. 6-8, 2006, <http://www.interpol.int/Public/BioTerrorism/Workshops/KievNov2006/OutcomeStatement.asp>.

70. INTERPOL, Bioterrorism Incident Pre-Planning & Response Guide (2007), available at <http://www.interpol.int/Public/BioTerrorism/BioterrorismGuide.pdf>.

71. Ian Sample, *Poor Lab Controls Increase Risk of Bioterrorism, Experts Warn*, THE GUARDIAN (UK), Nov. 14, 2006.

72. See *id.*

called for a global forum on biological terrorism to develop new international bioterrorism initiatives.<sup>73</sup> Additionally, in November 2006, he urged the creation of international safeguards to regulate the growing biotechnology industry and harmonize conflicting national rules.<sup>74</sup> This push should ensure that bioterrorism issues remain a key part of the agenda in the international arena in the coming years.

#### B. NATIONAL: UNITED STATES

In June 2006, the United States began construction on a \$128 million facility to house the National Biodefense Analysis and Countermeasures Center (NBACC). The NBACC raises concerns that the use of deadly germs in government tests might represent a violation of international treaties that prohibit production of even small amounts of biological weapons. According to some critics, prioritizing the funding of NBACC and other bioterrorism research acts to the detriment of other fields of research. Thus, in 2006, more than 700 U.S. scientists wrote a letter expressing alarm that increased funding to research on biochemical threats had caused public health research to suffer.<sup>75</sup>

The U.S. Congress may consider these and other issues in 2007. In 2006, the U.S. Senate had not yet reauthorized the bioterrorism-preparedness legislation passed in 2001 and therefore will consider the bill again in 2007. The Senate has proposed legislation that would maintain the federal level of spending on public health preparedness, request matching state funds, and expand the disease surveillance system.<sup>76</sup>

### VII. Violence, Health, and Human Rights

This year also bore witness to the growing recognition that a wide range of human rights issues are, in fact, health issues. The issue of violence and its impact on the health and well-being of individuals was one of the many important matters highlighted in 2006, particularly with the completion of two major multi-year studies by the United Nations.

In July 2006, the U.N. Secretary General published an in-depth study on all forms of violence against women.<sup>77</sup> The study provides a more detailed understanding of the health, social, and economic costs of violence against women and emphasizes the importance of immediate and effective action to combat such violence. Later in the year, the U.N. Secretary-General's Study on Violence Against Children was published.<sup>78</sup> It represents a three-year study on the impact of violence in the home, schools, community, workplace, and juvenile justice settings on all children.<sup>79</sup> This seminal study highlights the

73. Reuters, *U.N. Leader Urges Biotech Safeguards*, N.Y. TIMES, Nov. 19, 2006.

74. *Id.*

75. Iain Hollingshead, *Whatever Happened to . . . the Anthrax Attacks?*, THE GUARDIAN (UK), Sept. 9, 2006, at 36.

76. Renae Merle, *Senate to Take Up Biological Threats: Firms Could Get Funding Sooner*, WASH. POST, Nov. 15, 2006, at D1.

77. The Secretary General, *In-Depth Study on All Forms of Violence Against Women*, U.N. DOC. A/61/122/Add.1 (July 6, 2006), available at <http://daccessdds.un.org/doc/UNDOC/GEN/N0641974.pdf?OpenElement>.

78. The Secretary General, *Promotion and Protection of the Rights of Children*, U.N. DOC. A/61/299 (Aug. 29, 2006), available at <http://www.violencestudy.org/IMG/pdf/English.pdf>.

79. *Id.*

dramatic and often unseen effects of violence on children's health and well-being. The U.N. General Assembly also adopted a resolution supporting the Study on Violence Against Children and calling upon all countries to implement the Study's recommendations and put an end to abusive treatment of children.<sup>80</sup> These two key studies and their recommendations provide a better understanding of the risks that women and children face and compel government action.

Additional initiatives were launched in late 2006 to address issues of violence. For example, the Pan American Health Organization (PAHO) launched a new public awareness campaign to help prevent violence against women, a widespread problem in the Americas as in other regions.<sup>81</sup> In addition, noting the growing evidence of linkages between violence and HIV, the Global AIDS Alliance started a new program to combat violence against women and children.<sup>82</sup> Research shows that 20 percent of girls and 10 percent of boys experience sexual abuse as children and that refugees and displaced persons, 80 percent of whom are women and children, also experience increased sexual or physical violence.<sup>83</sup> All of these individuals are at greater risk of HIV infection, as well as a range of other health problems.

The U.N. studies and other initiatives mentioned above represent important steps in understanding the incidence and effects of violence and in developing effective programs to reduce, and ultimately eliminate, such violence. Further action is required at all levels to combat violence and to ensure the health and human rights of all individuals.

## VIII. Obesity

In the past decade, the incidence of obesity worldwide has increased dramatically. Today, at least 400 million adults are obese.<sup>84</sup> The world's 1.6 billion overweight people now outnumber the 800 million hungry, and the WHO projects that by 2015, 2.3 billion adults will be overweight and 700 million will be obese.<sup>85</sup> Although obesity is more prevalent in the developed world, it now constitutes a global epidemic, affecting every region with the exception of sub-Saharan Africa.<sup>86</sup> In China alone, sixty million people are obese.<sup>87</sup> Overweight and obesity both result in chronic diseases, such as cardiovascular conditions, diabetes, and respiratory diseases, which account for 46 percent of the global disease bur-

80. Rights of the Child, U.N. GAOR, 61st Sess., U.N. Doc. A/C.3/61/L.16/Rev/1, ¶¶ 13-19, (Nov. 17, 2006).

81. Press Release, Pan American Health Org., PAHO Calls for End to Violence Against Women (Nov. 21, 2006), available at <http://www.paho.org/English/DD/PIN/pr061121.htm>.

82. GLOBAL AIDS ALLIANCE, ZERO TOLERANCE: STOP THE VIOLENCE AGAINST WOMEN AND CHILDREN 3 (2006), available at [http://www.globalaidsalliance.org/GAA\\_Violence\\_Against\\_Women\\_Advocacy\\_Brief.cfm](http://www.globalaidsalliance.org/GAA_Violence_Against_Women_Advocacy_Brief.cfm).

83. *Id.*

84. World Health Org., Obesity and Overweight, Sept. 2006, <http://www.who.int/mediacentre/factsheets/fs311/en/index.html>.

85. *Id.*

86. WORLD HEALTH ORG., EUROPEAN MINISTERIAL CONFERENCE ON COUNTERACTING OBESITY: DIET AND PHYSICAL ACTIVITY FOR HEALTH, THE CHALLENGE OF OBESITY IN THE WHO EUROPEAN REGION AND THE STRATEGIES FOR RESPONSE 51, Doc. No. EUR/06/5062700/6 (Aug. 28, 2006), available at [http://www.euro.who.int/Document/NUT/Instanbul\\_conf\\_edoc06.pdf](http://www.euro.who.int/Document/NUT/Instanbul_conf_edoc06.pdf) [hereinafter WHO CHALLENGE].

87. Agence France-Presse, *Number of Obese Chinese Swells to 60 Million*, LIFESTYLE NEWS, Nov. 6, 2006, available at <http://news.lifestyle.co.uk/lifestyle/101529-lifestyle.htm>.

den.<sup>88</sup> Morbidity and mortality associated with increased weight problems inflict huge burdens and costs on families and health systems.<sup>89</sup> Despite this evidence, governments and international agencies still have much work to do to address the problem.<sup>90</sup> A multi-sectoral response is required to address factors that contribute to high-fat diets and sedentary lifestyles and to treat obesity and disease and reduce their impact.<sup>91</sup>

#### A. INTERNATIONAL

Although obesity received significant attention as a newly emerging issue in 2006, the WHO, in fact, began sounding the alarm in the 1990s on the problems of overweight and obesity through expert consultations and public awareness campaigns.<sup>92</sup> Thanks to the WHO's support, several international policy instruments have been adopted since that time. In 2004, the World Health Assembly adopted the WHO Global Strategy on Diet, Physical Activity, and Health.<sup>93</sup> This population-wide, prevention-oriented strategy calls for action at the international, regional, and national levels and seeks to address the risk factors for obesity and chronic disease, unhealthy diet, and physical inactivity. The Codex Alimentarius Commission, the standard-setting body for food of the WHO and U.N. Food and Agriculture Organization, also is working to support the global strategy through food labeling and identification of healthy foods.<sup>94</sup> Moreover, in October 2005, the WHO proposed a global goal of a 2 percent reduction in chronic disease death rates each year for a decade.<sup>95</sup>

In 2006, the International Congress on Obesity, a private organization of obesity experts, also met to outline draft standards to protect children from exploitative techniques for the marketing of junk food.<sup>96</sup> They called upon the United Nations and governments to use the principles to develop globally enforceable standards to protect children and reduce the incidence of overweight and obesity among the very young.<sup>97</sup>

#### B. REGIONAL

Significant progress toward the adoption of measures to address overweight and obesity has been made at the regional level. The European region has made the most progress in

---

88. Global Strategy on Diet, Physical Activity and Health, WHA Res. 57.17, World Health Assembly, 57th Assembly (May 22, 2004), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA57/A57\\_R17-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf) [hereinafter Global Strategy].

89. World Health Org., Regional Office for the Western Pacific, Health Topics: Obesity, available at [http://www.wpro.who.int/health\\_topics/obesity/](http://www.wpro.who.int/health_topics/obesity/) [hereinafter WHO, Regional].

90. World Health Org., Nutrition, Controlling the Global Obesity Epidemic, available at <http://www.who.int/nutrition/topics/obesity/en/index.html> [hereinafter WHO, Controlling].

91. WHO, Regional, *supra* note 89.

92. WHO, Controlling, *supra* note 90.

93. Global Strategy, *supra* note 88.

94. WHO CHALLENGE, *supra* note 86, at 52.

95. World Health Org., Regional Office for the Western Pacific, Noncommunicable Disease Prevention and Control, Doc. No. WPR/RC57/6, 57th Sess., Prov. Agenda Item 11, July 24, 2006, available at [http://www.wpro.who.int/NR/rdonlyres/27424342-F4E5-4739-BFFC-6AA3D2C4BA2D/0/Item11\\_RC5706NCD.pdf](http://www.wpro.who.int/NR/rdonlyres/27424342-F4E5-4739-BFFC-6AA3D2C4BA2D/0/Item11_RC5706NCD.pdf) [hereinafter WHO, Disease Prevention and Control].

96. Tamara McLean, *World Junk Food Ban*, HERALD SUN (Aust.), Sept. 6, 2006, at 14.

97. *Id.*

developing and implementing a region-wide strategy to reduce overweight and obesity. Within the European region, more than one million deaths annually are caused by disease related to excess body weight.<sup>98</sup> The prevalence of obesity has risen three-fold in the last two decades, and one-half of adults and one-fifth of children are now overweight.<sup>99</sup> In the past few years, the European Union has adopted several regional instruments to counteract the problem. Since 2005, the EU Platform on Diet, Physical Activity, and Health, which will be reviewed in 2007, has provided a series of workshops for commercial, professional, and consumer organizations with a stake in the issues.<sup>100</sup> In September 2006, the WHO Regional Committee for Europe approved the European Strategy for the Prevention and Control of Noncommunicable Diseases, a comprehensive program that targets individuals at high risk, maximizes effective treatments, and strengthens national health systems to improve prevention and control.<sup>101</sup>

Most importantly, on November 16, 2006, European health ministers from fifty-three countries approved the first charter to fight obesity.<sup>102</sup> Drafted by the WHO in consultation with European countries, the European Charter on Counteracting Obesity aims to curb the obesity epidemic within five years and reverse the trend by 2015.<sup>103</sup> It also plans to harmonize the marked policy differences in the marketing of food to children across Europe as a possible precursor to the adoption of an international code of practice.<sup>104</sup>

While the European Union has made more progress than other regions on obesity, it is not alone in responding to this public health concern. In 2004, for example, the Pan-American Health Organization adopted a Protocol for the Nutritional Management of Obesity, Diabetes, and Hypertension for the Caribbean.<sup>105</sup> The Protocol sets forth guidelines for standardizing nutritional care and managing overweight-related disease that are the main causes of disability, illness, and death in the region.<sup>106</sup> The Western Pacific Region has also worked to stem the chronic noncommunicable diseases within that region. On the basis of the 2005 WHO proposal to prevent and control such diseases, the Western Pacific Regional Committee endorsed a framework of action focused on national planning, surveillance with periodic national surveys, health promotion, and clinical prevention accessible by all members of society.<sup>107</sup>

### C. NATIONAL: UNITED STATES

In the United States, obesity and overweight have reached record levels. Today, nearly two-thirds of adult Americans are either overweight or obese, and the rates only continue

98. WORLD HEALTH ORG., EUROPEAN MINISTERIAL CONFERENCE ON COUNTERACTING OBESITY: DIET AND PHYSICAL ACTIVITY FOR HEALTH, EUROPEAN CHARTER ON COUNTERACTING OBESITY I, Doc. No. EUR/06/5062700/8, (Nov. 16, 2006), available at <http://www.euro.who.int/Document/E89567.pdf>.

99. *Id.*

100. *Id.* at 52.

101. *Id.*

102. Maria Cheng, *Europeans OK Anti-Obesity Charter*, WASH. POST, Nov. 16, 2006.

103. *Id.*

104. *Id.*

105. PAN AMERICAN HEALTH ORG., PROTOCOL FOR THE NUTRITIONAL MANAGEMENT OF OBESITY, DIABETES AND HYPERTENSION IN THE CARIBBEAN, available at <http://www.paho.org/English/CFNI/cfni-ProtocolNMODH.pdf>.

106. *Id.*

107. See WHO, Disease Prevention and Control, *supra* note 95.

to rise.<sup>108</sup> From 1980 to 2004, childhood overweight rates more than tripled, up from 5 percent to 17 percent.<sup>109</sup>

In the past few years, the vast majority of states have considered bills to combat obesity by, among other things, improving school nutrition, banning certain foods from schools, and limiting the use of unhealthy fats in restaurants.<sup>110</sup> Civil lawsuits have also been filed by several individuals against food companies.<sup>111</sup> Most famously, parents of minors brought suit against McDonald's alleging state consumer protection law violations for representing its food as substantially more healthy than it is.<sup>112</sup> Litigation against McDonald's and other food chains has prompted federal and state legislation to ban certain lawsuits against food companies or make them more difficult. Eighteen states have banned personal injury suits against the food industry and, in the past few years, the U.S. Congress has also introduced bills to prevent individuals from claiming fast food restaurants made them fat.<sup>113</sup>

The emergence of obesity issues as a prominent public health concern reflects the trend of an ever increasing number of health issues that require the attention of governments, international organizations, and the general public.

## IX. Conclusion

There is growing acknowledgement at all levels of government and in the private and nonprofit sectors of the importance and far-reaching impact of health issues. As the WHO has stated:

Health is increasingly seen as a key aspect of human security. Actual or potential health emergencies are objects of intense public attention and debate. Violence contributes significantly to preventable morbidity and mortality. Diseases linked to poverty accelerate societal breakdown. Wider concerns about security include the dependence of health on safe food and water, financial security, and protection from the effects of climate change. . . . Countries, at all levels of development, are realizing the need for sustained, equitable increases in health investment for them to become or remain stable and prosperous nations.<sup>114</sup>

All sectors of society are affected, and thus all fields of the legal profession are implicated. Ultimately, a comprehensive, multi-sector approach to international health law issues is the best way of ensuring health and security for all.

108. Press Release, Trust for America's Health, *America's Obesity Epidemic Getting Worse; New Report Finds Adult Obesity Rates Up in 31 States; The South is the "Biggest Belt"* (Aug. 29, 2006), available at <http://healthyamericans.org/newsroom/releases/release082906.pdf>.

109. *Id.*

110. Edward L. Palmer & Lisa Sofio, *Food and Beverage Marketing to Children in School*, 39 LOY. L.A. L. REV. 33, 57-58 (2006).

111. See Adam Benforado et al., *Broken Scales: Obesity and Justice in America*, 53 EMORY L.J. 1645 (2004).

112. *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512 (S.D.N.Y. 2003).

113. Jeffrey Gilbert, *Senate OKs Obesity Bill that Limits Lawsuits*, HOUS. CHRON., May 26, 2005, at 3; Brooke Courtney, *Is Obesity Really the Next Tobacco? Lessons Learned from Tobacco for Obesity Litigation*, 15 ANNALS HEALTH L. 61, 74-75 (2006).

114. WORLD HEALTH ORG., *ENGAGING FOR HEALTH: ELEVENTH GENERAL PROGRAMME OF WORK 2006-2015, A GLOBAL AGENDA 2* (2006), available at [http://www.who.int/gpw/GPW\\_En.pdf](http://www.who.int/gpw/GPW_En.pdf).