

Extensively Drug-Resistant Tuberculosis

An Isolation Order, Public Health Powers, and a Global Crisis

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CENTURIES AFTER THE FORMAL CREATION OF QUARANTINE, the practice continues to evoke concern when implemented to halt the spread of dangerous microbes. Witness the controversy generated by US citizen Andrew Speaker, whom the US Centers for Disease Control and Prevention (CDC) detained and isolated because he was diagnosed with pulmonary disease caused by extensively drug-resistant tuberculosis (XDR-TB). Speaker's case made compelling news, but it also raised questions about the emergence of XDR-TB, the adequacy of public health powers in the United States, and the international dimensions of the XDR-TB threat.

The Recent Encounter With XDR-TB

According to media reports,¹⁻³ congressional testimony,⁴ and official reports,⁵ physicians diagnosed Speaker with pulmonary TB in March 2007. He was prescribed a regimen of standard anti-TB medications. Susceptibility testing determined that Speaker's TB was multidrug resistant, which prompted county public health authorities to advise Speaker orally on May 10 not to travel but to consider specialized treatment. Instead, Speaker advanced his travel by 48 hours and flew from Atlanta, Georgia, to Paris, France, on May 12. From May 11 through 13, county public health officials tried to deliver written notice to Speaker that travel would be against medical advice and would risk harming others' health. On May 22, the CDC confirmed that Speaker had XDR-TB.

Speaker's wedding and honeymoon took him to Greece and then Rome, where the CDC contacted him by telephone on May 22 to inform him that he had XDR-TB, should not travel further on commercial airlines, and should report to Italian health authorities while US officials pursued options for his return home. Instead, Speaker flew to Prague, then to Montreal, Canada, and then drove into the United States.

Although the CDC placed Speaker's name on a health surveillance list, a US border guard allowed Speaker into the United States despite seeing the CDC's warning.¹ Once in the country, CDC located Speaker, instructed him to re-

port to Bellevue Hospital in New York City, New York, and indicated that failure to do so would violate federal quarantine law. After 72 hours at Bellevue under a provisional isolation order, Speaker was transported by the CDC to Atlanta and a federal isolation order was issued against him. This order was the first such federal order since a suspected smallpox carrier was quarantined in 1963.⁶ Speaker's travels forced the CDC and other public health authorities from multiple countries to try to locate hundreds of airline passengers who may have been exposed to XDR-TB. Later, Speaker was transferred under escort by a CDC quarantine officer to the National Jewish Medical Center in Denver, Colorado, for treatment.

The Emergence of the XDR-TB Problem

Media coverage of Speaker's situation provided many people with an introduction to XDR-TB, which is the latest chapter in humanity's battle with the "white plague." Once thought under control in developed countries, TB cases increased in the 1980s after funding cuts for TB prevention and treatment programs and the emergence of the AIDS pandemic. The reemergence of TB had the harshest consequences in the developing world, particularly with the impact of HIV/AIDS on susceptibility to TB infection. The increase in TB cases led to an increase in inadequate or incomplete antibiotic treatments, which produced resistant TB strains.⁷

Multidrug-resistant TB (MDR-TB) arose during this period and includes TB strains that are resistant to at least 2 of the most commonly prescribed anti-TB drugs: isoniazid and rifampin. MDR-TB often appears when a patient takes an incomplete course of anti-TB medications or is acquired during exposure to air shared with other persons harboring MDR-TB, if infection control precautions are not implemented or are inadequate. But XDR-TB is more problematic because it is also resistant to any fluoroquinolone and at least 1 of the 3 second-line drugs: capreomycin, kanamycin, and amikacin.⁸

Surveillance data on XDR-TB are still rudimentary, but even with incomplete information, public health officials are

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alarmed. XDR-TB has appeared in many countries, including the United States, and is of particular concern in Eastern Europe, South Africa, and Asia.⁹ The issuance in 2006 by the World Health Organization (WHO) of a global alert about XDR-TB¹⁰ underscores 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 20th century.

XDR-TB and Quarantine

Speaker's isolation has focused attention on the exercise of public health powers, especially with respect to quarantine and isolation at the local, state, federal, and international levels. Definitions of quarantine have changed over the centuries, but so too have political, legal, and cultural frames of reference.

For most of the history of quarantine, the biggest concerns related to lost commerce caused by closing ports or cities to goods and travelers. During many historical eras, governments sometimes abused quarantine powers by applying them against socially undesirable segments of populations perceived to be sickly or contagious.¹¹ In other periods, quarantine has been contested for political and nationalistic reasons. More recently, the perceived conflict between individual rights and public health has dominated quarantine debates. This trend has been strongest in democratic nations that emphasize civil liberties. Each frame of reference remains important, which highlights the need to understand how the law authorizes governments to engage in quarantine activities.¹¹

Legal Authority for Isolation and Quarantine in the United States

The Complexity of Quarantine Law. Legal authority for public health powers, including isolation and quarantine, exists at local, state, and federal levels. This situation produces problems related to federalism: Which level of government may act? Which laws apply, and in what circumstances? Theoretically, local and state law addresses threats confined to a single city, county, or state; federal law applies to diseases arriving from foreign countries or being transmitted across state lines.

Behind that theory lies a complex problem regarding the "lead" government official in any given situation. Public health emergencies require clear lines of authority, and the Speaker case illustrates some breakdowns in this respect: county public health officials were allegedly not clear in their instructions to Speaker because they told him not to travel but that he did not pose a risk to others; and a federal border guard let Speaker into the United States despite being aware of CDC's notification that Speaker should be detained.¹

State Quarantine Authority. State authority to compel isolation and quarantine derives from the police power (*Gibbons v Ogden*, 22 US 1, 25 [1824]). Although all states have

authorized isolation and quarantine, these laws vary considerably. Often, different approaches are not a problem, but variation could prevent or delay effective responses to a multistate emergency. Disparate legal structures can also undermine cooperation among state and federal officials. In addition, state quarantine laws are often old and do not reflect contemporary scientific understandings of disease or changes in the protection of civil liberties.

In light of recent threats, states have begun to reconsider quarantine authority within their emergency response systems. The president urged states to review their quarantine authorities as a homeland security priority,¹² and 38 states have adopted, in whole or in part, the Model State Emergency Health Powers Act (MSEHPA). Drafted in response to the 2001 anthrax attacks, the MSEHPA requires the state's governor to declare an emergency before special quarantine powers are exercised.¹³ The "Turning Point" Model State Public Health Act, drafted in 2003, provides a range of public health powers that do not require an emergency declaration, but few states have used this model act to revise their laws.¹⁴ The Speaker case will, again, encourage state governments to revisit their quarantine laws.

Federal Quarantine Authority. Federal quarantine authority grants the secretary of the US Department of Health and Human Services the power to issue regulations to prevent the introduction, transmission, or interstate spread of communicable diseases into or within the United States and to apprehend, detain, or conditionally release individuals infected with "quarantinable diseases" specified by executive order.¹⁵ Infectious TB is a quarantinable disease.¹⁶

The Speaker case illustrates weaknesses in federal quarantine authority. First, federal powers apply only to a small number of diseases, depriving the CDC of flexibility to respond to novel threats. For a new threat, the president must issue an executive order making the disease quarantinable, as happened with SARS (severe acute respiratory syndrome) and pandemic influenza. Second, federal rules do not authorize a range of powers, including screening, contact tracing, and directly observed therapy, which may be needed to address certain threats, including XDR-TB. Third, federal quarantine law lacks adequate due process protections because it does not give affected individuals a right to a fair hearing. Given constitutional requirements for an impartial hearing for anyone under civil detention or confinement,¹⁷ including people with TB,¹⁸ federal quarantine powers are arguably unconstitutional.

Proposed Revisions to the Federal Quarantine Regulations. Recognizing these problems, the Department of Health and Human Services proposed new regulations in late 2005.¹⁹ The proposed rules would expand the scope of federal power by defining "ill person" to include those with signs or symptoms commonly associated with quarantinable diseases (eg, fever, rash, persistent cough, or diarrhea), thus affording CDC greater flexibility. The proposed regulations would require airlines and other carriers to screen passengers at borders;

report cases of illness or death to the CDC; distribute health alert notices to crew and passengers; collect and transmit personal passenger information; order physical examination of exposed persons; and require passengers to disclose information about their contacts, travel itinerary, and medical history. The proposed rules also build more due process protections into federal quarantine law, protections the CDC included in Speaker's isolation order (ie, a right to a hearing, which Speaker decided not to pursue⁴).

The revisions to federal quarantine regulations proved controversial and have not yet been adopted. Although the public health community welcomed many proposed changes, those concerned with potential invasions of liberty, privacy, and property criticized aspects of the proposal. The travel industry complained about the costs imposed on it to collect passenger data. Civil libertarians argued that the new rules would not protect privacy adequately. Due process advocates criticized the proposal for providing no right to a hearing for "provisional" quarantines lasting up to 3 business days. In addition, the proposal did not address all concerns about due process requirements for full quarantine measures because it required quarantined individuals to request a hearing, provided for informal proceedings, and permitted a CDC employee to preside over the hearing rather than an impartial tribunal.

Speaker's case has drawn attention to the future application of quarantine powers by the federal government with respect to XDR-TB. As with other disease threats, public health officials need a range of powers, but they must exercise those powers fairly and in accordance with the rule of law. XDR-TB may test the ability of governments in the United States to balance public health and individual rights.

International Dimensions

Speaker's odyssey also reveals the international dimensions of XDR-TB, which highlight questions about how the United States exercises public health powers in a global context, how international law applies to XDR-TB, and what strategies exist to address the global XDR-TB crisis.

Travel Restrictions on Persons Leaving the United States. Speaker's case raises questions about the government's ability to prevent a person who poses a health risk from leaving the United States. County officials orally advised Speaker not to travel, but what government body could have prevented him from traveling to Europe? Given the international context, the federal government is the relevant constitutional authority. Federal law focuses, however, on preventing disease importation and does not mention preventing disease exportation.¹⁵ Neither statutory law nor existing or proposed federal quarantine regulations address the need to prevent persons in the United States who pose a health risk from leaving the country.

Extrajurisdictional Application of US Public Health Law. The CDC advised Speaker to report to Italian authorities, but he did not follow this advice.^{4,5} This raises the question

of whether the United States can enforce federal quarantine orders on US citizens in other countries. Federal law does not apply outside the United States unless Congress intends for it to so apply.²⁰ Congress expressed no such intent in federal public health law, prescribing that federal quarantine regulations "for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession."¹⁵

Screening for Public Health Threats at US Borders. Speaker's entry into the United States focuses attention on screening for health threats at US borders. Unlike Speaker's situation, the typical problems concern the failure or inability of border control systems to identify health threats. These problems point to weaknesses in the system of quarantine stations at US ports of entry. According to an Institute of Medicine study, the small number of and traditional activities undertaken by quarantine stations "no longer protect the US population against microbial threats of public health significance that originate abroad."²¹ This study recommended improvements in leadership, legal authorities, infrastructure, training, funding, and collaboration to improve the federal government's ability to prevent disease importation. Speaker's case suggests that, despite improvements, work remains to be done in this area.

XDR-TB and the New International Health Regulations. Speaker's case also raises broader concerns about the role of international law in addressing XDR-TB. Here, the new International Health Regulations, adopted in May 2005 and entered into force on June 15, 2007 (IHR 2005),²² deserve attention. First, public health reactions to Speaker's travels demonstrate that XDR-TB cases may constitute public health emergencies of international concern that must be notified to WHO under the IHR 2005.²² As illustrated by the Speaker episode, XDR-TB cases could satisfy the criteria of the IHR 2005 for determining whether an event may constitute a public health emergency of international concern. The United States notified WHO about the Speaker case on May 24 despite the IHR 2005 not being in force. An obligation to report XDR-TB cases could improve global surveillance. Following notification, the WHO director-general must determine whether notified events actually constitute public health emergencies of international concern and, if so, must issue temporary recommendations guiding countries in their response.²²

A WHO task force argued that XDR-TB does not constitute a public health emergency of international concern because such a declaration is "really only intended for outbreaks of acute disease, rather than the 'acute-on-chronic' situation of . . . XDR-TB."²³ This interpretation is questionable because the IHR 2005 never uses "acute disease" to define its scope. The reaction to Speaker's case indicates that XDR-TB is a dangerous pathogen of global concern. XDR-TB may be an early test case for how WHO and its member states apply the IHR 2005.

Second, Speaker's isolation order requires examination of whether compulsory measures may be increasingly necessary to contain XDR-TB around the world.^{24,25} The IHR 2005 recognizes the need for such measures but requires that countries apply them in a manner consistent with scientific, public health, and human rights principles.²²

Addressing the Global Crisis of XDR-TB

Speaker's travails partially lifted the veil on the global XDR-TB crisis. How do the United States and the international community confront the emergence of XDR-TB around the world? A host of challenges exist, including improving surveillance, designing nonpharmacological interventions that protect public health while respecting human rights, inventing better diagnostics, managing XDR-TB's deadly synergy with HIV/AIDS, creating new antibiotics that are available in developing countries, and building health system capacities to handle the burden of XDR-TB. The grim march of TB from MDR-TB to XDR-TB does not bode well for achieving the changes needed to produce robust global responses to the extremely drug-resistant manifestation of the white plague. XDR-TB threatens global health, challenges the rule of law, and requires improved international cooperation.

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Public Health Benefits of Recent Litigation Against the Tobacco Industry

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AS WITH LAWSUITS INVOLVING OTHER DANGEROUS products, litigation against the tobacco industry can serve several important functions. Lawsuits can compensate individuals harmed by the product and can serve a public health purpose by encouraging manufacturers to change their products, sales, or marketing strat-

egies to reduce risks. Information obtained in litigation also can be used to support future regulatory action.¹

Litigation against the tobacco industry has met with mixed success.² Between 1954 and 1994, private citizens filed more than 800 lawsuits against tobacco manufacturers.³ The tobacco companies achieved great success in court during this time by challenging the science that tied smoking to nega-

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