

# International Health Law

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In 2005, international health law issues continued to demand increasingly more attention from governments, international organizations, the private sector, and the general public. Public health concerns, such as HIV/AIDS and avian influenza, demonstrate both the far-reaching effects of public health emergencies and the need for coordinated multilateral responses. Global health issues have implications not only for health care professionals and health law attorneys but also for those working in many other areas, including trade, intellectual property, human rights, and corporate law.<sup>1</sup> As in recent years, multilateral efforts to respond to current and potential public health emergencies took center stage in 2005. Other ongoing key issues in international health law include changes in patent law, the continuing fight against HIV/AIDS, and developments in biomedical science (including stem cell research).

## I. Responding to Infectious Disease Outbreaks

### A. THE NEW INTERNATIONAL HEALTH REGULATIONS

The year 2005 was a milestone in the effort to combat public health emergencies, as the World Health Assembly adopted a revised version of the International Health Regulations (IHR) on May 23, 2005.<sup>2</sup> It marked the first significant revision of the regulations since 1969.<sup>3</sup> The old version of the IHR covered only three infectious diseases (cholera, plague,

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1. See Jonathan Todres, *Health Law Gets A More Global Focus*, NAT'L L.J., July 4, 2005, at S1.

2. See World Health Organization, *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. The IHR have existed since 1951.

and yellow fever), and thus was of no help during the severe acute respiratory syndrome (SARS) outbreak of 2003, which infected over 8000 people in more than twenty-five countries and cost the global economy billions of dollars.<sup>4</sup> As a result, while a revised draft of the IHR had been in the works for many years, the SARS outbreak spurred efforts to finalize the new version as quickly as possible.<sup>5</sup> The new IHR mark a significant step toward strengthening the international community's public health preparedness. They establish a clear mandate, stating that "[t]he purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."<sup>6</sup>

The IHR require every country to establish or designate a national center responsible for implementation of the IHR that will serve as the contact point for the World Health Organization (WHO).<sup>7</sup> Under the IHR, each country is required to develop and maintain the capacity to detect, assess, and report certain public health events.<sup>8</sup> Each country must also develop the ability to respond promptly and effectively to public health risks and emergencies.<sup>9</sup> Countries must develop such capabilities within five years of the new IHR's entry into force,<sup>10</sup> with WHO support available to those countries needing assistance.<sup>11</sup> Under the new IHR, states parties are also obligated to cooperate in the detection, assessment, and response to major diseases.<sup>12</sup> This is a significant change, mandating for the first time scientific cooperation in the fight to combat the spread of significant infectious diseases.<sup>13</sup>

Once the new IHR enter into force, countries will be required to notify the WHO of any event, such as an outbreak of infectious disease, that may constitute a public health emergency of international concern.<sup>14</sup> The WHO then will have the authority to coordinate any necessary international response. The IHR also establish certain health-related rules for international trade and travel; outline procedures for governmental health agencies in the area of public health controls related to goods at airports, ports, and other entry points; and set forth health procedures and documentation requirements for international travelers.<sup>15</sup> When fully implemented, the new IHR will significantly enhance the capacity of each country to respond to public health emergencies and improve coordination of multilateral efforts to address outbreaks of infectious disease and other public health emergencies. This

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4. See Todres, *supra* note 1, at S1; THOMAS ABRAHAM, TWENTY-FIRST CENTURY PLAGUE: THE STORY OF SARS 151-52 (2004).

5. See Todres, *supra* note 1, at S1.

6. IHR, *supra* note 2, at art. 2.

7. *Id.* at art. 4.

8. *Id.* at art. 5.

9. *Id.* at art. 13.

10. *Id.* at arts. 5, 13. The new IHR will enter into force in May 2007.

11. *Id.* at art. 5(3). As the new IHR do not provide details on the funding for such assistance, questions remain as to how the WHO assistance to developing countries will be financed.

12. IHR, *supra* note 2, at art. 44 & annex 1.

13. See Gerald S. Schatz, *International Health Regulations: New Mandate for Scientific Cooperation*, ASIL INSIGHT, Aug. 2, 2005, available at <http://www.asil.org/insights/2005/08/insights050802.html>.

14. IHR, *supra* note 2, at art. 6. Notably, the WHO also has authority to receive reports from sources other than states parties. *Id.* at art. 9. This could enable major multinational corporations, including pharmaceutical companies, to report both to the WHO and national governments in an effort to ensure a rapid response.

15. *Id.* at parts IV-VI.

improved capacity to respond to public health crises should save lives and help minimize potentially devastating economic losses caused by disease outbreaks.

## B. RECENT RESPONSES TO AVIAN INFLUENZA

### 1. *International Response*

Most experts agree that we are closer to an influenza pandemic than we have been at any time since 1968, the year in which the last pandemic occurred.<sup>16</sup> As a result, the WHO set its pandemic alert system to phase 3 (out of a possible 6). Phase 3 is reserved for situations where “a new influenza virus subtype is causing disease in humans, but is not yet spreading efficiently and sustainably among humans.”<sup>17</sup> In view of this threat level, international organizations have been mobilizing financial and human resources in an attempt to respond to the current H5N1 avian influenza and prepare for a potential human influenza pandemic. In September 2005, United Nations (U.N.) Secretary General Kofi Annan appointed a former senior public health expert at the WHO to coordinate the U.N. response on this front, reflecting the increased priority given to avian influenza at the international level.<sup>18</sup>

The WHO has taken the lead in coordinating a response to the threat of avian influenza, hosting a global meeting entitled *The H5N1 Agenda: Towards a global strategy*, in November 2005.<sup>19</sup> Representatives from over 100 countries met to identify the key components of a global response to control avian influenza and contain the threat of a human influenza pandemic.<sup>20</sup> Such a global response plan<sup>21</sup> would involve measures including proper controls at the site of infection in birds; surveillance, early detection, and rapid response; rapid containment of animal and human cases; national and international pandemic preparedness plans and strategies; as well as effective and transparent communication systems to ensure adequate information flow on all of these issues.<sup>22</sup>

In addition, the meeting also addressed international financial concerns. According to a World Bank analysis, it is estimated that over the next several years the needs of countries affected by the avian influenza threat could reach \$1 billion (excluding financing for vaccine development and antiviral medicines as well as compensation for culled animals).<sup>23</sup> In the interim, the meeting supported an urgent request for US\$35 million to fund imminently necessary national measures and international actions by the WHO, the Food and Agriculture Organization, and the World Organization for Animal Health.<sup>24</sup> Adequate funding

16. See World Health Organization, *Current WHO Phase of Pandemic Alert* (Nov. 2005), [http://www.who.int/csr/disease/avian\\_influenza/phase/en/index.html](http://www.who.int/csr/disease/avian_influenza/phase/en/index.html).

17. *Id.*

18. See Press Release, World Health Organization, *WHO Expert to Work with the UN System on Avian and Human Influenza* (Sept. 29, 2005), available at <http://www.who.int/mediacentre/news/releases/2005/pr45/en/index.html>.

19. See World Health Organization, *Meeting on Avian Influenza and Human Pandemic Influenza* (2005), [http://www.who.int/mediacentre/events/2005/avian\\_influenza/meeting\\_avian\\_influenza/en/index.html](http://www.who.int/mediacentre/events/2005/avian_influenza/meeting_avian_influenza/en/index.html).

20. See Joint Press Release, World Health Organization et al., *Global Influenza Meeting Sets Key Action Steps, Agrees on Urgent Need for Financing* (Nov. 9, 2005), available at <http://www.who.int/mediacentre/news/releases/2005/pr58/en/index.html> [hereinafter *Global Influenza Meeting*].

21. See WORLD HEALTH ORGANIZATION, *WHO GLOBAL INFLUENZA PREPAREDNESS PLAN* (2005), available at [http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_CSR\\_GIP\\_2005\\_5.pdf](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf).

22. *Id.* at 1-3.

23. See *Global Influenza Meeting*, *supra* note 20.

24. *Id.*

for these and other measures remains a key to ensuring an effective global response to avian influenza or other infectious disease outbreaks.

## 2. Regional Responses—European Union and Pan American Health Organization

Concurrent with these international responses, regional organizations have implemented preparedness strategies and developed emergency measures to prepare for, and respond to, international health crises. In light of the confirmation of avian flu cases in Europe, European foreign ministers convened an emergency meeting on October 18, 2005, acknowledging that the European Union and most European countries were significantly underprepared for a human influenza pandemic.<sup>25</sup> As a result, European Union health officials have since unveiled measures to help contain avian influenza in animals and prevent the spread of the virus to humans.<sup>26</sup> Such measures include keeping poultry indoors to reduce contact with migratory birds; encouraging individuals to avoid outdoor activities where there is a significant risk of contact with infected birds; and banning the importation of live birds.<sup>27</sup>

Subsequently, European health experts met to review the current preparedness levels of European governments and the need for additional measures.<sup>28</sup> The conference revealed that all twenty-five European Union Member States and twenty-one other countries in the WHO's European region currently have national preparedness plans.<sup>29</sup> It was noted, however, that additional efforts are needed in the areas of general funding; testing and implementation of these plans; and cooperation with international organizations.<sup>30</sup> In addition, the United Kingdom, which had taken over the European Union presidency in July 2005, introduced a new avian flu directive which it is hoped will come into force on January 1, 2007. The new legislation represents a significant change from the prior European Commission directive that focused solely on highly pathogenic strains of avian influenza, by requiring compulsory surveillance of wild birds in an attempt to detect even mild strains of the virus before they mutate.<sup>31</sup>

Meanwhile, in the Americas, in September 2005, officials of the Pan American Health Organization announced a regional plan designed to prepare for, and respond to, a potential

25. Dan Bilefsky & Tom Wright, *Europeans Declare Bird Flu a "Global Threat"*, INT'L HERALD TRIB., Oct. 19, 2005, available at <http://www.iht.com/articles/2005/10/18/news/flu.php>.

26. See Dan Bilefsky & Elisabeth Rosenthal, *Europe Steps Up Efforts to Stop Avian Flu*, N.Y. TIMES, Oct. 15, 2005, at A10; Press Release, European Commission, Avian Influenza: Further Preventive Measures Agreed and Russian Import Restrictions Adopted, Doc. IP/05/1326 (Oct. 20, 2005), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1326&format=HTML&aged=0&language=EN&guiLanguage=en> [hereinafter EC Press Release IP/05/1326]; Press Release, European Commission, Avian Influenza: EU Bans Imports of Captive Live Birds from Third Countries, Doc. IP/05/1351 (Oct. 25, 2005), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1351&format=HTML&aged=0&language=EN&guiLanguage=en> [hereinafter EC Press Release IP/05/1351].

27. See Bilefsky & Rosenthal, *supra* note 26; see also EC Press Release IP/05/1326, *supra* note 26; EC Press Release IP/05/1351, *supra* note 26.

28. See Press Release, European Commission, European Health Experts Take Stock of Influenza Pandemic Preparedness, Doc. IP/05/1355 (Oct. 26, 2005), available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1355&format=HTML&aged=0&language=EN&guiLanguage=en>.

29. See *id.*

30. See *id.*

31. See Tom Parfitt & Jamie Doward, *Europe Hunt Widens for Infected Birds*, THE OBSERVER, Aug. 28, 2005, available at <http://observer.guardian.co.uk/international/story/0,6903,1558028,00.html>.

influenza pandemic. Central to its plan are measures aimed at developing greater human influenza pandemic preparedness at the regional and national levels and increasing surveillance and containment of avian influenza in the region.<sup>32</sup>

### 3. *National Response—the United States*

Amid growing concerns that the United States is inadequately prepared for an influenza pandemic, on November 1, 2005, the U.S. government announced a national strategy to protect the country against avian influenza and a potential human influenza pandemic.<sup>33</sup> The plan revealed that the United States must take immediate action to ensure it is sufficiently prepared to deal with an outbreak of pandemic flu, which, in a worst case scenario, could result in 1.9 million Americans dying and upwards of 10 million Americans being hospitalized.<sup>34</sup> Such a pandemic could result in costs in excess of \$450 billion.<sup>35</sup> To avoid such an outcome, the plan's recommendations include improved surveillance, investigation, and protection capacities; selective use of travel restrictions and quarantine measures; a ten-fold increase in current vaccine production capacity; and effective communications and public outreach programs.<sup>36</sup>

To this end, President Bush requested \$7.1 billion in emergency funding from Congress to begin immediate implementation of this national strategy designed to meet three critical goals: (1) the detection of outbreaks having occurred anywhere in the world; (2) the protection of the American people by stockpiling vaccines and antiviral drugs and improving the ability to produce new vaccines against a pandemic strain; and (3) coordination and preparation at the federal, state, and local levels.<sup>37</sup> In addition, \$251 million will be specifically allocated to assisting the international community in its efforts to prevent and control the spread of avian influenza.<sup>38</sup> Earlier in the year, President Bush signed an emergency appropriations bill that allocated \$25 million to the development and implementation of programs designed to control the spread of avian influenza in Southeast Asia. Also, on September 14, 2005, President Bush announced the creation of the International Partnership on Avian and Pandemic Influenza in his remarks to the High-Level Plenary Meeting of the U.N. General Assembly. Through this Partnership, key nations and international organizations are encouraged to work together to achieve greater awareness and surveillance of avian influenza outbreaks; transparency in, and coordination of, global responses; as well as mobilization of technical and financial resources.<sup>39</sup>

32. See Press Release, Pan American Health Organization, PAHO To Assist Member Countries with Pandemic Planning (Sep. 19, 2005), available at <http://www.paho.org/English/DD/PIN/pr050929a.htm>.

33. See *Bush Unveils \$7.1 Billion Plan to Prepare for Flu Pandemic*, CNN, Nov. 2, 2005, <http://www.cnn.com/2005/HEALTH/conditions/11/01/us.flu.plan/index.html>. For a full copy of the U.S. report, see U.S. DEPT OF HEALTH AND HUMAN SERVICES, HHS PANDEMIC INFLUENZA PLAN (Nov. 2005), available at <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>.

34. HHS PANDEMIC INFLUENZA PLAN, *supra* note 33, at 18.

35. See Gardiner Harris, *U.S. Not Ready for Deadly Flu, Bush Plan Shows*, N.Y. TIMES, Oct. 8, 2005, at A1.

36. HHS PANDEMIC INFLUENZA PLAN, *supra* note 33, at 7-8.

37. See President George W. Bush, Remarks at William Natcher Center, National Naval Medical Center (Nov. 1, 2005), available at <http://www.state.gov/g/oes/rls/rm/55882.htm>.

38. *Id.*

39. See Press Release, USAID, Avian Influenza Response (Nov. 14, 2005), available at [http://www.usaid.gov/our\\_work/global\\_health/home/News/news\\_items/avian\\_influenza.html](http://www.usaid.gov/our_work/global_health/home/News/news_items/avian_influenza.html); see also Fact Sheet, U.S. Dep't of State, U.S. Launches International Partnership on Avian and Pandemic Influenza (Sept. 22, 2005), <http://www.state.gov/r/pa/prs/ps/2005/53865.htm>.

The multilateral and national efforts to respond to avian influenza undertaken in 2005, along with the adoption of the revised IHR, mark the beginning of a concerted effort to ensure that the global community is adequately prepared to respond to any outbreak of infectious disease. Ultimately, collaboration will be needed at the local, state, national, and international levels and among the public sector, private sector, and general public.

## II. Patent Law

In 2005, patent law remained an area of impact in international health law for a range of entities, from governments and pharmaceutical companies to non-governmental organizations, and for individual patients. Maintaining the balance between private and public concerns in an effort to encourage innovation and improve patient access to pharmaceuticals continued to be a challenge. In this regard, the 2003 World Trade Organization (WTO) decision, which expanded the right of developing countries to utilize compulsory licensing to access pharmaceuticals in situations of national emergency or extreme urgency, remains central to this balancing.<sup>40</sup> While the right of developing countries to manufacture generic pharmaceuticals was already established under the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement,<sup>41</sup> the 2003 decision also permits the importation of such pharmaceuticals to developing countries that lack the capacity to produce them.<sup>42</sup> However, at a WTO TRIPS Council meeting in October 2005, members continued to debate how to incorporate this decision into a permanent amendment to the TRIPS agreement, with substantial differences existing between the language proposed by industrialized and developing countries.<sup>43</sup>

The TRIPS agreement and political pressure continue to weigh heavily on developing countries seeking to compete in the global market place.<sup>44</sup> In an effort to comply with the TRIPS agreement, India—a leading international producer of generic drugs—passed new legislation in 2005, prohibiting domestic companies from manufacturing generic copies of patented pharmaceuticals.<sup>45</sup> Although some human rights and humanitarian organizations have raised concerns that the new law could result in higher prices for pharmaceuticals and reduced access to life-saving medications for the poor, proponents of the legislation hope that it will encourage greater investment in India's pharmaceutical industry.<sup>46</sup> In what may

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40. See Brett A. King, *WTO Members Fail to Make Progress on Incorporating Medicines Deal in TRIPS*, 70 BNA PAT., TRADEMARK & COPYRIGHT J. 1742 (2005); see also Trade Related Aspects of Intellectual Property Rights (TRIPS), Part II—Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, Apr. 15, 1994, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm#5](http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5) (providing the specific, relevant provisions of the TRIPS agreement) [hereinafter TRIPS Agreement].

41. TRIPS Agreement, *supra* note 40, at part II.

42. See King, *supra* note 40, at 1742.

43. See *id.*

44. See Jason Subler, *Portman Presses China on Market Access, IPR; Urges China to be Active in Doha Talks*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 1745 (2005); Rossella Brevetti, *House Democrats Express Concern With Andean FTA Negotiations on Drug IPR*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 1745 (2005); Jason Gutierrez, *Zoellick Says U.S. to Track Philippine Effort Against IP Piracy Over Next Six Months*, 70 BNA PAT., TRADEMARK & COPYRIGHT J. 1720 (2005).

45. See International Center for Trade and Sustainable Development, *Indian Parliament Approves Controversial Patent Bill*, BRIDGES WKLY TRADE NEWS DIG., Mar. 23, 2005, available at <http://www.ictsd.org/weekly/05-03-23/story1.htm>.

46. See *id.*

provide an early test of the new law, one of India's largest generic manufacturers announced plans to manufacture generic Tamiflu in response to avian influenza concerns.<sup>47</sup> This situation seems somewhat reminiscent of the United States' demand for Cipro several years ago and is another example of public health concerns driving interpretations of patent law. While the TRIPS agreement provides flexibility for dealing with public health emergencies, it is unclear how the Indian courts will apply the law if this issue is litigated.

The manufacture of generic pharmaceuticals by Indian companies was again an issue in a case between Pfizer, Inc. and Ranbaxy Laboratories, Ltd.<sup>48</sup> Ranbaxy challenged two patents involving Pfizer's cholesterol lowering drug Lipitor in the British courts, but neither side fully prevailed, as the court upheld one patent but invalidated the other. Pfizer faces a similar challenge in the U.S. courts, where the outcome will again be closely monitored.<sup>49</sup>

Consistent with the tension between patent rights and public health concerns, Brazil announced in June 2005 that it was prepared to start manufacturing a generic version of an anti-retroviral drug (Kaletra) made by Abbott Laboratories.<sup>50</sup> The Brazilian government provides free HIV/AIDS treatment to anyone in need and was threatening to become the first country to violate the patent on an antiretroviral pharmaceutical.<sup>51</sup> Upon closer examination, however, Brazil's stance toward Abbott appeared to be more of a negotiating position aimed at enabling it to obtain HIV/AIDS drugs for patients at low cost. Reflective of this, Brazil reached an agreement with Abbott in early July 2005, to obtain Kaletra at a lower price, which did not impact Abbott's patent rights.<sup>52</sup>

This interaction and similar negotiations by Brazil and other countries seem to indicate that pharmaceutical companies much prefer to lower the cost of drugs rather than face possible incursion into their intellectual property portfolio and that governments do not want to engage in litigation over patent rights unnecessarily. This suggests a compromise solution for both sides, but it is unclear if this balance will be maintained over time. Patent rights appear to be in no danger of losing their strong foothold in international law. The challenge, however, seems to be achieving an equitable balance among the rights of pharmaceutical companies to make a profit, the public interest in encouraging innovation, and the right of patients to affordable medicine. While various approaches to these issues are playing out in the global marketplace, a definitive solution has not yet been found.

### III. HIV/AIDS

Even as the threat of avian influenza dominated the headlines, HIV/AIDS continued to have a profound effect on the populations of numerous countries. There are currently an estimated 40.3 million people living with HIV.<sup>53</sup> Of this number, over 40 percent are women

47. See Donald G. McNeil, Jr., *Indian Company to Make Generic Version of Flu Drug Tamiflu*, N.Y. TIMES, Oct. 14, 2005, at A3.

48. *Ranbaxy U.K. Ltd. v. Warner-Lambert Co.*, [2005] EWHC 2142 (Pat), [2005] All ER (D) 124 (Oct), (approved judgment); see also Alex Berenson, *Pfizer Gets Mixed Verdict in British Lipitor Patent Case*, N.Y. TIMES, Oct. 13, 2005, at C3.

49. Berenson, *supra* note 48, at C3.

50. See Todd Benson, *Brazil to Copy AIDS Drug Made by Abbott*, N.Y. TIMES, Jun. 25, 2005, at C12.

51. *Id.*

52. See Todd Benson, *Brazil and U.S. Maker Reach Deal on AIDS Drug*, N.Y. TIMES, Jul. 9, 2005, at C2.

53. See JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS (UNAIDS) AND WORLD HEALTH ORGANIZATION (WHO), AIDS EPIDEMIC UPDATE, DECEMBER 2005 (2005), Doc. UNAIDS/05.19E, available at [http://www.unaids.org/epi/2005/doc/EPIupdate2005\\_en.pdf](http://www.unaids.org/epi/2005/doc/EPIupdate2005_en.pdf).

and almost 6 percent are children under fifteen years of age.<sup>54</sup> The number of people living with HIV increased in almost all regions of the world from 2003 to 2005.<sup>55</sup> In 2005, there were 4.9 million individuals newly infected with HIV and approximately 3 million AIDS deaths; of these deaths more than half a million were children.<sup>56</sup> While two-thirds of people living with HIV reside in sub-Saharan Africa, both Asia and Eastern Europe witnessed growing numbers of new HIV infections.<sup>57</sup> Additionally, the number of women living with HIV continued to climb.

In a number of African nations, 20 percent to 30 percent of pregnant women are HIV positive.<sup>58</sup> Moreover, although effective methods of preventing maternal-child transmission of HIV are available in the industrialized world, these interventions continue to be largely unavailable to women and children in developing countries.<sup>59</sup> The situation for children is compounded by the fact that fewer than 10 percent of children living with HIV/AIDS have access to treatment.<sup>60</sup> In an effort to highlight this and other issues facing children living with HIV/AIDS, in October 2005, UNAIDS and UNICEF launched the *Unite for Children, Unite Against AIDS* campaign aimed at raising awareness of pediatric HIV/AIDS issues.<sup>61</sup>

Access to treatment remained an issue for individuals of all ages, particularly in the developing world. UNAIDS and WHO continued the 3 by 5 Initiative, launched in 2003 with the aim of providing antiretroviral therapy to three million people living with AIDS in the developing world by the end of 2005.<sup>62</sup> In June 2005, UNAIDS and WHO announced that although coverage of the target population with HIV antiretroviral therapy had nearly doubled under the program, this resulted in only one million people receiving antiretroviral therapy in the developing world, well short of the program's goals.<sup>63</sup> The good news is that there has been steady progress toward greater access to antiretroviral therapy in areas of Africa, Asia and Eastern Europe.<sup>64</sup> Regions of concern remain, however, in many areas including the Russian Federation, Ukraine, North Africa, and the Middle East.<sup>65</sup> Additionally, it is unclear how accurate certain statistics (e.g., HIV incidence and prevalence) are for some developing countries. For instance, although UNAIDS data ranks South Africa as

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54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. See INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, REVIEW OF THE HIVNET 012 PERINATAL HIV PREVENTION STUDY (The Nat'l Acads. Press 2005).

60. See Kofi Annan, Remarks Accompanying Launch of Unite for Children Unite Against AIDS Campaign at U.N. Headquarters in New York (Oct. 25, 2005), available at [http://www.unicef.org/uniteforchildren/press/press\\_29411.htm](http://www.unicef.org/uniteforchildren/press/press_29411.htm).

61. See Press Release, UNICEF, Unite for Children, Unite Against AIDS, Children: The Missing Face of Aids, UNICEF and UNAIDS Launch Global Campaign to Invigorate Action for the Millions of Children Affected with HIV/AIDS (Oct. 25, 2005), available at [http://data.unaids.org/Media/Press-Releases03/PR\\_UNICEF\\_25Oct05\\_en.pdf?preview=true](http://data.unaids.org/Media/Press-Releases03/PR_UNICEF_25Oct05_en.pdf?preview=true).

62. See World Health Organization, About the 3 by 5 Initiative (2005), <http://www.who.int/3by5/about/initiative/en/index.html>.

63. See UNAIDS & WHO, PROGRESS ON GLOBAL ACCESS TO HIV ANTIRETROVIRAL THERAPY: AN UPDATE ON "3 BY 5" (June 2005), available at <http://www.who.int/3by5/fullreportJune2005.pdf>.

64. *Id.*

65. *Id.*



having the highest rate of HIV infection, some experts believe that India's rate of HIV infection may actually be higher.<sup>66</sup>

Concerns also continued during 2005 about the disparate treatment of individuals living with HIV/AIDS and the organizations that advocate for them. The U.S. Court of Appeals for the Ninth Circuit held that a Mexican national was statutorily eligible for asylum in the United States based on persecution and discrimination he would face in Mexico as a homosexual man with AIDS.<sup>67</sup> In a case in New York City, a group providing housing and services to people living with HIV/AIDS sued the city and city officials alleging that the city violated its rights under the First and Fourteenth Amendments in response to its opposition to the city's AIDS policies.<sup>68</sup> Although this case has not yet been decided, it demonstrates the tension that exists, even in industrialized nations, between people living with HIV/AIDS and local government officials.

Despite certain tensions, 2005 was a year of forward momentum in the fight against HIV/AIDS. Progress was made in early 2005 with the advent of global partnerships in HIV vaccine development at the first WHO/UNAIDS Meeting of Global Partners Promoting HIV Vaccine Research and Development.<sup>69</sup> Additionally, in October 2005, approximately two hundred HIV vaccine stakeholders participated in the Third Forum of the African AIDS Vaccine Programme in Cameroon.<sup>70</sup> The conference covered National HIV Vaccine Plans, the Global HIV Vaccine Enterprise, the International AIDS Vaccine Initiative, and the South African AIDS Vaccine Initiative, as well as development strategies and various medical, legal, and ethical issues associated with vaccine development.<sup>71</sup> Perhaps the most disturbing news on the vaccine front was a study of high-risk women in Kenya which demonstrated that re-infection with a new strain of HIV-1 was almost as common as first infection.<sup>72</sup> The implication of this study is that the immune response generated from vaccination may not be sufficient to ward off future infections.<sup>73</sup>

On the geopolitical front, the G8 Summit in Gleneagles, Scotland resulted in a number of positive commitments related to HIV/AIDS. Among these were agreements to double aid to Africa by 2010, immediately write off the debts of eighteen of the world's poorest countries, work toward universal access to HIV/AIDS treatment by 2010, and increase

66. See BBC News, *HIV is 'Out of Control' in India*, Apr. 19, 2005, available at <http://www.aegis.org/news/bbc/2005/BB050413.html>.

67. *Boer-Sedano v. Gonzales*, 418 F.3d 1082 (9th Cir. 2005) (stating that "Boer-Sedano would face significant social and cultural constraints as a gay man with AIDS in Mexico, as hostility towards and discrimination against HIV/AIDS patients is common in Mexico.")

68. *Hous. Works, Inc. v. Turner*, 362 F. Supp. 2d 434 (S.D.N.Y. 2005).

69. See Joint Press Release, UNAIDS & WHO, *HIV Vaccine Global Partners Strengthen Collaboration to Speed Up Progress* (Feb. 7, 2005), available at [http://data.unaids.org/media/Press-Releases03/PR\\_Vaccine\\_07Feb05\\_en.pdf](http://data.unaids.org/media/Press-Releases03/PR_Vaccine_07Feb05_en.pdf).

70. See Joint Press Release, UNAIDS & WHO, *Third Forum of the African AIDS Vaccine Programme: Africa Takes Action to Overcome Challenges for HIV Vaccine Development (2005)*, Doc. WHO/UNAIDS/53, available at <http://www.who.int/mediacentre/news/releases/2005/pr53/en/index.html>.

71. *Id.*

72. Mark Mascolini, *HIV Reinfection Almost as Common as First Infection*, INT'L AIDS Soc'y, July 30, 2005, available at <http://www.iasociety.org/article/show.asp?article=3657> (discussing Bhavna Chochan et al., *Evidence for Frequent Reinfection with Human Immunodeficiency Virus Type 1 of a Different Subtype*, 79 J. VIROLOGY 10,701 (Aug. 2005)).

73. Chochan, *supra* note 71, at 10,701.

children's access to education and health care by 2015.<sup>74</sup> Additionally, UNAIDS, France, the United Kingdom, and the United States convened a meeting in London in March 2005, entitled *Making the Money Work*, with the aim of achieving greater coordination, increased financial commitments, and measurable targets and indicators to address HIV/AIDS.<sup>75</sup>

Financial concerns continued to be part of the fight against HIV/AIDS. In 2005, UNAIDS reported that \$22 billion would be needed by 2008 to reverse the spread of AIDS in the developing world.<sup>76</sup> While this is a large number by any standard, renewed financial commitments from the private and public sectors were obtained. The Global Fund approved \$362 million in new grant funding, with AIDS grants accounting for 40 percent of this amount.<sup>77</sup> The United States awarded a \$77 million contract to a consortium of companies and charities to help manage the flow of AIDS drugs to Africa.<sup>78</sup> The Bill and Melinda Gates foundation continued its financial commitment to address disease in the developing world, having already contributed almost \$1.5 billion to HIV, tuberculosis, and reproductive health.<sup>79</sup>

Overall, 2005 was a year of renewed challenges and commitments with regard to HIV/AIDS. Efforts to raise awareness and provide education continue to shed greater light on the lives of people with HIV/AIDS and the issues they face. And, increasingly, not only researchers, scientists, physicians, and patients, but also governments and geopolitical organizations, are focusing attention and resources on meeting the challenge of HIV/AIDS.

#### IV. Stem Cell Research and Funding

##### A. INTERNATIONAL

For over two years, the international community attempted to reach an agreement on the controversial issue of human cloning. Finally, on February 18, 2005, the legal committee of the U.N. General Assembly voted, by a slim majority, in favor of an agreement that encourages members to adopt legislation prohibiting "all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."<sup>80</sup> This non-binding agreement was based on a proposal submitted by Italy in November 2004, which was drafted as a compromise between two deeply divided groups.<sup>81</sup> On one hand, the proposal submitted by Costa Rica, and endorsed by the United States, advocated for a complete ban on all forms of cloning. On the other hand, the proposal submitted by Belgium, and

74. See G8 Gleneagles 2005, Policy Issues: Africa, <http://www.g8.gov.uk/servlet/Front?pagename=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1094235520151> (last visited Feb. 27, 2006).

75. See Press Release, UNAIDS et al., UNAIDS, UK, France and the US Call For Coordinated Global Action to Reverse AIDS (Mar. 9, 2005), available at [http://data.unaids.org/media/Press-Releases03/PR\\_Coordination\\_09Mar05\\_en.pdf](http://data.unaids.org/media/Press-Releases03/PR_Coordination_09Mar05_en.pdf).

76. See Press Release, UNAIDS & WHO, US\$22 Billion Needed in 2008 to Reverse Spread of AIDS (Jun. 21, 2005), available at [http://data.unaids.org/media/Press-Releases03/PR\\_FUNDING\\_22June05\\_en.pdf](http://data.unaids.org/media/Press-Releases03/PR_FUNDING_22June05_en.pdf).

77. See Press Release, The Global Fund, The Global Fund Approves US\$382 Million Worth of New Grants (Sept. 30, 2005), available at [http://www.theglobalfund.org/en/media\\_center/press/pr\\_050930.asp](http://www.theglobalfund.org/en/media_center/press/pr_050930.asp).

78. See *AIDS Drugs for Africa*, N.Y. TIMES, Sept. 28, 2005, at A7.

79. See Bill and Melinda Gates Foundation, Global Health Grants 2005, <http://www.gatesfoundation.org/GlobalHealth/Grants/default.htm?showYear=2005>.

80. Alison McCook, *UN Bans Reproductive Cloning*, THE SCIENTIST, Feb. 21, 2005, at 20050221-01, available at <http://www.the-scientist.com/news/20050221/01/>.

81. *Id.*

endorsed by the United Kingdom, provided for a complete ban on human reproductive cloning, while nevertheless permitting member states to address therapeutic cloning in an individual manner.<sup>82</sup>

Subsequently, on March 3, 2005, the U.N. General Assembly adopted, by a vote of eighty-four in favor (including the United States), thirty-four against, and with thirty-seven abstentions, the U.N. Declaration on Human Cloning.<sup>83</sup> The Declaration reiterates the essential wording of the legal committee's agreement and calls on U.N. member states to adopt legislation "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."<sup>84</sup> Pursuant to the Declaration, member states are also encouraged to "protect adequately human life in the application of life sciences; to prohibit the application of genetic engineering techniques that may be contrary to human dignity; to prevent the exploitation of women in the application of life sciences; and to adopt and implement national legislation in that connection."<sup>85</sup>

Delegations that voted against the Declaration cited the ambiguity of its terms as the primary reason for their negative vote. In their view, the reference to "human life" allows for an interpretation pursuant to which all forms of cloning, including therapeutic cloning, would be banned. Nevertheless, in view of their commitment to ongoing research in the field of therapeutic cloning, they intimated that the non-binding Declaration would not affect their current research position. Delegations that voted in favor of the Declaration were confident that it constituted significant progress in the direction of a complete ban on human cloning and greater protection of human dignity and human rights.<sup>86</sup>

## B. NATIONAL—UNITED STATES AND UNITED KINGDOM

In 2005, legislative efforts in the field of stem cell research and funding continued in both the United States<sup>87</sup> and the United Kingdom. The U.S. Congress considered several bills on stem cell research.<sup>88</sup> In particular, in May 2005, the U.S. House of Representatives passed a Republican-backed proposal pursuant to which federal funds would be used for research on stem cells harvested from adults and umbilical cord blood.<sup>89</sup> It also passed a

82. See Namrita Talwar, *Searching for Consensus in International Law*, U.N. CHRON., Jan. 2005, at 28, available at <http://www.un.org/Pubs/chronicle/2005/issue1/0105p28.html>.

83. United Nations Declaration on Human Cloning, G.A. Res. 59/280, U.N. Doc. A/RES/59/280 (Mar. 23, 2005); see also Press Release, U.N. Gen. Assembly, The United Nations Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37, U.N. Doc. GA/10333 (Mar. 8, 2005), available at <http://www.un.org/News/Press/docs/2005/ga10333.doc.htm>.

84. United Nations Declaration on Human Cloning, *supra* note 83, ¶ (b).

85. Press Release, U.N. Gen. Assembly, *supra* note 83.

86. *Id.*

87. At the state level, Connecticut has joined California, New Jersey, and Wisconsin in providing public financing for stem cell research. See Fran Silverman, *\$100 Million Commitment for Stem Cell Research*, N.Y. TIMES, Jun. 19, 2005, at C14.

88. See, e.g., Matthew Davis, *Emotive Power of US Stem Cell Debate*, BBC NEWS, May 25, 2005, available at <http://news.bbc.co.uk/1/hi/world/americas/4580299.stm>; *Bush 'Would Veto' Stem Cell Bill*, BBC NEWS, May 20, 2005, available at <http://news.bbc.co.uk/1/hi/world/americas/4567253.stm>; Dana Bash & Ed Henry, *Bush Threatens Veto on Stem Cell Research Bill*, CNN, May 20, 2005, <http://www.cnn.com/2005/POLITICS/05/20/bush.stem.cells/>; *House Passes Embryonic Stem Cell Bill*, CNN, May 25, 2005, <http://www.cnn.com/2005/POLITICS/05/24/stem.cells/>; *Cultural Differences in Stem Cell Research*, THE NEW SCIENTIST, June 4, 2005, <http://www.newscientist.com/article.ns?id=mg18625022.300>.

89. *Cord Blood Stem Cell Act of 2005*, H.R. 596, 109th Cong. (2005).

more controversial bill, the Stem Cell Research Enhancement Act<sup>90</sup> that provided for increased federal funding for research on stem cells harvested from embryos. President Bush threatened to veto the Act if passed.<sup>91</sup> In November 2005, however, an agreement was reached to defer a Senate debate over federal funding for stem cell research until Congress reconvenes in 2006.<sup>92</sup>

In the United Kingdom, following a commitment to update the Human Fertilisation and Embryology Act (1990),<sup>93</sup> on August 16, 2005, the British government began a comprehensive examination of the current framework “governing the technology and techniques used to assist human reproduction and embryo research.”<sup>94</sup> This examination will consider a broad range of topics, in particular the rules relating to the selection of embryos for medical purposes and the definition of embryo for research purposes.<sup>95</sup> Notwithstanding the adoption of the U.N. Declaration on Human Cloning, the debate over whether all embryonic stem cell research, including measures that allow for therapeutic cloning, should be banned still continues. In the interim, countries remain free to, and do, take individual positions in their national legislation. As a result, despite the apparent international agreement, in practice we remain far from a uniform standard for all.

## V. Other Notable Developments

### A. TOBACCO

In February 2005, the WHO Framework Convention on Tobacco Control (FCTC) entered into force.<sup>96</sup> It is the first international treaty designed to reduce tobacco-related disease and deaths.<sup>97</sup> The FCTC requires states parties to “adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other [countries] in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.”<sup>98</sup> In particular, the FCTC requires that states parties (1) implement restrictions on tobacco advertising, sponsorship and promotion; (2) establish new packaging and labelling guidelines for tobacco products; (3) establish clean indoor air controls; (4) implement or revise legislation to eliminate tobacco smuggling; and (5) prohibit the sale of tobacco products to minors.<sup>99</sup>

90. *Stem Cell Research Enhancement Act of 2005*, H.R. 810, 109th Cong. (2005).

91. *Id.*

92. See Carl Hulse, *Senate Pushes Back Debate on Stem Cell Research to '06*, N.Y. TIMES, Oct. 22, 2005, at A18.

93. Human Fertilisation and Embryology Act 1990, c. 37 (Eng.).

94. Stephen Pincock, *UK Consults on Embryo Law*, THE SCIENTIST, Aug. 18, 2005, at 2005086-01, available at <http://www.the-scientist.com/news/20050816/01>.

95. *Id.*

96. WHO Framework Convention on Tobacco Control (2005), available at [http://www.who.int/tobacco/framework/WHO\\_FCTC\\_english.pdf](http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf) [hereinafter FCTC]. As of November 28, 2005, 168 countries had signed the FCTC and 114 had become states parties to the FCTC. For Ratification information, see <http://www.who.int/tobacco/framework/countrylist/en/index.html>. The United States has signed, but not ratified, the FCTC.

97. See World Health Organization, *An International Treaty for Tobacco Control* (Aug. 12, 2003), available at <http://www.who.int/features/2003/08/en/>. Currently, over 1.2 billion people in the world smoke and approximately 4.9 million tobacco-related deaths occur each year, more than the annual number of deaths related to AIDS, legal drugs, illegal drugs, road accidents, murder and suicide combined. *Id.*; see also WORLD HEALTH ORGANIZATION, *BUILDING BLOCKS FOR TOBACCO CONTROL: A HANDBOOK 6* (2004).

98. FCTC, *supra* note 96, at art. 5(2)(b).

99. See generally *id.*

## B. NATURAL DISASTERS

The combined devastation of Hurricanes Katrina and Rita, which most severely affected residents of the Gulf Coast, brought into focus significant gaps in U.S. emergency response and public health systems.<sup>100</sup> People who remained in New Orleans and other heavily affected areas during and after the hurricanes struggled to find adequate food, shelter, and clean water. Many struggled simply to stay alive. Tragically, 1253 individuals died as a result of the combined impact of Hurricanes Katrina and Rita.<sup>101</sup>

Immediately following the hurricanes, basic public health issues presented a challenge for authorities. Disease surveillance and infection control activities—both in storm-ravaged areas and in evacuation centers—were implemented by local, state, and national public health authorities. However, these and other health care activities were complicated by infrastructure disruptions, the large number of displaced persons, and numerous other challenges.<sup>102</sup> Additionally, there were allegations that public health concerns were downplayed by those in positions of authority.<sup>103</sup> Perhaps one of the most salient public health lessons of Hurricane Katrina is the inadequacy of the current U.S. system to deal with large-scale disasters, particularly where infrastructure is significantly disrupted. In the wake of these natural disasters, a number of legal questions have surfaced. There have been questions about the award of government contracts by the Federal Emergency Management Agency<sup>104</sup> and others, as well as a number of questions regarding states' rights, federalism, and the role of the military in domestic disaster response efforts.<sup>105</sup> While it remains unclear how these and other relevant issues will be resolved, there is now, perhaps, the public attention and political will to address them.

## VI. Conclusion

The increased coverage provided to these and other related developments reflects the growing prominence given to international health issues on the agendas of governments,

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100. U.S. Gov't Accountability Office, *Hurricane Katrina Providing Oversight of the Nation's Preparedness, Response, and Recovery Activities*, Statement of Norman J. Robkin, Managing Director of Homeland Security and Justice Issues, Testimony Before H.R. Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, GAO-05-1053T (Sept. 28, 2005), available at <http://www.gao.gov/new.items/d051053t.pdf>; Press Release, Oxfam America, *Oxfam Team Finds Glaring Gaps in Disaster Assistance in Biloxi* (Sept. 16, 2005), available at [http://www.oxfamamerica.org/whatwedo/emergencies/hurricane\\_katrina/news\\_publications/feature-story.2005-09-16.3217315061](http://www.oxfamamerica.org/whatwedo/emergencies/hurricane_katrina/news_publications/feature-story.2005-09-16.3217315061).

101. See Centers for Disease Control, *Update on CDC's response to Hurricanes* (Oct. 7, 2005), <http://www.cdc.gov/od/katrina/>.

102. See U.S. Gov't Accountability Office, *supra* note 100 (noting that "most emergency departments across the country lacked the capacity to respond to large-scale infectious disease outbreaks."); see also, Centers for Disease Control, *Update on CDC's Response to Hurricane Katrina* (Sept. 6, 2005), <http://www.cdc.gov/od/katrina/09-06-05.htm>.

103. See John Heilprin, *Some Say Officials Downplay New Orleans Health Dangers*, HOUSTON CHRON., Oct. 6, 2005, available at <http://www.chron.com/disp/story.mpl/special/05/katrina/3385927.html> (discussing the presence of "high levels of bacteria, fecal contamination, metals, fuel oils, arsenic and lead" in addition to other health concerns).

104. See John J. Pavlick, Jr. & Rebecca E. Pearson, *Learning from Katrina: Build a Better Emergency Response With Multiple-Award Contracts*, LEGAL TIMES, Nov. 7, 2005.

105. STEVE BOWMAN ET AL., HURRICANE KATRINA: DOD DISASTER RESPONSE, CRS REPORT FOR CONGRESS (Sept. 19, 2005) (discussing the role of the National Guard in response to natural disasters, in particular addressing the issue that the National Guard may "act under state control or may be federalized . . .").

international organizations, non-governmental organizations, and the private sector. Today, good governance and effective management require states and private organizations to prepare for, and take account of, issues such as outbreaks of infectious disease, the impact of HIV/AIDS, the challenge of balancing patent protections with the public's health needs, and implications of other public health issues. The question is no longer whether we can meet the public health needs of the general population—we must. Rather, the question is how best to go about doing so. The developments of 2005 reflect some of the efforts undertaken at the national, regional, and international levels to meet these increasing global health demands.