Order Code RL34144

# **CRS Report for Congress**

# Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation

Updated April 1, 2008

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Prepared for Members and Committees of Congress

# Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation

## Summary

The international saga of Andrew Speaker, a traveler thought to have XDR-TB, a drug-resistant form of tuberculosis, placed a spotlight on existing mechanisms to contain contagious disease threats and raised numerous legal and public health issues. This report presents the factual situation presented by Andrew Speaker; briefly addresses the existing law relating to quarantine and isolation, with an emphasis on the interaction of state and federal laws and international agreements; and examines the relationship of quarantine and isolation to civil rights protections. It will be updated as necessary.

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# Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation

"Infectious diseases are not a thing of the past.... We need to continually adapt our prevention and response capabilities in an era of increasing threat and globalization."<sup>1</sup>

#### Introduction

The international saga of Andrew Speaker, a traveler thought to have XDR-TB, an extensively drug-resistant form of tuberculosis, placed a spotlight on existing mechanisms to contain contagious disease threats and raised numerous legal and public health issues. This report presents the factual situation presented by Andrew Speaker, existing law relating to quarantine and isolation, including state and federal laws and international agreements, and the relationship of quarantine and isolation to civil rights protections.

### Background

Tuberculosis (TB) is a bacterial infection which usually attacks the lungs but can also damage other parts of the body. It is spread when an infected person coughs, sneezes, sings, or talks and another person breathes in the bacteria.<sup>2</sup> The risk of becoming infected depends on various factors including the extent of the disease in the person with TB, the duration of the exposure, and ventilation. For example, when an infected individual travels on an airplane, the risk to other passengers is increased by proximity to the infected person, and the time spent on board.<sup>3</sup> The World Health Organization (WHO) has stated that one in three people in the world is infected with dormant TB bacteria.<sup>4</sup> Generally, these individuals become ill only when the bacteria

<sup>2</sup> [http://www.nlm.nih.gov/medlineplus/tuberculosis.html].

<sup>&</sup>lt;sup>1</sup> Impact of One Tuberculosis Patient on International Public Health Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the S. Comm. on Appropriations, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. (June 6, 2007) (statement of Julie L. Gerberding, MD, MPH, Director, Centers for Disease Control and Prevention).

<sup>&</sup>lt;sup>3</sup> Centers for Disease Control and Prevention (CDC), "Extensively Drug-Resistant Tuberculosis (XDR-TB)," [http://www.cdc.gov/tb/pubs/tbfactsheets/xdrtb.htm].

<sup>&</sup>lt;sup>4</sup> In 2007, 13,293 tuberculosis (TB) cases were reported in the United States, a decline in the rate of infection from 2006. Centers for Disease Control and Prevention (CDC),57 (continued...)

become active, often as a result of lowered immunity, such as when an individual has AIDS. Generally, TB is treatable with antibiotics, but antibiotic resistance has been increasing as a result of the misuse or mismanagement of the medication.<sup>5</sup> Multidrug resistant TB (MDR-TB) is resistant to two of the most effective antibiotics.<sup>6</sup> Extensively drug resistant TB (XDR-TB) is a type of MDR-TB which is resistant not only to the first line antibiotics, but also to other second line drugs. XDR-TB is a serious condition because the treatment options are limited and successful treatment is not always possible.<sup>7</sup> In 2006 WHO issued a global alert about XDR-TB<sup>8</sup> which has been described as underscoring "the harsh reality that XDR-TB has the potential to transform a once treatable infection into an infectious disease as deadly, if not more so, than TB at the beginning of the 20<sup>th</sup> century."<sup>9</sup>

On May 12, 2007, Andrew Speaker, a man with tuberculosis, flew from Atlanta, Georgia, to Europe, where he was married in Greece, and then traveled to Italy. While Mr. Speaker was in Europe, the Centers for Disease Control and Prevention (CDC) completed testing showing that he was infected with XDR-TB. At that point, CDC attempted to reach the patient in Europe, and to prevent his use of public transportation, such as passenger aviation, for his return to the United States.<sup>10</sup> Fearing he would not be able to return to the United States for treatment, Mr.

<sup>6</sup> For 2006, a total of 116 MDR-TB cases were reported in the United States. Centers for Disease Control and Prevention (CDC), *57 Morbidity and Mortality Weekly Report* 283(March 21, 2008) [http://www.cdc.gov/mmwr/PDF/wk/mm5711.pdf].

<sup>7</sup> Centers for Disease Control and Prevention (CDC), "Extensively Drug-Resistant Tuberculosis (XDR-TB)," [http://www.cdc.gov/tb/pubs/tbfactsheets/xdrtb.htm]. The CDC noted that "[s]ome TB control programs have shown that cure is possible for an estimated 30% of affected people."

<sup>8</sup> World Health Organization, "Emergence of XDR-TB: WHO concern over extensive drug resistant TB strains that are virtually untreatable," [http://www.who.int/mediacentre/news/ notes/2006/np23/en/index.html]. WHO's Global MDR-TB and XDR-TB Response Plan 2007-2008, launched on June 22, 2007, allocates \$2.15 billion to contain drug-resistant tuberculosis, with an emphasis on providing access to drugs in underserved countries. [http://www.who.int/tb/xdr/global\_response\_plan/en/index.html].

<sup>9</sup> Howard Markel, Lawrence O. Gostin, David P. Fidler, "Extensively Drug-Resistant Tuberculosis: An Isolation Order, Public Health Powers, and a Global Crisis," 298 *JAMA* 83 (July 4, 2007).

<sup>10</sup> CDC has published a timeline of its actions at [http://www.cdc.gov/tb/XDRTB/ timeline.htm]. Certain matters have been the subject of disagreement between Mr. Speaker and public health authorities at the local and federal levels, particularly those matters relating to information, recommendations, or advisories provided to Mr. Speaker at various times. It is not the intent of this report to resolve those matters of disagreement.

<sup>&</sup>lt;sup>4</sup> (...continued)

*Morbidity and Mortality Weekly Report* 281 (March 21, 2008) [http://www.cdc.gov/mmwr/PDF/wk/mm5711.pdf].

<sup>&</sup>lt;sup>5</sup> World Health Organization, "XDR-TB: Extensively Drug-Resistant Tuberculosis," [http://www.who.int/tb/challenges/xdr/en/].

Speaker, without CDC's knowledge, flew to Canada and entered the United States by car on May 24.<sup>11</sup>

Although CDC had alerted U.S. Customs and Border Protection (CBP) in the Department of Homeland Security to the possibility that Mr. Speaker was en route to the United States, Mr. Speaker was not stopped at the border.<sup>12</sup> Once in the United States, Mr. Speaker contacted CDC, and voluntarily went to a hospital in New York City. On May 25, CDC issued a federal order of provisional quarantine and medical examination pursuant to Section 361 of the Public Health Service Act.<sup>13</sup> (This was the first such order since 1963.<sup>14</sup>) Mr. Speaker was then flown in a CDC aircraft to an Atlanta hospital, and later to the National Jewish Medical and Research Center in Denver, for treatment. On June 2, the federal order was rescinded when Denver health officials assumed public health responsibility for Mr. Speaker's case.

On July 3, doctors determined the Mr. Speaker had multi-drug resistant tuberculosis (MDR-TB) rather than XDR-TB.<sup>15</sup> On July 17, he had surgery to

<sup>13</sup> CDC has released the text of the three orders issued for the detention of the XDR-TB patient between May 25 and May 30, 2007, and the final order, issued June 2, 2007, rescinding the earlier orders. The Order for Provisional Quarantine is at [http://www2a.cdc.gov/phlp/docs/quarantine1.pdf]; the Order Pursuant to Public Health Service Act Section 361 is at [http://www2a.cdc.gov/phlp/docs/quarantine2.pdf]; the Revised Order Pursuant to Section 361 is at [http://www2a.cdc.gov/phlp/docs/quarantine3.pdf]; and the Order Rescinding Movement Restrictions is at [http://www2a.cdc.gov/phlp/docs/quarantine4.pdf].

<sup>14</sup> See *United States v. Shinnick*, 219 F. Supp. 789 (1963), where the court upheld the Public Health Service's quarantine of an arriving passenger because she had been in Stockholm, Sweden, a city declared by the World Health Organization to be a smallpox-infected area, and she could not show proof of vaccination. CDC routinely uses its authority under the Public Health Service Act to monitor passengers arriving in the United States for communicable diseases, sometimes delaying incoming planes and interviewing passengers for health reasons. [http://www.cdc.gov/ncidod/sars/quarantineqa.htm].

<sup>&</sup>lt;sup>11</sup> Testimony of Andrew Speaker before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, hearing regarding the tuberculosis travel incident, June 6, 2007, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess., Washington, DC.

<sup>&</sup>lt;sup>12</sup> Testimony of CBP Commissioner Ralph Basham before the House Committee on Homeland Security, hearing regarding the XDR tuberculosis incident, June 6, 2007, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess., Washington, DC. Issues relating to ports of entry, including issues relating to quarantine stations, are beyond the scope of this report. For a discussion of these issues see Institute of Medicine, *Quarantine Stations at Ports of Entry: Protecting the Public's Health* (National Academies Press 2006).

<sup>&</sup>lt;sup>15</sup> Lawrence K. Altman, "Traveler's TB not as Severe as Officials Thought," [http://www.nytimes.com/2007/07/04/health/04tb.html?ex=1184990400&en=39a65f739 d333727&ei=5070]. Dr. Charles Daley, head of the infectious disease division at National Jewish Medical Center, was quoted stating: "[t]his discrepancy among results happens all the time in labs that do drug-resistance testing, including reference labs." *Id.* Despite the change in diagnosis, the CDC response has generally been supported by infectious-disease experts. See Lawrence K. Altman, "Experts Mostly Back Way U.S. Reacted in TB Case," (continued...)

remove diseased and damaged tissue in his lung.<sup>16</sup> Mr. Speaker was released from the National Jewish Medical and Research Center in Denver on July 26 after doctors determined that he was no longer contagious and had no further detectible evidence of infection. He is to continue antibiotic treatment for two years and is required to check in with local health authorities five days a week and have his treatment directly observed by health care workers.<sup>17</sup>

### Federal Quarantine and Isolation Authority

Although the terms are often used interchangeably, quarantine and isolation are two distinct concepts.<sup>18</sup> Quarantine typically refers to the "(s)eparation of individuals who have been exposed to an infection but are not yet ill from others who have not been exposed to the transmissible infection."<sup>19</sup> Isolation refers to the "(s)eparation of infected individuals from those who are not infected."<sup>20</sup> Primary quarantine authority typically resides with state health departments and health officials; however, the federal government has jurisdiction over interstate and border quarantine.

Federal quarantine and isolation authority may be found in Section 361 of the Public Health Service Act, 42 U.S.C. § 264, wherein Congress has given the Secretary of Health and Human Services (HHS) the authority to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."<sup>21</sup> While also providing the Secretary with broad authority to apprehend, detain, or conditionally release a

<sup>&</sup>lt;sup>15</sup> (...continued)

<sup>[</sup>http://www.nytimes.com/2007/07/05/us/05tb.html?ex=1185076800&en=0c68daff1c1b4 fc5&ei=5070]. For a discussion of MDR-TB see [http://www.cdc.gov/tb/pubs/tbfactsheets/mdrtb.htm].

<sup>&</sup>lt;sup>16</sup> Lawrence K. Altman, "TB Patient Has Surgery to Remove Part of Lung," [http://www.nytimes.com/2007/07/18/health/18tb.html?\_r=1&n=Top%2fReference%2fT imes%20Topics%2fPeople%2fS%2fSpeaker%2c%20Andrew&oref=slogin].

<sup>&</sup>lt;sup>17</sup> Dan Forsch, "Traveler with TB is Released After Treatment in Denver," [http://www.nytimes.com/2007/07/27/health/27tb.html?ex=1187409600&en=bddfee426 efef352&ei=5070]

<sup>&</sup>lt;sup>18</sup> For a detailed discussion of quarantine and isolation, see CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by Kathleen S. Swendiman and Jennifer K. Elsea.

<sup>&</sup>lt;sup>19</sup> Homeland Security Council, National Strategy for Pandemic Influenza: Implementation Plan 209 (GPO May 2006). For a discussion of the history of quarantines in the United States see Felice Batlan, "Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future," 80 TEMP. L. REV. 53 (2007).

<sup>&</sup>lt;sup>20</sup> Id. at n. 207.

<sup>&</sup>lt;sup>21</sup> 42 U.S.C. § 264(a). Violation of federal quarantine and isolation regulations is a criminal misdemeanor, punishable by fine and/or imprisonment, 42 U.S.C. § 271.

person, the law limits the Secretary's authority to the communicable diseases published in an Executive Order of the President.<sup>22</sup> Executive Order 13295 lists the communicable diseases for which this quarantine authority may be exercised, and specifically includes infectious tuberculosis.<sup>23</sup> In 2000, the Secretary of HHS transferred certain authorities, including interstate quarantine authority, to the Director of the CDC.<sup>24</sup> Both interstate and foreign quarantine measures are now carried out by CDC's Division of Global Migration and Quarantine.<sup>25</sup>

HHS also works closely with the Department of Homeland Security (DHS) and its agencies. HHS and DHS signed a memorandum of understanding in 2005 that sets forth specific cooperation mechanisms to implement their respective statutory responsibilities for quarantine and other public health measures.<sup>26</sup> DHS has three agencies that may aid CDC in its enforcement of quarantine rules and regulations pursuant to 42 U.S.C. § 268(b). They are U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, and the United States Coast Guard. In addition to DHS, CDC may also rely on other federal law enforcement agencies and state and local law enforcement agencies.

While the federal government has authority to authorize quarantine and isolation under certain circumstances, it should be noted that the primary authority for quarantine and isolation exists at the state level as an exercise of the state's police power. States conduct these activities in accordance with their particular laws and policies. CDC acknowledges this deference to state authority as follows:

In general, CDC defers to the state and local health authorities in their primary use of their own separate quarantine powers. Based upon long experience and collaborative working relationships with our state and local partners, CDC continues to anticipate the need to use this federal authority to quarantine an exposed person only in rare situations, such as events at ports of entry or in similar time-sensitive settings.<sup>27</sup>

<sup>24</sup> 42 C.F.R. Part 70. Regulations regarding quarantine upon entry into the United States from foreign countries are also administered by the CDC, see 42 C.F.R. Part 71.

<sup>25</sup> See CDC Division of Global Migration and Quarantine home page at [http://www.cdc.gov/ncidod/dq/index.htm].

<sup>26</sup> [http://www.dhs.gov/xnews/testimony/testimony\_1181229544211.shtm].

<sup>&</sup>lt;sup>22</sup> 42 U.S.C. § 264(b).

<sup>&</sup>lt;sup>23</sup> See also E.O. 13375, April, 2005, which amended E.O. 13295. [http://www.fas.org/irp/ offdocs/eo/eo-13295.htm] and [http://www.whitehouse.gov/news/releases/2005/04/ 20050401-6.html]. The diseases listed are cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza viruses which have the potential to cause a pandemic. Other new threats would have to be added to E.O. 13295 in order to be "quarantinable diseases."

<sup>&</sup>lt;sup>27</sup> Q&A on Executive Order 13295, available at [http://www.cdc.gov/ncidod/dq/ qa\_influenza\_amendment\_to\_eo\_13295.htm]. The complexities of this shared power have been noted. One analysis observed that "When it comes to the exercise of isolation and quarantine powers, reality tends to be messier than the conceptual realm. Public health officials need clear lines of authority in emergency situations, often the moments when (continued...)

The situation involving Andrew Speaker highlights a possible limitation of the federal quarantine and isolation power in that the federal statute authorizing quarantine authority does not directly address persons leaving the country. The law is clear in its application to persons coming into the United States from a foreign country or U.S. possession, and for persons moving from state to state. But the law does not address preventing the movement of persons with communicable diseases out of the country. Historically, quarantine has been used to keep people out of an area and/or to contain them if they may be contagious, but as the case of Mr. Speaker illustrates, in this age of global travel, public health authorities may have to deal with the possibility of detaining a person to prevent the exportation of an infectious disease.<sup>28</sup>

The CDC, on November 22, 2005, announced proposed changes to its quarantine regulations.<sup>29</sup> If adopted, these changes would constitute the first significant revision of the regulations in Parts 70 and 71 in 25 years. The proposed changes are an outgrowth of the CDC's experience during the spread of Severe Acute Respiratory Syndrome (SARS) in 2003, when the agency experienced difficulties locating and contacting airline passengers who might have been exposed to SARS during their travels. In announcing the proposed regulations, CDC Director Julie Gerberding said, "[t]hese updated regulations are necessary to expedite and improve CDC operations by facilitating contact tracing and prompting immediate medical follow up of potentially infected passengers and their contacts."<sup>30</sup>

 $<sup>^{27}</sup>$  (...continued)

isolation and quarantine might be required. Unfortunately, confusion about which level of government should take the lead often occurs, thus revealing the ability of quarantine powers to spotlight difficulties federalism poses for public health." David P. Fidler, Lawrence O. Gostin, and Howard Markel, "Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law and Ethics," 35 J. OF LAW, MEDICINE & ETHICS 616 (2007). Another commentator has noted that "Given the variation in due process rights in connection with quarantine, which may be afforded under federal and state law, one can foresee the possibility of considerable conflict." Felice Batlan, "Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future," 80 TEMP. L. REV. 53, 119 (2007).

<sup>&</sup>lt;sup>28</sup> CDC Director Julie Gerberding, in her opening statement in a hearing on *Threat Posed* by *Patient with Drug Resistant Tuberculosis, before the Senate Appropriations* Subcommittee on Labor, Health and Human Services, Education and Related Agencies, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. (June 6, 2007), raised this issue: "We also think we need clarification in the quarantine statute. It does not explicitly address exportation, meaning movement of patients out of the country.... So we may be able to use [the] existing statute with a clarification of intent, but we do need to identify what our responsibilities and authorities are under the statute and make a decision about whether a change is needed."

<sup>&</sup>lt;sup>29</sup> See 70 *Fed. Reg.* 71892 (November 30, 2005), [http://www.cdc.gov/ncidod/dq/nprm/]. These proposed regulations were available for a 60-day comment period, and later extended for an additional 30 days, closing on March 1, 2006. See 71 *Fed. Reg.* 4544 (January 27, 2006). Proposed Section 70.20 and 71.23 of 42 C.F.R.

<sup>&</sup>lt;sup>30</sup> "CDC Proposes Modernizing Control of Communicable Disease Regulation, USA," *Medical News Today*, November 23, 2005, at [http://www.medicalnewstoday.com/ medicalnews.php?newsid=34042]. Since the SARS outbreak, the CDC has increased its (continued...)

The proposed regulations would expand reporting requirements for ill passengers<sup>31</sup> onboard flights and ships arriving from foreign countries. They would also require airlines and ocean liners to maintain passenger and crew lists with detailed contact information and to submit these lists electronically to CDC upon request.<sup>32</sup> The lists would be used to notify passengers of their suspected exposure if a sick person were not identified until after the travelers had dispersed from an arriving carrier. The proposed regulations address the due process rights of passengers who might be subjected to quarantine after suspected exposure to disease; the regulations also provide for an appeal process.

In her congressional testimony regarding XDR-TB and the situation involving Andrew Speaker, CDC Director Dr. Julie Gerberding summarized CDC efforts to control the spread of tuberculosis, particularly emerging drug-resistant TB threats:

To control TB, HHS/CDC and its partners must continue to apply fundamental principles including: (1) State and local TB programs must be adequately prepared to identify and treat TB patients so that further drug resistant cases can be prevented; (2) TB training and consultation must be widely available so that private health care providers recognize and promptly report tuberculosis to the public health system; (3) State and local public health laboratories must be able to efficiently perform and interpret drug susceptibility and genotyping results in TB specimens; and (4) CDC and local health authorities must work collaboratively to ensure that isolation and quarantine authorities are properly and timely exercised in appropriate cases.<sup>33</sup>

#### **International Health Regulations**

In May 2005 the World Health Assembly adopted a revision of its 1969 International Health Regulations (IHR), giving a new mandate to WHO and member states to increase their respective roles and responsibilities for the protection of international public health.<sup>34</sup> The IHR(1969) had focused on just three diseases

 $<sup>^{30}</sup>$  (...continued)

quarantine stations nationwide from 8 to 20. See [http://www.cdc.gov/ncidod/dq].

<sup>&</sup>lt;sup>31</sup> The definition of ill person would be expanded to include anyone who has a fever of at least 100.4 degrees plus one of the following: severe bleeding; jaundice; severe, persistent cough accompanied by bloody sputum; or respiratory distress. (Section 70.1 of proposed regulations.) It should be noted that Mr. Speaker apparently did not have any symptoms.

<sup>&</sup>lt;sup>32</sup> *Id.* The lists, in electronic format, would have to be kept for 60 days after arrival, and be able to be submitted within 12 hours of a CDC request. The lists would include names, contact information, and seat assignments.

<sup>&</sup>lt;sup>33</sup> Recent Case of Extensively Drug Resistant TB: CDC's Public Health Response: Statement to the US House of Representatives Committee on Homeland Security, 110<sup>th</sup> Cong. 1<sup>st</sup> Sess. (June 6, 2007) (testimony of Julie Gerberding, MD, MPH, director of the CDC), [http://www.hhs.gov/asl/testify/2007/06/t20070606a.html].

<sup>&</sup>lt;sup>34</sup> Fifty-eighth World Health Assembly, agenda item 13.1, Revision of the International Health Regulations, May 23, 2005, at [http://www.who.int/csr/ihr/en/]. For a discussion of (continued...)

(cholera, plague, and yellow fever). In addition, compliance of State Parties<sup>35</sup> with the IHR(1969) was uneven, a result of, among other things, resource limitations in poorer countries, and political factors, such as the reluctance to announce the presence of a contagious disease within one's borders and face economic and other consequences.<sup>36</sup>

The IHR(2005), which entered into force in June 2007, have broadened the scope of the 1969 regulations by addressing existing, new, and re-emergent diseases, as well as emergencies caused by non-infectious disease agents. The IHR(2005) require State Parties to notify WHO of all events that may constitute a "public health emergency of international concern," and to provide information regarding such events.<sup>37</sup> The IHR(2005) also include provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls, and others. The IHR(2005) require WHO to recommend, and State Parties to use, control measures that are no more restrictive than necessary to achieve the desired level of health protection.

The IHR were agreed upon by a consensus process among the member states, and represent a balance between sovereign rights and a commitment to work together to prevent the international spread of disease. The IHR(2005) are binding on all WHO member states as of June 15, 2007, except for those that have rejected the regulations or submitted reservations.<sup>38</sup> The United States accepted the IHR(2005) with three reservations, including the reservation that it will implement the IHR(2005) in line with U.S. principles of federalism.<sup>39</sup> State Parties now have a two-year period in which to assess the ability of existing national structures and resources for meeting the core surveillance and response capacities requirements set out in the regulations and to develop plans of action to ensure that these capacities are in place. Within five years of the entry into force date, State Parties must complete development of public health infrastructure that ensures full compliance with the regulations.

<sup>38</sup> IHR(2005), Article 59.2.

 $<sup>^{34}</sup>$  (...continued)

these regulations, state sovereignty, and federalism issues see Eric Mack, "The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-Fated Response to Global Health Issues," 7 *CHI. J. INT'L L.* 365 (2006).

<sup>&</sup>lt;sup>35</sup> "State Party" is the name for WHO member states that have agreed to be bound by the IHR.

<sup>&</sup>lt;sup>36</sup> M.G. Baker and D.P. Fidler, "Global Public Health Surveillance under New International Health Regulations," *Emerging Infectious Diseases*, vol. 12, no. 7, July 2006, at [http://www.cdc.gov/ncidod/EID/vol12no07/05-1497.htm].

<sup>&</sup>lt;sup>37</sup> A "public health emergency of international concern" is defined as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response." IHR(2005), Article 1.

<sup>&</sup>lt;sup>39</sup> HHS Secretary Michael Leavitt announced the acceptance of the IHR(2005) by the United States on December 13, 2006. See News Release at [http://www.pandemicflu.gov/plan/federal/index.html].

According to the revised (2005) International Health Regulations, State Parties are not to bar the entry of a conveyance for public health reasons, but are rather to manage the public health threat through isolation, quarantine, disinfection, or other such applicable methods.<sup>40</sup> Article 43 of the IHR allows nations to implement additional health measures in accordance with their relevant national law and obligations under international law in response to specific health concerns. If a State Party implements additional health measures significantly interfering with international traffic, the public health rationale and relevant scientific information for the measures must be provided to WHO. The WHO shall share the information with State Parties and institute procedures to find a mutually acceptable solution.<sup>41</sup>

In 2006 WHO issued a document containing guidelines for tuberculosis and air travel.<sup>42</sup> WHO notes in the guidelines that TB and other airborne infectious diseases can fall within the scope of the IHR(2005) in cases where public health risks present a serious and direct danger to human health that may spread internationally. While TB is not listed in the IHR(2005) as a disease that would always be considered as a potential public health emergency of international concern requiring notification to WHO, it may be the subject of a potential international emergency under the IHR(2005). The guidelines state that airline companies are expected to comply with the IHR and the laws of the countries in which they operate. IHR requirements as implemented by State Parties which may affect airlines include those relating to detection and control of public health risks, such as information-sharing requirements, notification of cases of illness, and medical examination or other health measures for ill or possibly ill travelers. WHO guidelines also note that confidentiality issues may arise when health authorities request the release of passenger and crew lists, as well as when health authorities need to release the name of a passenger with TB to an airline in order to confirm that the passenger was on a particular flight or flights.

One of the difficulties raised by Mr. Speaker's situation was the interaction of the varying state, federal, and international laws, regulations, and authorities. The Director of CDC, Dr. Julie Gerberding, observed that there were difficulties determining how CDC was to use its assets and how the statements of principle in the international health regulations were to be applied in a specific situation to

<sup>&</sup>lt;sup>40</sup> IHR, Article 28.1, "Ships and aircraft at points of entry."

<sup>&</sup>lt;sup>41</sup> IHR, Article 43, "Additional Health Measures." While the IHR(2005) do not include an enforcement mechanism for State Parties that fail to comply with their provisions, the WHO considers the potential consequences of non-compliance within the global community, especially in economic terms, to be a powerful compliance tool. The IHR(2005) (Article 56) contain a dispute settlement mechanism to resolve conflicts which may arise among State Parties when applying or interpreting the regulations, including options such as negotiation, mediation, conciliation, or arbitration, or referral to the Director-General of WHO, if agreed to by all the parties to the dispute.

<sup>&</sup>lt;sup>42</sup> World Health Organization, "Tuberculosis and Air Travel: Guidelines for Prevention and Control" (2d ed. 2006), [http://www.who.int/tb/en/].

determine, for example, who should pay to move a patient, and who should care for a patient in isolation or quarantine.<sup>43</sup>

## **Civil Rights**

#### Introduction

The situation presented by Andrew Speaker raises a classic civil rights issue: to what extent can an individual's liberty be curtailed to advance the common good? The U.S. Constitution and federal civil rights laws provide for individual due process and equal protection rights as well as a right to privacy, but these rights are balanced against the needs of the community. With the advance of medical treatments in recent years, especially the use of antibiotics, the civil rights of the individual with a contagious disease have been emphasized. However, classic public health measures such as quarantine, isolation, and contact tracing are, nevertheless, available in appropriate situations and, as new or resurgent diseases have become less treatable, some of these classic public health measures have been increasingly used. Therefore, the issue of how to balance these various interests in a modern culture which is sensitive to issues of individual rights has become critical.<sup>44</sup>

#### **Constitutional Rights to Due Process and Equal Protection**

Constitutional rights to due process and equal protection may be implicated by the imposition of a quarantine or isolation order.<sup>45</sup> The Fifth and Fourteenth

<sup>45</sup> It has been argued that the federal quarantine authority may not pass constitutional muster since it does not specifically provide for a right to a fair hearing. See Howard Markel, Lawrence O. Gostin, and David P. Fidler, "Extensively Drug-Resistant Tuberculosis: An Isolation Order, Public Health Powers, and a Global Crisis," 298 JAMA 83-84 (July 4, 2007). It should be noted that the proposed CDC quarantine regulations contain detailed due process procedures including a right to a hearing for full quarantine. 70 *Fed. Reg.* (continued...)

<sup>&</sup>lt;sup>43</sup> CDC, "Update on CDC Investigation into People Potentially Exposed to Patient With Extensively Drug Resistent TB," (June 1, 2007) [http://www.cdc.gov/od/oc/media/transcripts/2007/t070601.htm].

<sup>&</sup>lt;sup>44</sup> For a detailed discussion of constitutional issues relating to quarantine see Michelle A. Daubert, "Pandemic Fears and Contemporary Quarantine: Protecting Liberty Through a Continuum of Due Process Rights," 54 BUFFALO L. REV. 1299 (January 2007). For an analysis of how to balance the sometimes competing interests of personal and economic liberties with the public's health and security see Lawrence O. Gostin, "When Terrorism Threatens Health: How Far are Limitations on Personal and Economic Liberties Justified?" 55 *Fla. Law Rev.* 1105 (December 2003). See also David P. Fidler, Lawrence O. Gostin, and Howard Markel, "Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law and Ethics," 35 J. OF LAW, MEDICINE & ETHICS 616 (2007), where the authors note that courts have set four limits on isolation and quarantine authority: the subject must actually be infectious or have been exposed to infectious disease, the subject must be placed in a safe and habitable environment, the authority must be exercised in a non-discriminatory manner, and there must be procedural due process.

Amendments prohibit governments at all levels from depriving individuals of any constitutionally protected liberty interest without due process of law. What process may be due under certain circumstances is generally determined by balancing the individual's interest at stake against the governmental interest served by the restraints, determining whether the measures are reasonably calculated to achieve the government's aims,<sup>46</sup> and deciding whether the least restrictive means have been employed to further that interest.

In O'Connor v. Donaldson<sup>47</sup> the Supreme Court examined the civil commitment of an individual to a mental hospital and held that "a State cannot constitutionally confine without more a nondangerous individual who is capable of surviving safely in freedom by himself or with the help of willing and responsible family members or friends."<sup>48</sup> Clearly an individual who is highly contagious with a serious illness may be considered dangerous and thus subject to involuntary confinement if there is no less restrictive alternative. The lesson of *Donaldson* is that such confinements must be carefully examined in order to comport with the constitutional right to due process. *Donaldson* also raises the issue of whether less restrictive programs are required prior to the imposition of the more restrictive application of isolation or quarantine. It could be argued that the least restrictive alternative must first be applied or more restrictive alternatives will run afoul of constitutional requirements.<sup>49</sup>

<sup>46</sup> See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 27 (1905) (enforcement of public health laws must have some "real or substantial relation to the protection of the public health and the public safety"); *Jew Ho v. Williamson*, 103 F. 10 (C.C.N.D. Cal. 1900) (quarantine of San Francisco district inhabited primarily by Chinese immigrants purportedly to control the spread of bubonic plague was invalidated).

<sup>&</sup>lt;sup>45</sup> (...continued)

<sup>71,892 (</sup>November 30, 2005), [http://www.cdc.gov/ncidod/dq/nprm/]. However, these proposed regulations have been strongly criticized for what commentators have described as constitutional failings. These criticisms have highlighted the lack of independent judicial review for individuals subject to guarantine, the broad discretion accorded to directors of federal quarantine stations, the lack of hearings during provisional quarantine, and privacy concerns. See e.g., Lawrence O. Gostin, Benjamin E. Berkman, and David P. Fidler, Comments on Department of Health and Human Services, Control of Communicable Diseases (Proposed Rule), 42 C.F.R. Parts 70 and 71 (November 30, 2005), [http://www.publichealthlaw.net/Resources/BTlaw.htm]; The New England Coalition for Law and Public Health, Comments on the Interstate and Foreign Quarantine Regulations Proposed by the Centers for Disease Control and Prevention, [http://64.233.169.104/u/UMBaltimore?q=cache:fsSm0xxCULQJ:www.umaryland.edu/h ealthsecurity/docs/New%2520England%2520Coalition%2520Comments%2520CDC%2 520revisions.pdf+%22new+england+coalition+for+law+and+public+health%22&hl=en &ct=clnk&cd=1&gl=us&ie=UTF-8]; Felice Batlan, "Law in the Time of Cholera: Disease, State Power, and Quarantines Past and Future," 80 TEMP. L. REV. 53 (2007).

<sup>&</sup>lt;sup>47</sup> 422 U.S. 563 (1975).

<sup>&</sup>lt;sup>48</sup> *Id.* at 576.

<sup>&</sup>lt;sup>49</sup> See Wendy D. Parmet, "Legal Power and Legal Rights — Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis," 357 NEW ENG. J. OF MEDICINE 433, 435 (August 2, 2007). Professor Parmet argues that compulsory measures are not the most effective and may prompt individuals who may be subject to them to evade authorities. "By ensuring that (continued...)

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The unequal treatment of certain socially disfavored groups with regard to quarantine also raises equal protection issues. For example, in *Wong Wai v*. *Williamson*<sup>50</sup> a board of health resolution mandated Chinese residents to be quarantined for bubonic plague unless they submitted to inoculation with a serum with "the only justification offered for this discrimination ... a suggestion ... that this particular race is more liable to the plague than any other."<sup>51</sup> The court struck the resolution as a violation of the equal protection clause.<sup>52</sup>

#### **Federal Nondiscrimination Laws**

In addition to constitutional issues, discrimination against an individual with an infectious disease may be covered by certain federal laws, notably the Americans with Disabilities Act (ADA),<sup>53</sup> Section 504 of the Rehabilitation Act,<sup>54</sup> and the Air Carriers Access Act (ACAA).<sup>55</sup> However, under these statutes, an individual with a contagious disease does not have to be given access to a place of public accommodation or employment if such access would place other individuals at a significant risk.<sup>56</sup>

<sup>&</sup>lt;sup>49</sup> (...continued)

coercion is used only when less restrictive alternatives will not work and with due regard for the rights of those detained, the law can foster public trust, minimizing the need for compulsion and laying the groundwork for the comprehensive and costly control programs needed to prevent the spread of XDR tuberculosis and other contagious pathogens." *Id.* 

<sup>&</sup>lt;sup>50</sup> 103 F. 1 (N.D. Cal. 1900).

<sup>&</sup>lt;sup>51</sup> *Id.* at 15.

<sup>&</sup>lt;sup>52</sup> One commentator observed that it is unlikely that such blatantly discriminatory actions would occur today but noted that "studies of New York City's use of isolation orders for tuberculosis in the 1990s show that more than 90% of the people detained were non-white and more than 60% were homeless.... Although these figures may reflect the democracy of non-compliant patients with tuberculosis in New York City at that time, the fact that the most potent public health tool was used primarily against marginalized, nonwhite persons underscores the need for legal oversight — if only so that affected communities can be assured of the absence of discrimination." Wendy D. Parmet, "Legal Power and Legal Rights — Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis," 357 *NEW ENG. J. OF MEDICINE* 433, 434 (August 2, 2007).

<sup>&</sup>lt;sup>53</sup> 42 U.S.C. §§12101 *et seq*. For a more detailed discussion of the ADA generally see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by Nancy Lee Jones.

<sup>&</sup>lt;sup>54</sup> 29 U.S.C. §794. For a more detailed discussion of Section 504 generally see CRS Report RL34041, Section 504 of the Rehabilitation Act of 1973: Prohibiting Discrimination Against Individuals with Disabilities in Programs or Activities Receiving Federal Assistance, by Nancy Lee Jones.

<sup>&</sup>lt;sup>55</sup> 42 U.S.C. §1374(c). For a more detailed discussion of the ACAA generally see CRS Report RL34047, *Overview of the Air Carrier Access Act*, by Anna Henning.

<sup>&</sup>lt;sup>56</sup> For a more detailed discussion of this issue in the ADA context see CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by Nancy Lee Jones.

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Although the language of Section 504 does not specifically discuss contagious diseases, the Supreme Court dealt with discrimination issues in the context of tuberculosis and Section 504 in School Board of Nassau County v. Arline.<sup>57</sup> The Court found that in most cases an individualized inquiry is necessary in order to protect individuals with disabilities from "deprivation based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to such legitimate concerns of grantees as avoiding exposing others to significant health and safety risks."<sup>58</sup> The Court adopted the test enunciated by the American Medical Association (AMA) amicus brief and held that the factors which must be considered include "findings of facts, based on reasonable medical judgments given the state of medical knowledge, about (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm." The Court also emphasized that courts "normally should defer to the reasonable medical judgments of public health officials."59

The ADA provides nondiscrimination protections to individuals with contagious diseases but balances this protection with requirements designed to protect the health of other individuals. Title I of the ADA, which prohibits employment discrimination against otherwise qualified individuals with disabilities, specifically states that "the term 'qualifications standards' may include a requirement that an individual shall not pose a direct threat to the health or safety of other individuals in the workplace."<sup>60</sup> In addition, the Secretary of Health and Human Services (HHS) is required to publish, and update, a list of infectious and communicable diseases that may be transmitted through handling the food supply.<sup>61</sup>

Similarly, Title III, which prohibits discrimination in public accommodations and services operated by private entities, states the following:

Nothing in this title shall require an entity to permit an individual to participate in or benefit from the goods, services, facilities, privileges, advantages and accommodations of such entity where such individual poses a direct threat to the health or safety of others. The term 'direct threat' means a significant risk to the

<sup>&</sup>lt;sup>57</sup> 480 U.S. 273 (1987).

<sup>&</sup>lt;sup>58</sup> *Id.* at 287.

<sup>&</sup>lt;sup>59</sup> *Id.* at 288. These standards are incorporated into the regulations for the Air Carriers Access Act at 14 C.F.R. §382.51.

<sup>&</sup>lt;sup>60</sup> 42 U.S.C. §12113(b).

<sup>&</sup>lt;sup>61</sup> 42 U.S.C. §12113(d). This provision was added in an amendment by Senator Hatch after a long debate over the Chapman Amendment, which was not enacted. The Chapman Amendment would have allowed employers in businesses involved in food handling to exclude individuals with specific contagious diseases such as HIV infection. See 136 Cong. Rec. 10911 (1990).

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health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures or by the provision of auxiliary aids or services.<sup>62</sup>

Although Title II, which prohibits discrimination by state and local government services, does not contain such specific language, it does require an individual to be "qualified" and this is defined in part as meeting "the essential eligibility requirements of the receipt of services or the participation in programs or activities."<sup>63</sup> This language has been found by the Department of Justice to require the same interpretation of direct threat as in Title III.<sup>64</sup>

Contagious diseases were discussed in the ADA's legislative history. The Senate report noted that the qualification standards permitted with regard to employment under Title I may include a requirement that an individual with a currently contagious disease or infection shall not pose a direct threat to the health or safety of other individuals in the workplace and cited to *School Board of Nassau County v. Arline*,<sup>65</sup> the Section 504 case discussed previously.<sup>66</sup> Similarly, the House report of the Committee on Education and Labor reiterated the reference to *Arline* and added "[t]hus the term 'direct threat' is meant to connote the full standard set forth in the Arline decision."<sup>67</sup>

The Air Carriers Access Act (ACAA) prohibits discrimination by air carriers against "otherwise qualified individual[s]" on the basis of disability.<sup>68</sup> Enacted in 1986,<sup>69</sup> prior to the ADA, the ACAA contains no statutory reference to communicable diseases. However, the regulations, like the ADA and its regulations, generally treat individuals with communicable diseases as falling within the definition of "individual with a disability."<sup>70</sup> The regulations prohibit various actions by carriers against individuals with communicable diseases. A carrier may not "(1) refuse to provide transportation to the person, (2) require the person to provide a medical certificate, or (3) impose on the person any condition, restriction, or

<sup>65</sup> 480 U.S. 273, 287, note 16 (1987).

<sup>66</sup> S.Rept. 101-116, 101<sup>st</sup> Cong., 1<sup>st</sup> Sess. reprinted in Vol. I, Committee Print Serial No. 102-A Legislative History of Public Law 101-336 The Americans with Disabilities Act, prepared for the House Committee on Education and Labor at 139 (December 1990).

<sup>67</sup> H.Rept. 101-485, 101<sup>st</sup> Cong., 2<sup>nd</sup> Sess., reprinted in Vol. I, Committee Print Serial No. 102-A Legislative History of Public Law 101-336 The Americans with Disabilities Act, prepared for the House Committee on Education and Labor at 349 (December 1990). See also 136 Cong. Rec. 10858 (1990).

<sup>68</sup> 49 U.S.C. §41705. For a more detailed discussion of the ACAA see CRS Report RL34047, *Overview of the Air Carrier Access Act*, by Anna Henning.

<sup>69</sup> Air Carrier Access Act of 1986, 100 Stat. 1080 (1986) (current version at 49 U.S.C. §41705).

<sup>70</sup> See, e.g., 14 CFR §382.51(c) (referring to "qualified individual with a disability with a communicable disease").

<sup>62 42</sup> U.S.C. §12182(3).

<sup>&</sup>lt;sup>63</sup> 42 U.S.C. §12131(2).

<sup>&</sup>lt;sup>64</sup> 28 C.F.R. Part 35, Appx A.

requirement not imposed on other passengers."<sup>71</sup> However, an exception applies when an individual "poses a direct threat to the health or safety of others."<sup>72</sup> "Direct threat" is defined as "a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services."<sup>73</sup>

<sup>73</sup> 14 CFR §382.51(b)(2).

<sup>&</sup>lt;sup>71</sup> 14 CFR §382.51(a).

<sup>&</sup>lt;sup>72</sup> 14 CFR §382.51(b)(1).