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I. Introduction

2007 saw numerous health law issues impact the international community and garner world-wide attention. Some of these issues involved business and financial concerns related to international health law (e.g., patents, trade, business development, and pharmaceutical pricing); others pertained to the myriad ways in which the health of individuals and communities around the world can be impacted by health-related laws and regulations. The events of 2007 seem to highlight, once again, that globalization is occurring more quickly than the law on pertinent topics is emerging. As this trend continues, the international health law community will be challenged to keep pace, to establish and maintain relevant rule of law initiatives, and to become more proactive in establishing broad-based and widely-accepted, enforceable standards that the global community can agree upon and that will positively impact the health of individuals and communities.

II. Trade and Intellectual Property Law

A. PATENT LAWS

Efforts to conform U.S. patent laws to international standards continued in 2007, with discussions between the United States and other "Group B-Plus" countries.[1] Although these discussions were ostensibly intended to result in an international patent harmonization treaty, accord has yet to be reached on several critical issues. In particular, the European Union and others have insisted on uniform recognition of a "first to file" patent

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1. "Group B-Plus" countries are members of the World Intellectual Property Organization (WIPO) and include Australia, Canada, the European Patent Convention Member States, the European Union Member States, Japan, New Zealand, Norway, and the United States. *See Comments Sought on Harmonization of U.S. Patent Laws with Those of Other Countries*, 74 PAT.,TRADEMARK & COPYRIGHT J. (BNA) 67, 67-68 (2007).

standard,[2] which is not consistent with the "first to invent" standard under current U.S. law. A "grace period" has been offered as a potential solution, permitting patent protection if information relevant to the patent application has entered the public domain. But the United States and other countries have not reached agreement on the scope of such a grace period, with the United States requesting an eighteen-month grace period and other countries seeking a limited application of the grace period.[3] Further discussions between the Group B-Plus countries have been proposed,[4] but legislation pending in both houses of the U.S. Congress would change the U.S. priority standard to the generally favored first to file, presumably rendering negotiations over the scope of a grace period moot.[5]

In addition to harmonization, patent law regimes in developing countries remain a fertile ground for legal challenges by multinational drug manufacturers. For example, recent changes to Indian patent law demonstrate controversies arising from jurisdiction-specific patentability standards. In May 2006, Novartis AG filed an action challenging the Indian patent office's rejection of a patent application covering the Novartis oncology drug Gleevec. The Indian patent office based its rejection on section 3(d) of the Indian patent statute, which precludes patenting modifications or new uses of an existing drug unless such modifications or new uses significantly increase the drug's effectiveness.[6] Novartis argued that section 3(d) was in violation of the Indian Constitution and the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). On August 6, 2007, the Madras High Court in Chennai rejected the constitutional challenge but deferred conclusion as to TRIPS compliance to the WTO.[7] Novartis has also filed a separate appeal with the Indian Intellectual Property Appellate Board concerning the patentability of Gleevec under Indian patent law.[8]

B. World Trade Organization

In December 2005, WTO members adopted a public health amendment to TRIPS, instituting an August 2003 WTO agreement allowing greater utilization of compulsory licenses to export generic pharmaceuticals to countries lacking production capabilities sufficient to produce the pharmaceuticals in-country.[9] While the proposed TRIPS amend-

2. Under the "first to file" standard, patent protection arises only from the date of patent filing. By contrast, under the "first to invent" standard under current United States law, patent protection is granted from the time an invention is made.

3. One limited application could arise in the context of academic research, where publication demands may require public disclosure of patentable subject matter prior to the filing of a patent application.

4. *See* Daniel Pruzin, *Unresolved Issues Stall Developed Country Talks on Global Patent Treaty*, 74 PAT., TRADEMARK & COPYRIGHT J. (BNA) 410 (2007).

5. H.R. 1908 and S. 1145 were approved respectively by the House and Senate Judiciary Committees in July 2007. *See, e.g.*, Anandashankar Mazumdai & Yousef Siddiqui, *Senate Judiciary Accepts Amendments to Patent Reform Bill, More Markup Expected*, 74 PAT.,TRADEMARK & COPYRIGHT J. (BNA) 341 (2007); *Senate Judiciary Committee Approves Patent Reform Bill in Evening Session*, 74 PAT.,TRADEMARK & COPYRIGHT J. (BNA) 370 (2007).

6. *See* The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, *available at* http://indiacode.nic.in/fullact1.asp?tfnm=200515.

7. *Novartis, Advocacy Group React to Indian Court's Rejection of Patent Law Challenge*, 74 PAT., TRADEMARK & COPYRIGHT J. (BNA) 455 (2007).

8. *Id.*

9. *See, e.g.*, William New, *Views Mixed on WTO Doha Declaration on Public Health After Five Years*, INTELLECTUAL PROPERTY WATCH, Nov. 16, 2006, *available at* http://www.ip-watch.org/weblog/index.php?p=460.

ment was formally accepted by WTO members in December 2005, it will not become effective until ratified by two-thirds of the WTO's 151 members. December 1, 2007, was initially established as the date by which the WTO expected to have the necessary ratifications. By that date, however, only eleven members had ratified the amendments, with the European Parliament recently ratifying the amendment and opening the door to ratification by European Union Member States.[10] Due to the extended length of time this process is taking, WTO members agreed in October 2007 to delay the ratification deadline until December 1, 2009.[11]

Although this amendment has not yet taken effect, a number of countries argue that such compulsory licensing is already permissible under TRIPS. For example, in late 2006, Thailand announced that it would use compulsory licensing as permitted under TRIPS for antiviral AIDS drugs efavirenz[12] and lopinavir/ritonavir[13] and for the cardiac therapy drug clopidogrel.[14] But Thailand's Health Minister Mongkol na Songkhla stated on May 15, 2007, that Thailand would not enforce such compulsory licenses if the companies responsible for these drugs "agree to reduce the price of their drugs below generic ones."[15] On May 4, 2007, after failing to reach a negotiated agreement with Merck,[16] Brazil issued a compulsory license for efavirenz, stating that it would import the drug from India and pay a royalty to Merck of 1.5 percent. [17] Finally, on July 19, Rwanda notified the WTO of its intention to import 260,000 packages of the antiviral cocktail Apo-triAvir[18] pursuant to TRIPS.[19]

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10. *See, e.g.*, International Centre for Trade and Sustainable Development, *European Parliament Ratifies TRIPS Amendment*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST 36, Oct. 24, 2007, *available at* http://www.ictsd.org/weekly/07-10-24/story2.htm. If each European Union Member State ratifies the amendment, the number of ratifying WTO members will rise to thirty-eight. *Id.*

11. *See id.*

12. Marketed by Merck & Co. under the brand name Stocrin.

13. Marketed by Abbott Laboratories under the brand name Kaletra.

14. Marketed by Bristol-Myers Squibb under the brand name Plavix.

15. *PhRMA Chief Says Thai Officials Indicate They Still Want Negotiations on Drug Prices*, 74 PAT., TRADEMARK & COPYRIGHT J. (BNA) 156 (2007) (May 15, 2007 statement made during conference call from Geneva, Switzerland).

16. Brazil offered to purchase efavirenz from Merck at $0.65 per pill, a price equivalent to the price paid to Merck by Thailand for efavirenz. Merck countered with an offer to reduce the per pill cost by 30 percent to $1.10. *See* Ed Taylor, *Brazil Breaks Patent on Merck AIDS Drug*, 74 PAT., TRADEMARK & COPYRIGHT J. (BNA) 65, at 65-66 (2007).

17. *Id.*

18. Apo-triAvir, manufactured by Apotex, Inc., is a combination therapy consisting of Zidovudine, Lamivudine, and Nevirapine.

19. *See Rwanda Notifies WTO of Plans to Import Medicines Under New TRIPS Rules*, 74 PAT., TRADEMARK & COPYRIGHT J. (BNA) 412 (2007). It is noteworthy that neither Brazil nor Thailand is required to apply the proposed TRIPS amendment to issue compulsory licenses for efavirenz, as each intended to import generic copies from India where the drug is not patented. But Rwanda has proposed to import Apo-triAvir from Canada under WTO procedures identical to the proposed amendment. *See* International Centre for Trade and Sustainable Development, *Canadian WTO Notification Clears Path for Rwanda to Import Generic HIV/AIDS Drug*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST 34, Oct. 10, 2007, *available at* http://www.ictsd.org/weekly/07-10-10/story4.htm.

C. World Health Organization

In 2007, the World Health Organization (WHO) continued to emphasize its strong interest in the application of TRIPS in service of its mission to promote increased access to pharmaceuticals and its intention to provide guidance and assistance regarding TRIPS-related matters. At the close of the World Health Assembly on May 23, 2007, the Assembly reached agreement on a resolution requesting that the WHO Director-General continue to support the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IWG) and guide the IWG in the creation of a strategy and plan of action.[20] Additionally, the May 23 WHO resolution directed the Director-General "to provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities" authorized under TRIPS.[21] On July 31, 2007, the IWG issued its draft strategy and plan of action to promote "needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries."[22] To be implemented in full by 2015, the proposed global strategy acknowledges the vital importance of intellectual property in research and development but stresses that "alternative and/or additional incentive schemes for research and development" into certain diseases should be explored and implemented.[23]

The WHO also continues to expand its international clinical trial registry in order to promote transparency with regard to clinical research and the dissemination of information concerning diseases and potential treatments. On July 25, 2007, the WHO announced that registers from China and India would be included in the WHO registry.[24]

It should be noted that response to the WHO's initiatives concerning public health, intellectual property, and innovation has not been uniformly positive. The United States did not endorse the May 23, 2007, World Health Assembly resolution, and international pharmaceutical companies have been outspoken in their disagreement with the WHO's strategy pertaining to intellectual property matters.[25]

D. United States Trade Representative

The United States Trade Representative (USTR) has continued to promote protection and enforcement of intellectual property rights (IPR) and innovation, creating in June 2006 a new Office of Intellectual Property and Innovation and appointing a Chief Negoti-

20. Press Release, World Health Organization, World Health Assembly Closes: Agreement Reached on Influenza Virus Sharing, Intellectual Property (May 23, 2007), *available at* http://www.who.int.mediacentre/news/releases/2007/wha02/en/index.html [hereinafter WHA Closes].

21. Daniel Pruzin, *WHO Urged to Aid Governments in Implementing TRIPS/Medicines Deal*, 74 Pat., Trademark & Copyright J. (BNA) 157 (2007); *see also* WHA Closes, *supra* note 20.

22. WHO, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Report by the Secretariat: Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, A/PHI/IGWG/2/2 (Jul. 3, 2007), at 3, *available at* http://www.who.int/gb/phi/E/index_E.html.

23. *Id.* at 8.

24. *See* Press Release, World Health Organization, China and India Join WHO Clinical Trial Registry Platform (Jul. 25, 2007), *available at* http://www.who.int/mediacentre/news/releases/2007/pr41/en/index.html.

25. *See, e.g.*, Daniel Pruzin, *Drug Industry Slams WHO Draft Global Strategy for Public Health Rights, IP Rights*, 75 Pat., Trademark & Copyright J. (BNA) 42, 42-43 (2007).

ator for Intellectual Property Enforcement. In its annual Special 301 Report,[26] the USTR again highlighted its concerns with respect to IPR protection by China and Russia. The USTR indicated that while the United States and Russia entered into a bilateral market access agreement in November 2006, Russia would nonetheless be subject to an "Out-of-Cycle Review"[27] to evaluate progress in IPR protection; additionally, the USTR has filed requests for WTO dispute settlement consultations with China to address deficiencies in China's legal protection and enforcement of trademarks and copyrights on a wide range of products, as well as China's barriers to trade in books, videos, and music.[28] Specifically, the USTR has alleged violations of TRIPS related to three aspects of China's IPR regime: (1) "quantitative thresholds in China's criminal law" to initiate prosecution for copyright piracy and trademark counterfeiting; (2) "rules for disposal of IPR-infringing goods seized by Chinese customs authorities"; and (3) "denial of copyright protection for works poised to enter the market but awaiting Chinese censorship approval."[29]

The USTR 2007 Special 301 Report articulates the following concern with the global trade in counterfeit pharmaceuticals:

> The manufacture and distribution of counterfeit pharmaceuticals is a growing problem that poses special concerns for consumer health and safety. The United States notes its concern with the proliferation of the manufacture of counterfeit pharmaceuticals in China, India, and Russia, and the sale and distribution of counterfeit pharmaceuticals in many countries. A significant contributing factor in this problem is the unauthorized use of bulk active pharmaceutical ingredients (APIs) to manufacture counterfeit pharmaceuticals. Countries must do more to provide its [sic] relevant agencies with the authority to regulate and enforce against the unauthorized use of APIs domestically and to ensure that they are not exported for unauthorized use abroad. Also, countries must do more to enforce vigilantly against the manufacture and distribution of counterfeit pharmaceuticals.[30]

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26. OFFICE OF THE U.S. TRADE REPRESENTATIVE, SPECIAL 301 REPORT 5 (2007), *available at* http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf [hereinafter SPECIAL 301 REPORT]. "The 'Special 301' Report is an annual review of the global state of intellectual property rights (IPR) protection and enforcement, conducted by the Office of the United States Trade Representative (USTR) pursuant to Special 301 provisions of the Trade Act of 1974." *Id.* at 2.

27. An "Out-of-Cycle Review" is a review by the USTR of a country's IPR policies and practices generally undertaken outside the standard annual review. Other countries to be subject to an Out-of-Cycle Review in 2007-2008 include Brazil, the Czech Republic, and Pakistan. *See id.* at 8, 30, 34.

28. *See id.* at 15-16.

29. Press Release, Office of the United States Trade Representative, United States Requests WTO Panel in Case Challenging Deficiencies in China's Intellectual Property Rights Laws (Aug. 13, 2007), available at http://www.ustr.gov/Document_Library/Press_Releases/2007/August/United_States_Requests_WTO_Panel_in_Case_Challenging_Deficiencies_in_China's_Intellectual_Property_Rights_Laws.html.

30. SPECIAL 301 REPORT, *supra* note 26, at 6. The WHO estimates that counterfeit pharmaceuticals comprise approximately 1% of sales in developed countries, more than 10% in developing countries, more than 20% in former Soviet republics, and approximately 30% in parts of Africa, Asia, and Latin America. *See* Press Release, World Health Organization, WHO-Led Anti-Counterfeiting Coalition Examines Technology to Prevent Fake Drugs (Mar. 13, 2007), *available at* http://www.who.int/mediacentre/news/releases/2007/pr07/en/index.html.

While this statement addresses the potential public health risks arising from counterfeit pharmaceuticals, the 2007 Special 301 Report also provides further documentation of continued USTR preference for strong intellectual property protection and the apparent tension between policies of innovation and public health. For example, while the 2007 Special 301 Report does not directly condemn Thailand's use of compulsory licensing under TRIPS, acknowledging a "country's ability to issue such licenses in accordance with WTO rules," it raises concerns with "the lack of transparency and due process" involved in Thailand's decision.[31] Similarly, while the 2007 Special 301 Report downgraded Brazil from the USTR's "Priority Watch List" to the "Watch List," the USTR urges that Brazil engage "in open and transparent discussions with all relevant stakeholders" when it considers utilization of compulsory licenses, and it also noted that Brazil would be subject to an Out-of-Cycle Review, suggesting that utilization of compulsory licenses may be the focus of increased USTR scrutiny in the future.[32]

While the USTR acknowledges rights provided to countries under TRIPS, a 2007 U.S. Government Accountability Office (GAO) report, drafted at the request of members of the U.S. Congress, provides an analysis of what is sometimes viewed as the USTR's overemphasis on intellectual property protections at the expense of public health benefits arising from early and enhanced access to generic drugs.[33] Ultimately, the GAO report recommended congressional clarification of U.S. trade policy and public health policy in order to eliminate potential disparities between USTR practice and congressional intent.[34]

III. Transparency in Pharmaceutical Pricing

A. Regulating the Reimbursement and Pricing of Medicines

Governments continue to experiment with procedures for making decisions about the appropriate use of medicines in public health programs, including procedures that determine which medicines will be reimbursed, at what price, and for which patients.[35] In 2007, several countries moved to revisit and modify reimbursement and pricing schemes in an attempt to control drug prices. In February 2007, the United Kingdom's Office of Fair Trading (OFT) recommended a complete overhaul of the price and profit controls system utilized under the Pharmaceutical Pricing Regulation Scheme (PPRS), advising that the system be replaced with a value-based approach to pricing in order to more effectively utilize government funds allocated for healthcare services, as well as to provide drug

31. *Id.* at 27.

32. *Id.* at 30.

33. U.S. Gov't Accountability Office, U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification (Sept. 2007), *available at* http://www.gao.gov/new.items/d071198.pdf.

34. *Id.* at 58.

35. *See e.g.*, Alan Maynard & Karen Bloor, *Dilemmas in the Regulation of the Market for Pharmaceuticals*, 22 Health Aff. 31 (2003), *available at* http://content.healthaffairs.org/cgi/reprint/22/3/31.pdf; AARP Public Policy Inst., European Experiences with Prescription Drug Pricing (Oct. 2006), *available at* http://assets.aarp.org/www.aarp.org_/cs/gap/ldrstudy_prescdrugs.pdf.

companies with better incentives to invest in drugs that would benefit patients.[36] Japan's Ministry of Health, Labor, and Welfare followed with an announcement in May 2007 that the Ministry is considering policies to double the use of generic drugs by 2012.[37] And U.S. lawmakers proposed bills to improve consumer access to generic biologic drugs[38], as well as to allow the Department of Health and Human Services to negotiate Medicare Part D prices.[39]

Increased attention has been focused on the transparency of government reimbursement and pricing processes as well as on the opportunity for meaningful participation in the system by interested stakeholders, such as patients and drug companies. This year, for the first time, a drug manufacturer, Eisai Limited (Eisai),[40] filed a case in the United Kingdom High Court, challenging a decision by the National Institute for Health and Clinical Excellence (NICE) – a health authority within the National Health Service (NHS) that develops drug coverage guidance for the NHS – not to reimburse Alzheimer's drugs for patients with less severe forms of the disease.[41] Eisai argued that the process by which the decision was reached was procedurally unfair, irrational, and discriminated against certain patient groups. The High Court ruled that while the petitioner did not demonstrate that the decision was procedurally unfair or irrational, NICE's failure to provide sufficient guidance with respect to the treatment of atypical patient groups was discriminatory.[42] The High Court ruling does not require NICE to reconsider its initial coverage decision, and Eisai has filed an appeal to the Court of Appeal based on NICE's refusal to disclose the full record on which they based their decision.

The USTR also continued its focus on increased transparency in reimbursement and pricing decisions. In June 2007, the USTR finalized a bilateral free trade agreement (FTA) with South Korea that included provisions aimed at providing additional transparency and meaningful participation rights for interested stakeholders in the South Korean drug pricing and reimbursement process.[43] As part of South Korea's obligations, the government has committed to establishing an independent body – separate from the health authority responsible for making coverage and pricing decisions – to review coverage and pricing decisions for drugs and devices upon a company's request.[44] The U.S.-South Korea FTA builds upon the obligations set forth in the 2005 U.S.-Australia FTA[45]

36. OFFICE OF FAIR TRADING, THE PHARMACEUTICAL PRICE REGULATION SCHEME: AN OFT MARKET STUDY 5 (Feb. 2007), *available at* http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft885.pdf.

37. Tomoki Matsubara & Yasushi Kouchi, *The Brave New World of Generic Drugs*, DAILY YOMIURI (Tokyo), Jul. 11, 2007, at 4.

38. Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007).

39. Medicare Prescription Drug Price Negotiation Act of 2007, S. 3, 110th Cong. (2007).

40. Pfizer and the Alzheimer's Society participated in the case as interested parties.

41. *See* Eisai Ltd. v. Nat'l Inst. for Health & Clinical Excellence, [2007] EWHC (Admin) 1941 (England).

42. *See id.* at [60]-[61], [96], [116], [122].

43. Free Trade Agreement Between the United States and the Republic of Korea, U.S.-Korea, art. 5.3, June 30, 2007, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Final_Text/Section_Index.html [hereinafter U.S.-Korea FTA].

44. Confirmation Letter (Indep. Review Body) from Hyun Chong Kim, S. Korean Minister of Trade, to Hon. Susan Schwab, U.S. Ambassador (June 30, 2007), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Final_Text/asset_upload_file511_12725.pdf.

45. U.S.-Australia Free Trade Agreement, U.S.-Austl., Annex 2-C, art. 2 (May 18, 2004), available at http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html [hereinafter U.S.-Australia FTA]. The transparency provisions of the U.S.-Australia FTA include requirements for timely

but includes more detailed obligations with respect to rights of participation and transparent processes.[46]

IV. Individual and Community Rights Related to Public Health Law

A. The Example of Drug-resistant Tuberculosis

The widely-publicized case of Andrew Speaker, a patient with drug-resistant tuberculosis who traveled through a number of countries, including the United States, Greece, Italy, and Canada, served to underscore the lack of a clear, comprehensive, and standardized approach to sharing information and taking appropriate action quickly and efficiently in response to communicable diseases that may threaten the health of the international community.[47]

In the United States, this situation led to concerns about vulnerability to bioterrorism and subsequent congressional hearings reaffirmed the need to examine and update the system for addressing such issues.[48] Additionally, the incident raised concerns in the international community, and although the WHO added its voice to those criticizing the manner in which the United States handled the case, this incident also calls attention to the need for oversight and enforcement as individual countries attempt to establish a coherent system of health care laws and regulations consistent with the newly-revised International Health Regulations promulgated by the WHO.[49]

While the law has historically recognized that individual rights may be circumscribed for the public health benefit of the community (e.g., mandatory vaccinations, quarantine), there has almost always been some debate about where and how to draw the line between individual rights, the public health rights of the community, and the government's right to enforce public health laws and regulations.[50] Furthermore, there has traditionally been a significant debate regarding whether laws and regulations are an effective means to address communicable diseases or whether such laws make the situation worse by driving people underground, away from screening and treatment resources.

Another recent case that drew attention to these concerns and also raised the issue of whether current laws and regulations effectively address international travel and communicable diseases is that of Robert Daniels, who was born and diagnosed with tuberculosis

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decision-making, an opportunity for comment at key stages in the decision-making process, publication of procedural rules, access to detailed information on the basis for the decision, written information to the public concerning decision, and establishment of an independent review mechanism.

46. *Compare* U.S.-Korea FTA, *supra* note 43, art. 5.3, *with* U.S.-Australia FTA, *supra* note 45, Annex 2-C, art. 2.

47. *See* Denise Grady, *TB Patient Says Officials are Trying to Blame Him to Cover Mistakes*, N.Y. Times, June 9, 2007, *available at* http://www.nytimes.com/2007/06/09/us/09tb.html.

48. *See* Lawrence K. Altman & Jaqueline Palank, *TB Patient Gives His Account to Congress*, N.Y. Times, June 7, 2007, *available at* http://www.nytimes.com/2007/06/07/us/07tb.html.

49. *See* David Brown, *WHO Faults Handling of TB Case*, Wash. Post, June 6, 2007, at A3, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/06/05/AR2007060502438.html; *see* WHO, International Health Regulations (2005), http://www.who.int/csr/ihr/en/ (last visited Feb. 11, 2008).

50. *See, e.g.*, John D. Blum & Norchaya Talib, *Balancing Individual Rights Versus Collective Good in Public Health Enforcement*, 25 Med. & L. 273 (2006); Robyn Martin, Commentary, *The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications*, 14 Med. L. Rev. 132 (2006).

in Russia, then later, while still sick, flew to the United States.[51] In the United States, Daniels was diagnosed with drug-resistant tuberculosis, and after failing to comply with his treatment regimen, he was confined by court order to the jail unit of an Arizona hospital.[52] Daniels received medical treatment while in the jail unit, but he was also treated like an inmate (e.g., he could not leave, was subject to strip searches, and was not permitted to go outside the facility), and the situation became a case study for examining the wisdom of using the criminal justice system to address public health issues.[53] Due to concerns about violations of Daniels' civil rights, the American Civil Liberties Union (ACLU) sued on his behalf, arguing that his confinement was unconstitutional.[54] Following the filing of the ACLU lawsuit and almost a year after his confinement started, Daniels was transferred out of the jail unit and to a Colorado hospital for treatment.[55]

B. TRADE AND PUBLIC HEALTH

In addition to people traveling internationally, the global marketplace has resulted in increasing numbers of goods traveling internationally. A number of newsworthy stories in 2007 focused on the role of international trade, inconsistent health regulations, and ineffective enforcement mechanisms pertaining to international exposure to contaminants.

Toothpaste from China mixed with diethylene glycol, an antifreeze ingredient, was found in Panama, Costa Rica, Australia, the Dominican Republic, and the United States.[56] A similar situation occurred in Panama involving the same ingredient from China mixed into cold medicine and resulted in the deaths of at least 100 people.[57] Additionally, toys manufactured in China have been found to contain unacceptable levels of lead paint, pet food from China has been found to contain a contaminant thought to have contributed to a number of animal deaths, and various food products from China have been reported as being of questionable safety.[58]

China has clearly taken this situation seriously. Following the publicity surrounding a number of these situations, China signed an agreement prohibiting lead paint in toys ex-

51. *See* Richard Knox, *Arizona TB Patient Jailed as a Public Health Menace* (NPR radio broadcast June 11, 2007), *available at* http://www.npr.org/templates/story/story.php?storyId=10874970.

52. *See id.*

53. *See* Press Release, American Civil Liberties Union, ACLU of Arizona Lawsuit Triggers Transfer of TB Patient to Denver Hospital (Jul. 17, 2007), *available at* http://www.aclu.org/prison/gen/30618prs20070717.html [hereinafter ACLU Lawsuit Triggers].

54. *See* Press Release, American Civil Liberties Union, ACLU of Arizona Sues County Officials Over Inhumane Confinement of TB Patient (May 31, 2007), *available at* http://www.aclu.org/privacy/gen/29941prs20070531.html.

55. *See* ACLU Lawsuit Triggers, *supra* note 53.

56. *See* Walt Bogdanich & Renwick McLean, *Poisoned Toothpaste in Panama is Believed to be From China*, N.Y. TIMES, May 19, 2007, *available at* http://www.nytimes.com/2007/05/19/world/americas/19panama.html; Reuters, *Costa Rica Seizes Contaminated Toothpaste Imported From China*, N.Y. TIMES, May 26, 2007, *available at* http://www.nytimes.com/2007/05/26/world/americas/26toothpaste.html; Walt Bogdanich, *Toxic Toothpaste Made in China is Found in U.S.*, N.Y. TIMES, June 2, 2007, *available at* http://www.nytimes.com/2007/06/02/us/02toothpaste.html.

57. *See* Bogdanich & McLean, *supra* note 56.

58. Louise Story, *Lead Paint Prompts Mattel to Recall 967,000 Toys*, N.Y. TIMES, Aug. 2, 2007, *available at* http://www.nytimes.com/2007/08/02/business/02toy.html; Nicholas Zamiska, *Who's Monitoring Chinese Food Exports?*, WALL ST. J., Apr. 13, 2007, *available at* http://yaleglobal.yale.edu/display.article?id=9053.

ported to the United States.[59] Also, to the dismay of some human rights groups, China executed the former head of the State Food and Drug Administration in July 2007, ostensibly because he took bribes to approve medicines—although there has been speculation that the harsh sentence was more likely attributable to recent bad press and trade concerns.[60]

Moreover, while recent news stories may have focused on China, it is not clear that these product safety and quality control issues are limited to China. The more important message seems to be that as our world becomes an increasingly global community, stronger, more consistent regulations are needed in order to establish safe international trade that provides equal protection for all people.

V. Conclusion

As the world becomes a more integrated, mobile, and shared community, the international health, legal, and business sectors will have to adopt innovative new strategies if they hope to successfully address the needs of this emerging global community. Consistent with history, the rights of all people, including vulnerable populations, are key to international health and security. The WHO, the WTO, and numerous countries, businesses, organizations, and individuals have provided and continue to provide progressive international health law leadership to the global community; all of these entities, however, must do more to establish a cohesive, coherent, secure framework that promotes, supports, and protects the health of all.

59. *See* Associated Press, *China Signs Pact to Ban Lead Paint in Export Toys*, N.Y. TIMES, Sept. 12, 2007, *available at* http://www.nytimes.com/2007/09/12/business/worldbusiness/12lead.html.

60. *See* Joseph Kahn, *China Quick to Execute Drug Official*, N.Y. TIMES, Jul. 11, 2007, *available at* http://www.nytimes.com/2007/07/11/business/worldbusiness/11execute.html.