



Committee on Homeland Security
Report Prepared by the Majority Staff:

The 2007 XDR-TB Incident: A Breakdown at the Intersection of Homeland Security and Public Health



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON HOMELAND SECURITY
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Executive Summary

In May 2007, Mr. Andrew Speaker, an attorney from Atlanta, Georgia, caused a major health scare in the United States and abroad when he flew to and from Europe while knowingly infected with a drug resistant form of tuberculosis (TB). Though initially diagnosed with multi-drug resistant tuberculosis (MDR-TB),¹ Mr. Speaker was subsequently confirmed to be infected with extensively drug resistant tuberculosis (XDR-TB).² When public health officials realized he left the U.S. to travel in Europe, they began working with other Federal and state authorities, as well as international bodies, to limit the spread of the disease.

Disregarding a directive from the Centers for Disease Control and Prevention (CDC) to seek medical treatment in Italy, Mr. Speaker returned to the U.S. by altering his flight itinerary, flying to Canada, and then driving across the border. Although Mr. Speaker's name appeared on a list of individuals who should be denied entry into the country, Federal agents failed to detain him at the border crossing. Shortly thereafter, Mr. Speaker notified the CDC of his entry into the U.S., and the CDC placed him under involuntary isolation – first in New York City, then Atlanta, and finally Denver. In July 2007, he was released from a hospital in Colorado, whereupon he returned to his home state of Georgia for outpatient treatment.

A number of homeland security and public health processes were utilized to manage this incident, many of which failed at different points. In addition to providing a comprehensive timeline of events from January to June 2007, this report (1) explores the interactions between the Department of Homeland Security and the CDC regarding public health security issues; (2) identifies weaknesses in homeland security processes designed to prevent entry into the U.S.; and (3) makes recommendations for agency improvements in these areas.

Although there were certain circumstances in which U.S. federal departments and agencies worked well together, the 2007 XDR-TB incident was handled ineffectively and inefficiently. As is always the case with events for which we are poorly prepared, the situation cast a harsh light on the gaps in communication, coordination, response, patient management, implementation of quarantine and isolation laws, public messaging, information management, training, awareness, and professionalism. Though it is clear that all parties involved in this situation are aware of these shortfalls, it is not as clear to the Committee that they are being addressed with the urgency and attention necessary to prevent a similar series of events from occurring again today. The twin specters of diseases that are increasingly resistant or completely without current treatments and antimicrobials, and the ability of diseases to spread more quickly than ever before due to rapid transit and other enablers, place public health concerns squarely on the homeland, national, and transnational security agendas. How we address these gaps now will serve as a direct predictor of how well we will handle future events, especially those involving emerging, reemerging, and pandemic infectious diseases.



The Committee expects that the agencies involved – including the CDC, the Department of Homeland Security, and the Homeland Security Council – will soon complete their own analyses of the incident, which will enhance the findings and recommendations contained herein. This event seriously impacted the ability of these organizations to ensure the public health security of the Nation, prevent the spread of the disease throughout the world, and maintain credibility as a leader in disease control. All departments and agencies must identify the lessons they observed and learned, and describe how they intend to overcome the glaring inefficiencies and weak points in their systems and organizations.



Key Findings

Key Findings on Public Health

- Governmental officials could have legally prevented Mr. Speaker from traveling within, outside, and back into the U.S.
- Operating under the “covenant of trust” between a patient and his health care provider, government officials failed to use the most aggressive measures earlier in the process that would to prevent Mr. Speaker from leaving the country.
- The CDC relied too heavily on strong interpersonal relationships [between CDC and Customs and Border Protection (CBP) personnel collocated at the Atlanta quarantine station, and between the CDC and a former employee working at the Italian Ministry of Health], rather than formal channels, to manage the incident.
- No single plane (including the CDC’s) could have been used to transport Mr. Speaker back to the U.S. on one long transatlantic flight, as the risk to others flying in the same airplane for periods longer than eight hours would have been dangerous. However, splitting an overseas flight into shorter legs, using different planes and crews, and taking proper precautions would have made it possible to fly Mr. Speaker back to the U.S. To-date, the CDC has not developed a plan to repatriate a patient given the exact same set of circumstances.
- The CDC did not properly adhere to the International Health Regulations. CDC informed CBP that they believed Mr. Speaker to be a significant public health risk on May 22. Under the International Health Regulations, CDC should have informed the World Health Organization (WHO) that same day of this significant public health risk. Instead, CDC delayed an additional 48 hours before informing WHO on May 24. Had the CDC informed WHO earlier of the situation, European authorities may well have been able to apprehend Mr. Speaker while he was still overseas.
- The Department of Homeland Security’s Office of Health Affairs assigned the responsibility of establishing and maintaining a relationship with the CDC to one of its associate chief medical officers.
- The CDC does not have direct access to passenger manifests for U.S. carriers or traveler contact information, and must rely on the cooperation of airlines, federal partners, and other ministries of health to obtain passenger information.



- CDC is finalizing changes to 42 CFR Parts 70 and 71 that update and clarify interstate and foreign quarantine regulations, and include requirements for airlines to collect passenger contact information and transmit it to the Federal government.

Key Findings on Border Security

- The CBP officer that let Mr. Speaker into the U.S. across the Canadian border could reasonably have been expected to comply with the directives found in the posted TECS message. The egregious failure of this officer remains unexplained.
- Adequate measures are in place for CBP that, if followed, should have resulted in the detainment of Mr. Speaker and his wife at the border crossing.
- CBP is implementing changes to prevent a similar incident from reoccurring. Most importantly, officers can no longer overrule a lookout notice without a supervisor's approval.

Key Findings on Aviation Security

- Attorneys at the Department of Homeland Security either failed to understand their authority, or were unable to convince other entities of their authority, to place Mr. Speaker on the “no-fly” list of the Transportation Security Agency (TSA). After receiving the request from CDC to place Mr. Speaker on the “no-fly” list, there was considerable confusion at TSA about what list (if any) he could be placed on, because he was not a terrorist. This controversy existed for several hours.
- It was not reasonable for the CDC to cite confidentiality concerns in their delay in providing Mr. Speaker's information to the TSA, since they had already disclosed information about Mr. Speaker to the CBP days earlier.



Timeline of Events

JANUARY – MAY 10, 2007

In January, Andrew Speaker, a 31-year old Atlanta lawyer, falls and injures his ribs. He receives an X-ray, which reveals an abnormality in the upper lobe of his right lung. This suggests tuberculosis. Mr. Speaker begins meeting regularly with Fulton County health officials for treatment.³

In early March, Mr. Speaker undergoes a procedure to obtain a sputum sample from his lung. By the end of the month, laboratory tests confirm the diagnosis of TB.⁴

On May 10, 2007, Fulton County health officials determine Mr. Speaker has MDR-TB.⁵

- **How common are TB cases in the U.S.? What is the CDC's involvement in testing for TB?**

Though certainly not as prevalent as it once was, TB continues to thrive in the U.S.. After a surge in TB cases between 1985 and 1992, the annual TB rate steadily decreased from 1993 to 2005. However, according to the CDC, the decline has recently decelerated, raising concerns that the progress toward eliminating TB is slowing.⁶ In 2005, a total of 14,093 TB cases were reported in the U.S., representing a 3.8 percent decline in the rate from 2004.⁷ For 2004, 128 cases of MDR-TB were identified, representing 1.2 percent of the 10,846 cases for which drug-susceptibility test results were reported.⁸

The CDC receives reports of all verified cases of tuberculosis. Health officials must also notify the CDC whenever MDR-TB appears also to be extensively drug resistant, forwarding specimens so that the CDC can provide laboratory confirmation of XDR-TB. Upon request, CDC will also perform drug-susceptibility testing for *Mycobacterium tuberculosis* isolates referred from state and other authorized health facilities that may not have the capacity to conduct tests for drug resistance or that may want additional confirmatory tests.⁹

- **Why did it take so long to identify Mr. Speaker's form of drug resistant TB? Can anything be done to improve diagnostics in order to speed the identification of drug resistant forms of TB? Where are the research gaps?**

The length of time it took to identify Mr. Speaker's TB is typical for these cases. Though CDC epidemiologists are satisfied that cultures received for drug-susceptibility testing are sent to CDC in a timely manner, there is little that can be done to accelerate the testing process. CDC's



drug-susceptibility testing relies on growth of tuberculosis bacilli, which are notoriously slow-growing. The process usually takes at least one month to complete. However, when performed properly, it allows laboratorians to quantify the portion of the bacteria in the isolate that are resistant to a drug, which is important for predicting if a tuberculosis treatment regimen is likely to fail.¹⁰

The CDC continues to work on creating testing protocols that will allow for testing with much smaller amounts of the organism, as well as other advanced diagnostics that would allow for quicker identification. Currently, culture-based tests are the standard, validated methods for drug-susceptibility testing of *M. tuberculosis* isolates. Protocols for rapid tests for detecting rifampin (a first-line drug) resistance (based on detecting mutations associated with this particular drug) have been validated and are available in a number of public health laboratories. However, public health departments may opt not to use this test because of the resources required to validate the findings, or because they do not have sufficient numbers of cases to make this expenditure worthwhile.¹¹

This does not, however, address the need for rapid second-line drug tests. Rapid, molecular-based tests have not yet been developed to detect resistance to the second-line anti-tuberculosis drugs because the mutations that are associated with resistance to each of the second-line drugs have not been identified. Basic research is still needed to identify the genetic basis of resistance to each of the second-line drugs. The National Institutes of Health (NIH) and the CDC are funding and participating in basic research as well as in transitional research to use this information to develop reliable rapid diagnostic tests.¹²

Though basic research in this area will take years, one shorter term improvement that can be made is in the distribution of advanced laboratory diagnostics to state public health laboratories so that they can conduct these tests on their own. National guidelines recommend second-line drug-susceptibility testing for strains with rifampin-resistance or resistance to any two anti-tuberculosis drugs.¹³ Ideally, all states should have the capacity to conduct second-line drug-susceptibility testing or the capacity to refer isolates for this testing.¹⁴ Unfortunately this is not the case. Currently 42 states conduct first-line drug-susceptibility testing using “rapid” broth-based methods (which take seven to fourteen days once the culture tests positive) that allow them to identify MDR-TB, while only eight states have and exercise the ability to test for all second-line drug-susceptibility that would allow them to identify XDR-TB.¹⁵ Only those states with higher incidence of tuberculosis (such as New York, California, Texas, and Florida) conduct tests to determine whether the organism is susceptible to the second-line of drugs used to treat the disease.¹⁶ Many laboratories simply do not have adequate funding to obtain and utilize newer tools (such as direct specimen Nucleic Acid Amplification Tests – including polymerase chain reaction), that allow for more rapid detection of microorganisms such as those causing tuberculosis.

There are difficulties associated with distributing diagnostics to state public health laboratories. Drug susceptibility testing for the second-line drugs is a difficult procedure to standardize.¹⁷ Maintaining the proficiency, supplies, and drugs to perform these tests reliably, when only a few tests may be performed each year, is both challenging and expensive.¹⁸ In order to demonstrate proficiency, one must understand the origin of and criteria for drug resistance,



potency and stability of drugs during laboratory manipulation, anti-mycobacterial activity of drugs when incorporated into different media – as well as the reading, interpreting and reporting of results.¹⁹ For those states that do not conduct second-line testing, public health laboratories submit isolates to the CDC to determine susceptibility to these drugs.²⁰ Approximately 20 state public health laboratories take advantage of this service.²¹

The CDC and the Association of Public Health Laboratories recently started a full-scale assessment of tuberculosis testing capabilities to use current testing technologies throughout the U.S., including the illustration of capability gaps. These gaps must be filled, and new technology, processes and procedures emplaced.²² As the CDC does with some technology and methods to identify certain bioterrorist agents, it would be better to transfer some technology and methods from the CDC to at least those laboratories that conduct testing for tuberculosis on a regular basis, with large numbers of specimens and the highest numbers of samples determined to be extensively drug resistant.²³ Additional research is necessary regarding drug-susceptibility, but since many public health laboratories test for tuberculosis, such research is best conducted by Federal organizations like the CDC and/or the NIH, in conjunction with the Association of Public Health Laboratories.

MAY 11, 2007

Fulton County health officials give Mr. Speaker a “verbal warning” of the danger and the “prohibition” against travel,²⁴ and attempt to hand-deliver a medical directive telling him not to travel.²⁵

Mr. Speaker believes Fulton County health officials tell him they “preferred” he not travel.²⁶ Dr. Julie Gerberding, Director of the CDC, states “the patient really was told that he shouldn’t fly.”²⁷

Discrepancies exist in the official story of who told what to Mr. Speaker. According to Mr. Speaker, “Everyone knew... The CDC knew, doctors knew, Kaiser knew. They said, ‘We would prefer you not go on the trip.’ And that’s when my father said, ‘OK, are you saying because he’s a risk to anybody or are you simply saying it to cover yourself?’ And they said, ‘We have to tell you that to cover ourselves, but he’s not a risk.’”²⁸ Dr. Steven Katkowsky, Director of Public Health and Wellness for Fulton County said, “Certainly the recommendation would be that if you have an active infection with tuberculosis, you ought not to be getting on a commercial airliner.”²⁹

- **What laws allow public health officials to prevent an infected citizen from traveling within and outside the U.S.?**

This case presented a unique challenge for public health officials, some of whom apparently did not believe Mr. Speaker to be a risk in leaving the country. There are conflicting accounts of what was told to whom. This report does not take a position on the communications between the parties, focusing instead on the policy considerations raised during the incident.



According to Dr. Julie Gerberding, Director of the CDC, health officials “usually rely on a covenant of trust to assume that a person with tuberculosis just isn’t going to go into a situation where they would transmit disease to someone else.”³⁰ The CDC asserts that in the vast majority of situations when a patient is diagnosed with an infectious disease and told not to travel, the patient cooperates with those orders.³¹ However, as this incident makes clear, the “covenant of trust” is occasionally broken.

If a patient is non-cooperative, the state has the legal authority to isolate or quarantine the individual. Isolation is defined as the “separation of persons who have a specific infectious illness from those who are healthy, and the restriction of their movement to stop the spread of that illness.”³² Quarantine refers to the “separation and restriction of movement of persons who, while not yet ill, have been exposed to an infectious agent and therefore may become infectious.”³³ Each individual state is responsible for intrastate isolation and quarantine, and states conduct these activities in accordance with their respective statutes.

Authorities vary widely by state. In Georgia, for example, a court order is necessary for a patient to be isolated involuntarily, and the patient must first demonstrate that he or she is not compliant with medical advice. Therefore, in the case involving Mr. Speaker, the state could not issue such an order until the patient actually did something that was against medical advice. If a state felt that it could not adequately isolate a patient, it could contact CDC to determine whether Federal quarantine authorities could be used. Federal authorities allow CDC to act in the event of inadequate local control, if the patient has a specified communicable disease and is moving between states, or if the patient has a specified communicable disease and represents a public health threat to other persons who may then be moving between states.³⁴ Following the letter of the Georgia law, state and county officials could not obtain a court order to detain Mr. Speaker until he actually violated their medical advice; ironically, this meant that they would have to wait until he left the country. Dr. Steven Katkowsky, Director of Public Health and Wellness for Fulton County, noted this incongruity when he said that the law is “kind of a Catch-22...a patient has to be noncompliant before you can intervene,” and “there’s no precedent for a court stepping in before a patient has proven himself to be non-compliant.”³⁵

The CDC has been supporting work undertaken by Georgetown University and Johns Hopkins University to develop the Turning Point Model State Public Health Act and the Model State Emergency Health Powers Act.³⁶ These Model Acts were developed as planning tools to assist state, territorial, tribal and local governments in assessing their current public health laws and to identify areas that may need updating or improving.

The CDC is also examining the application of its quarantine authority to situations involving patient movement out of the country. Historically, the use of quarantine has been devoted to keeping people out of an area, not containing them in an area. This case represents the first time that CDC has had to address preventing a person in the U.S. from leaving.³⁷



- **Is a “covenant of trust” between the state and an infected patient enough, or should states strengthen their laws to restrict the movement of patients before they are noncompliant with a medical order?**

This case represents the difficult choice of balancing the needs of the patient and protecting the public’s health. If a state believes the patient has a strong intent to put others at risk, the health officials of that state need to have the authority to take action absent documentation of intent to cause harm.³⁸ In this situation, officials gave the patient the benefit of the doubt, failing to use the most aggressive measures earlier in the process. However, in future such situations, it would be unwise for officials to go so far in the opposite direction that the result is unnecessarily restricting the movement of people. This balance will be difficult to attain. However, even as the covenant of trust continues to be the foundation of patient health care, there is no need to allow that covenant to be broken more than once for officials at any level of the government to enforce the laws that protect the health of the public.

MAY 12 – 16, 2007

On Saturday, May 12, Mr. Speaker departs Atlanta on Air France Flight 385.³⁹ He arrives in Paris on May 13.⁴⁰ On May 14, Mr. Speaker flies from Paris to Athens on Air France flight 1232.⁴¹ On May 16, he flies from Athens to Thira Island on Olympic Air flight 560.⁴²

MAY 17, 2007

The Georgia State Public Health Laboratory requests that the CDC test for XDR-TB.⁴³

The Georgia Division of Public Health is notified that Mr. Speaker has flown overseas.⁴⁴

- **Why did it take so long for CDC to test the specimen for XDR-TB?**

CDC is a reference laboratory that routinely assists state and local public health laboratories by conducting testing, particularly drug-susceptibility testing, on *M. tuberculosis* isolates. State public health laboratories may request CDC assistance at any time. The Georgia State Public Health Laboratory is one of about 20 state public health laboratories that rely on the CDC laboratory to assist in drug-susceptibility testing for second-line drugs. The Georgia laboratory followed the established procedure in alerting CDC that the Speaker culture be tested.⁴⁵

According to documents provided to the Committee on Homeland Security, the CDC increased funding to strengthen public health laboratories, placing emphasis on increasing the promptness and reliability of laboratory results. When an isolate is identified that requires priority testing, CDC works with the state public health laboratories to conduct that testing as



rapidly as possible. In almost all cases, the most time- and cost-effective method for getting an isolate to the CDC laboratory is for the state public health laboratory to send it to CDC using one of the commercial overnight delivery systems. An exception is the Georgia State Public Health Laboratory for which the most efficient method is courier. On occasion, a CDC laboratory employee will stop by the Georgia State Public Health Laboratory to pick up specimens since the laboratory is in close proximity to the CDC campus.⁴⁶

MAY 21, 2007

Tests come back positive for XDR-TB.⁴⁷

Mr. Speaker flies from Mykonos to Athens on Olympic Air 655.⁴⁸

Mr. Speaker flies from Athens to Rome on Olympic Air 239.⁴⁹

- **What are the policies, procedures, and laws that allow the Federal government to prevent a sick individual from entering the country? What are the roles of the CDC and the Department of Homeland Security in enforcing these efforts?**

Although primary isolation and quarantine authority belongs to the state and territorial health officials, interstate and border quarantine authority belongs to the Federal government.⁵⁰ The Public Health Service Act gives the Secretary of Health and Human Services the authority to make and enforce regulations “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.”⁵¹ Executive Order 13295 identifies the following diseases that fall under this authority: cholera, diphtheria, infectious tuberculosis, plague, Severe Acute Respiratory Syndrome, smallpox, viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, etc.), yellow fever,⁵² and influenza (with pandemic potential or expression).⁵³ In 2002, quarantine authority was transferred from the Secretary of Health and Human Services to the Director of the CDC, who delegated the execution of isolation and quarantine activities to the CDC Division of Global Migration and Quarantine (DGMQ).⁵⁴

Procedures exist to isolate and quarantine individuals by both the private and public sectors, and at all governmental levels from local to Federal. Individual organizations possess their own procedures for implementation. The CDC carries out a variety of activities to isolate and quarantine individuals, including but not limited to: screening international travelers for symptoms of illness, and providing health education and information.⁵⁵ The U.S. Coast Guard, CBP, and Immigration and Customs Enforcement (ICE) within the Department of Homeland Security may be called upon to help enforce federally-ordered isolation and/or quarantine when the people so ordered refuse to comply, and to prevent non-U.S. citizens from entering the U.S. for these purposes.⁵⁶ The Department of Homeland Security may also exercise its authority to require medical screening of international travelers before flying into the U.S.⁵⁷ Unfortunately,



personnel from the Department of Homeland Security [the Office of Health Affairs (OHA), U.S. Coast Guard, CBP, and ICE] and the CDC have only recently begun to develop specific procedures to enable them to work together to implement and enforce isolation and quarantine.

MAY 22, 2007

CDC/DGMQ contacts the Assistant Port Director for the Atlanta office of CBP.⁵⁸ CDC notifies CBP Atlanta that Mr. Speaker poses a public health risk. CDC requests that CBP Atlanta attach a message to Speaker's passport.⁵⁹ An Atlanta CBP officer enters a Treasury Enforcement Communications System (TECS) subject record on Mr. Speaker. The officer also enters a TECS subject record for his wife.⁶⁰

This text note includes instructions to "place mask on subject, place in isolation, well-ventilated room if possible." The note indicates that Mr. Speaker "has multiple drug resistant TB and is a public health risk."⁶¹ The note contains instructions that the CBP officer contact the CDC upon encountering Mr. Speaker.⁶²

CDC learns that Mr. Speaker is in Rome.⁶³

Dr. David Kim, a CDC quarantine officer, phones Mr. Speaker in Rome and informs him of his XDR-TB diagnosis. He explains the severity of the disease; instructs him to terminate all travel and to cease use of commercial air carriers; and initiates conversations about isolation, treatment, and travel alternatives.⁶⁴ Mr. Speaker is told he will be contacted by CDC the next day with travel information.⁶⁵

- **Why didn't CDC contact CBP Headquarters in Washington, rather than CBP Atlanta?**

Upon learning that Mr. Speaker was out of the country, and that he tested positive for XDR-TB, the CDC requested that the local CBP Atlanta office place a message on Mr. Speaker's passport to inform other officials in case he decided to return to the U.S. In this case, CDC reached out to CBP Atlanta because both organizations had personnel collocated in the same facility. According to the CDC, quarantine stations have developed strong relationships with their local Department of Homeland Security partners, and typically work directly with them at the local level. The Atlanta quarantine station took the lead on the initial part of the investigation until it was determined that additional resources and broader expertise were needed.

As a result of the incident, a team of individuals from the Department of Homeland Security, the Department of Health and Human Services (HHS), and CDC [DGMQ and Division of Tuberculosis Elimination (DTBE) staff] met to review the response and to develop standard operating procedures (SOPs) for future responses. Two areas in which the SOPs are intended to formalize actions are in CDC/DGMQ requests for Department of Homeland Security assistance in taking actions to protect the public from infectious threats during travel and at U.S. ports of entry; and internal CDC/DGMQ procedures for determining the need for requesting Department



of Homeland Security assistance. The meeting resulted in draft SOPs that are under revision but currently in use.⁶⁶

- **What is TECS? What is a TECS message? How frequently do CBP officers encounter these messages?**

CBP created a TECS Lookout record in the system to advise its officers of Mr. Speaker's condition and what to do when he was encountered. TECS is a computerized information system containing more than a billion records utilized by many Department of Homeland Security component agencies such as CBP and ICE, as well as other law enforcement agencies.⁶⁷ TECS is an overarching law enforcement information collection, targeting, and sharing environment.⁶⁸ This environment is comprised of several modules designed to collect, maintain, and screen data, conduct targeting, and share information. TECS is designed to identify individuals and businesses suspected of or involved in the violation of federal law.⁶⁹ One of the TECS modules is the Automated Targeting System (ATS), that scrutinizes a large volume of data related to a person crossing U.S. borders.⁷⁰ TECS is also a communications system permitting message transmittal between some Departmental components and other national, state, territorial, tribal, and local law enforcement agencies.⁷¹ TECS provides access to the FBI National Crime Information Center and the National Law Enforcement Telecommunication System with the capability of communicating directly with state and local enforcement agencies. Many, but not all of the names on the Federal "no-fly" list are also contained in TECS.

Every day, CBP officers come across thousands of TECS subject records. CBP Field Offices are not required to contact CBP Headquarters in Washington each time an alert is placed in the system. Local CBP management is authorized to approve placement in and removal of these subject records from the system. In this case, once the subject record was placed in the system, it was available for viewing by all CBP officers.

- **Could a CBP officer be expected to comply with the medical directive in a TECS message? What medical training currently exists for CBP officers?**

The majority of the 327 ports of entry into the U.S. are manned by law enforcement officials from CBP who have received no advanced medical training.⁷² CBP officers do, however, have procedures to follow when a U.S. citizen or non-U.S. citizen appears to be ill and in need of medical attention at the border, and each is trained in those procedures.

According to CBP, the Occupational Safety and Health Handbook⁷³ addresses the use of personal protective Equipment (PPE), respiratory protection, and TB exposure control.⁷⁴ Policy requires that PPE, including respiratory protection, be readily available to all CBP employees. CBP managers and employees have a shared responsibility to ensure that PPE is available, maintained, and in working condition. In addition, annual training is required of all officers in order to respond to both bloodborne pathogens and TB incidents.⁷⁵

As part of the Office of Field Operations Pre-Academy Training, CBP requires new officers to complete the following training: (1) Annual Blood borne Pathogens; (2) Avian Flu;



(3) Bird Handling Procedures; and (4) Pandemic Influenza Safety: Protecting Yourself. Additionally, during basic training, CBP officers receive two hours of training from the U.S. Public Health Service on public health threats. CBP officers receive instruction about their responsibilities at the border. They are responsible for (1) observing travelers for obvious signs and symptoms of suspected quarantinable and communicable diseases; (2) identifying arriving passengers traveling from areas with known communicable disease outbreaks; (3) recognizing cargo that poses a public health threat; and (4) providing this information to CDC quarantine stations. In addition, CBP officers are responsible for ensuring that immigrant visa packages contain the required medical clearance forms.⁷⁶

In CBP's on-the-job training at the ports, responding to biological threats is now included in anti-terrorism training modules presented to CBP personnel. Several courses within CBP's Office of Training and Development's Virtual Learning Center concentrate on biological threats, including avian and pandemic influenza.

Although CBP officers are trained on how to handle passengers with a quarantinable or communicable disease, CBP officers are not trained as medical personnel.⁷⁷ Department of Homeland Security personnel assist with surveillance for quarantinable or serious communicable diseases of public health significance among persons arriving in the U.S. from foreign countries, with the understanding that they are not expected to physically examine or diagnose illness among arriving travelers. According to CDC, surveillance by Department personnel would generally consist of the recognition and reporting of overt visible signs of illness or information about possible illness provided to them in the course of their routine interactions with arriving passengers, and does not include eliciting a medical history or the performance of a medical examination. In situations where a known quarantinable or communicable disease is detected abroad, CDC may request that Department of Homeland Security personnel assist with active surveillance to assess the risk of whether individual passengers arriving from affected countries or regions are carrying a quarantinable disease. CDC will ensure that a quarantine officer or designated official with public health training will be available to assist in the evaluation of individuals identified through this active surveillance.

Tools are also available at CBP field locations to utilize when an agent encounters a sick individual. On April 30, 2007, a memorandum entitled *Potentially Ill Travelers and Response Protocols* was issued to all CBP field locations. The memorandum advises CBP officers that PPE is available and should be utilized in all cases where travelers are suspected of having a contagious illness or disease, until a competent medical authority determines there is no threat. The memorandum also states that any potentially infected traveler should be segregated from other travelers in an isolated area.⁷⁸

The CDC, through the DGMQ, has established twenty quarantine stations at major ports of entry throughout the country to limit the introduction and spread of infectious diseases into the U.S.; each quarantine station has responsibility for all ports in an assigned geographic area.⁷⁹ Quarantine stations are generally equipped with specialized respiratory isolation rooms that can house individuals that might contain infectious diseases such as TB. A port of entry that does not contain a quarantine station may still have designated holding cells or medical facilities that can house potentially infectious travelers.



If there is no public health inspector at a port of entry, a CBP officer is supposed to notify the appropriate quarantine station⁸⁰ and follow the procedures established to process potentially infected travelers described in the CBP Occupational Health and Safety Handbook.⁸¹ The TB Exposure Program was designed to provide information for the prevention and early detection of TB among CBP employees who are at significant risk of exposure to the disease. This program is primarily geared toward employee exposure; however, it includes information regarding decontaminating spaces occupied by a person with TB, respiratory protection and required training for the employee. The training involves information about the disease, signs and symptoms, risk factors, PPE, and a review of the medical surveillance program. The Occupational Exposure to Blood borne Pathogen Diseases course is also geared toward employee safety. It describes universal precautions (such as gloves and masks), barrier precautions, hand-washing, other protective gear, conducting safe searches, evidence handling, decontamination, proper disposal of affected clothing or equipment, regulating waste, and mandatory training.



MAY 23, 2007

Mr. Speaker receives another call from CDC physician Dr. David Kim.⁸² Dr. Kim tells Mr. Speaker to turn himself in to Italian health authorities (with the assistance of American Citizens Services in Rome) the next morning and agree to go into isolation and treatment in that country for an indefinite period of time.⁸³

Dr. Kim tells Mr. Speaker “we have tools to keep you from flying into the U.S.”⁸⁴ Mr. Speaker later asserts that he was “aware” he was placed on a no-fly list, which is why he decided not to fly into a U.S. airport.⁸⁵

Mr. Speaker understands that hiring a private jet to fly back to the U.S. would cost \$100,000.⁸⁶ Dr. Kim tells Mr. Speaker that a former CDC staff member and TB expert working at the Italian Ministry of Health will meet with him the next day to provide assistance. Mr. Speaker provides hotel information for where he is staying so that this health official can visit with him the following day.⁸⁷

Mr. Speaker agrees to cancel planned travel to Florence on May 24, 2007.⁸⁸

- **What options are available for the Federal government to repatriate infected American citizens? Why was the CDC unable to use their plane to fly Mr. Speaker back to the U.S.?**

Dr. Kim discussed a number of different options for Mr. Speaker’s repatriation, including an air ambulance, chartering a private plane, and utilizing the CDC plane. Dr. Kim also told Mr. Speaker to call the American Citizens Services in Rome, explain his situation, and seek their assistance in repatriation.⁸⁹ However, it was only the next day – May 24 – that CDC officials convened to discuss among themselves options for transporting Mr. Speaker back to the U.S. According to CDC, the appropriateness of transportation via Department of Defense or the CDC airplane, the safety and health of crew and pilots, and CDC legal authorities in this setting were all examined. However, before any decision could be finalized regarding the use of the CDC plane or other means of transportation, CDC learned that Mr. Speaker had already flown commercially into Canada and then re-entered the U.S. Therefore, the discussion of the use of the CDC plane for a trans-Atlantic flight was discontinued.⁹⁰

During her testimony before the Committee on Homeland Security in June 2007, CDC Director Dr. Julie Gerberding indicated that she would not have authorized the CDC plane to transport Mr. Speaker based on scientific evidence indicating that transporting patients with TB for flights over eight hours would be dangerous to others riding in the same airplane.⁹¹ The use of the CDC plane to transport a sick person from one location to another must comply with the Federal Travel Regulation, be recommended by the CDC Director, and have the approval of the HHS Assistant Secretary for Administration and Management. Using the aircraft for this purpose also requires approval from the General Counsel if any non-Federal travelers would be traveling on the CDC plane. Consideration is also given to the medical condition of the patient,



and the safety of the crew and attendants before a decision is made related to the transport of an ill or infectious patient.⁹²

In the interest of pursuing this possibility, Committee staff suggested that an overseas flight could have been split into shorter legs, and requested a scientific justification for not utilizing the CDC aircraft for flights of less than eight hours in duration.⁹³ According to the CDC, breaking down the flight into shorter flight segments would not have substantially lowered the overall risk to the co-travelers or pilots (assuming they were all on board with the patient) throughout each leg of the journey. The risk increases cumulatively as more time is spent in close proximity with someone who can transmit the disease. If all persons were on each leg of the journey together, then the risk would have been basically the same as in one long journey, or perhaps even greater given the additional time needed for multiple take-offs and landings. In theory, the risk of each individual would have been potentially lower if there were no co-travelers or caregivers accompanying the patient and a different crew of pilots available for each leg of the flight. This of course would have posed logistical challenges. In addition, frequent ground stops would have potentially increased the number of potentially exposed persons on the ground, especially if the plane had to be serviced, or entered for any reason, or if the patient had to exit the plane.⁹⁴

Clearly, there is a significant deficiency in the Federal policy regarding the transport of an infected American citizen back to the U.S. It is unreasonable to expect that any individual would agree to pay \$100,000 to rent a private jet. The CDC's concern for the safety of Federal officials and pilots flying with Mr. Speaker precluded the option of using the CDC plane. In fact, Dr. Kim's suggestion that Mr. Speaker contact American Citizens Services in Rome suggests that the CDC was willing to simply "pass the buck" on to another agency to deal with the problem. Absent the existence of a reasonable alternative, it is hardly surprising that Mr. Speaker would simply board a plane back home. The Committee expects that the CDC will examine these policies closely and identify a new strategy in the event of similar future incidents.

- **What policies and procedures are in place to notify foreign health authorities (like WHO) in these situations? Was the CDC compliant with those policies and procedures? Do CDC and foreign governments share patient information with one another?**

The CDC relied on an informal connection to the Italian Ministry of Health – a former CDC staff member, expert in TB, who happened to be working for the Ministry – to begin notifying foreign governments of the situation involving Mr. Speaker. This informal connection raises questions about the correct use of international policies and procedures to deal with a case such as this, and concerns about whether the proper authorities exist to facilitate contact.

The International Health Regulations, which "officially" went into effect in the U.S. in June 2007, provide policies and procedures regarding disease notification to WHO.⁹⁵ The International Health Regulations provide a legal framework for the world community, designed to contain the threats from diseases that may spread from one country to another.⁹⁶ The International Health Regulations require that Member states notify WHO within 24 hours of



disease events and situations occurring within or outside of their borders that are serious in nature and have the potential to spread – recognizing that diseases know no borders. Notification must take place within 24 hours of assessment of information that indicates a public health emergency of international concern⁹⁷ within State borders in Article 6 (Notification)⁹⁸ or within 24 hours of receipt of evidence for public health risks⁹⁹ outside of State borders that may cause international disease spread in Article 9 (Other Reports).¹⁰⁰ Although Member States are not required to do so, the International Health Regulations obligate WHO to provide this information to other States.

Though the CDC operated under the International Health Regulations at the time of the incident, the agency did not comply with its requirements. CDC testing confirmed XDR-TB on May 21, and CDC personnel requested that a TECS subject record be generated for Mr. Speaker on May 22, informing CBP that they believed him to be a significant public health risk. If the CDC was indeed adhering to the International Health Regulations, they should have informed WHO on May 22 of this significant public health risk that was now outside its borders, known to be traveling through multiple countries, with the potential to spread disease internationally. Instead, CDC delayed an additional 48 hours before informing WHO on May 24.

After speaking informally with the former CDC staffer, Dr. Ken Castro, Director of the CDC/DTBE, formally notified Italy and WHO on May 24.¹⁰¹ There is a slight discrepancy in the official record about subsequent notifications. According to the CDC, WHO notified France, the Czech Republic, Greece, and Italy on May 25.¹⁰² However, according to WHO, the CDC notified WHO/EURO on May 25, and on May 26, WHO/EURO informed the IHR National Focal Points for the International Health Regulations in the Czech Republic, France, Greece, and Italy.¹⁰³

Although Italian health officials never medically treated Mr. Speaker, it would have been unusual for the CDC or any other U.S. governmental entity to receive notification about the results of patient testing by physicians in another country. However, in cases where there is regular collaboration with other health authorities and the disease is considered a threat to public health, the information likely would be shared. Furthermore, if it seems necessary, advisable, and/or possible, treating physicians might well share test results and discuss treatment options once patient permission has been documented – as would occur between two different physicians here in the U.S.

As a result of the incident, a team of individuals from the Department of Homeland Security, HHS, and CDC/DGMQ and /DTBE staff met to review the response and to develop SOPs for future responses. In addition to the areas described above, CDC/DGMQ communications with international partners around the issue of public health threats and the crossing of international borders will be addressed.¹⁰⁴ These draft SOPs are being revised while currently in use.¹⁰⁵



MAY 24, 2007

Dr. Martin Cetron, Director for the DGMQ at the CDC, dispatches the former CDC employee working with Italy's Ministry of Health to visit Mr. Speaker at his hotel and reiterate the previous day's messages. By the time the former employee arrives at the hotel, Mr. Speaker is gone.¹⁰⁶

CDC contacts WHO by phone, and is advised to provide details of the case to an email address that usually receives outbreak alerts. HHS sends official notification to WHO that CDC has determined the event meets reporting criteria for a "public health emergency of international concern" as defined in the International Health Regulations.¹⁰⁷

CDC contacts Department of Homeland Security OHA in the early afternoon (around 1:00 P.M.) to request assistance in preventing Mr. Speaker from traveling via commercial air. Citing confidentiality of patient information, CDC does not provide Mr. Speaker's name to OHA at this time.¹⁰⁸

Mr. Speaker boards flight to North America aboard Czech Air Flight 0104 from Prague to Montreal.¹⁰⁹ He wears a mask on the flight.¹¹⁰ Speaker lands at approximately 3:27 P.M.¹¹¹

Shortly after the flight lands in Montreal, CDC provides Mr. Speaker's name to TSA for inclusion on the "no-fly" list.¹¹²

Mr. Speaker and wife arrive at the Champlain, NY port of entry. Although the TECS subject record appears when he verifies their identities, the CBP officer clears both notices. At 6:18 P.M., Mr. Speaker crosses the border into the U.S.¹¹³ FOUO materials further describe this encounter with CBP.

At 7:30 P.M., TSA General Counsel gives approval for TSA Administrator Kip Hawley to place Mr. Speaker on a supplement to the "no-fly" list.¹¹⁴ Mr. Speaker's name appears on this list at 8:31 P.M.¹¹⁵ Canadian officials later inform Committee staff that Mr. Speaker's name appears on the Canadian "no-fly" list at 8:00 P.M.¹¹⁶

Mr. Speaker checks into a hotel in Albany, N.Y.¹¹⁷

- **Why didn't CBP officers stop Mr. Speaker and his wife at the border? What changes will CBP implement to prevent a similar incident from occurring again?**

According to CBP Commissioner Ralph Basham testifying before the Committee on Homeland Security in June 2007, "There appears to have been a single point of failure in this case – human error by an individual who may have failed to follow appropriate procedures."¹¹⁸ Though there were several missteps by Federal agencies along the way, the failure by the CBP officer who allowed Mr. Speaker and his wife to pass through the Port of Champlain entry was egregious and, to-date, unexplained. The Department of Homeland Security continues to conduct an official review of the officer's actions, and the Committee awaits the findings.



As noted earlier in the May 22 section of this report, the Committee on Homeland Security found adequate measures in place that, if followed, should have resulted in the detainment of Mr. Speaker and his wife at the border crossing. Furthermore, had the CDC informed WHO earlier of the situation, European authorities may well have been able to apprehend Mr. Speaker while he was still overseas. The officer at the border crossing in this case was an 18-year veteran of the Border Patrol, who would have been very familiar with the TECS system and received training on the procedures that would have allowed him to implement a medical directive.¹¹⁹ He was in his third hour of an eight-hour, 4:00 P.M. to 12:00 A.M. shift.¹²⁰ Furthermore, the Port of Champlain has local procedures in place for its officers to process potentially infected passengers and commercial shipments. Champlain has two locations to house a potentially infectious traveler at its main facility, including detention cells that are isolated and vented separately from normal building HVAC units.¹²¹ Therefore, it remains unclear why the officer in this case failed to follow orders; the Committee awaits the official report from the Department of Homeland Security for explanation.

CBP reports having taken several remedial measures in response to the incident. Officers, for instance, no longer have the discretion to overrule a TECS notice without the approval of a supervisor.¹²² According to the Department, changes were made in TECS that instruct officers at the land border primary inspection area to indicate whether a traveler is a match to a record.¹²³ If the traveler is a match, the system now requires the officer to enter a referral code and send the person into secondary inspection. The Department reports that additional enhancements are being programmed that will allow officers in the secondary area to receive more informative notifications of TECS matches at primary inspection, as well as requiring officers to indicate a reason code at primary inspection if a subject is not referred due to being a “no match” to a record. CBP reported that these enhancements were to have been implemented by August 2007. Furthermore, CBP has updated their policy documents concerning land border primary inspection requirements and will be retraining all land border officers who have primary inspection duties during summer 2007. Annual refresher training on public health issues will also be required of each land border officer.¹²⁴

In addition to these efforts, the Committee suggests that the Department of Homeland Security consider establishing a standard medical code (added to those already in use) to the TECS record, which can reflect whether a subject is a health threat to others or otherwise poses a medical risk. This code should carry the same weight as other codes that alert law enforcement officers that a person is considered dangerous, running from the law, etc. Furthermore, subjects entering or exiting the U.S. that are encountered by CBP officers with a TECS subject record containing a medical alert should not be cleared for entry or departure without supervisory approval. This approval should be notated and attached to the TECS subject record.

- **Why was there a four hour delay between the time that CDC provided Mr. Speaker’s name for inclusion on the “no-fly” list and the time that TSA added his name to the list?**

One of the most confusing issues that emerged from the entire incident was the four hour delay between the CDC request to TSA that Mr. Speaker be placed on the “no-fly” list and the



time that TSA finally placed Mr. Speaker on the list. The Department of Homeland Security asserts that even if TSA placed Mr. Speaker's name immediately on the "no-fly" list, it would not have prevented him from flying. While this is true – Mr. Speaker's plane landed in Canada at 3:27 P.M., approximately eight minutes before the CDC made the official request to TSA – it does not explain the issue of the four hour gap between the time that CDC notified TSA (around 3:35 P.M.) and the time that TSA authorized Mr. Speaker's name to appear on the addendum to the "no fly" list (7:35 P.M.).

The TSA "no-fly" list is composed of individuals known or appropriately suspected to be or have been engaged in conduct constituting, in preparation for, in aid of, or related to terrorism. However, TSA has broad authority to assess and address threats to transportation and passenger safety. If the TSA Administrator determines that the presence of such an individual aboard a commercial passenger airline flight poses a threat not only to that flight but to the entire transportation system, flights and flight crews, and others modes of transportation used by those individuals, TSA can direct airlines to deny boarding to an individual. Under this authority, the TSA can deny boarding to an individual if that person is identified by the CDC as a public health threat.¹²⁵

In interviews with Committee staff in June 2007, Department officials disclosed that after receiving the request from CDC to place Mr. Speaker on the "no-fly" list, there was considerable confusion about what list he could be placed on. Department officials told Committee staff that they believed they could not add Mr. Speaker to the "no-fly" list or the "selectee" list because he was not a terrorist. In fact, until 7:30 PM, TSA officials were not sure that they had the authority to enter Mr. Speaker onto any list. Department officials stated that this controversy existed for several hours, until the TSA General Counsel persuasively argued that the TSA Administrator could use his authority to place a non-terrorist on the "no-fly" list.¹²⁶ TSA asserted that at no time was Mr. Speaker considered for the terrorist screening databases.¹²⁷

During the Committee's June 6, 2007 hearing, Dr. Jeffrey Runge, Chief Medical Officer and Assistant Secretary for Health Affairs at the Department of Homeland Security, explained that the confusion resulted because Department officials "could not remember another case that someone who has been put onto what they have as an adjunct to the 'no-fly' list for health reasons. So we have no history in this regard. This was, in fact, a novel case."¹²⁸ Dr. Runge discussed the internal deliberations that day:

The Acting Deputy Administrator for TSA actually made the decision within about two hours after we received the name from the CDC. There were some issues – because the person is not a terrorist, there were some issues as to how he could be entered physically on the list. And there was a conference of lawyers taking place from the Department of Justice and the Department of Homeland Security and TSA, and possibly others, to make sure that the authorities that the Department has – and TSA knew that it had to enter someone on the "no-fly" list even though they were not a terrorist – were in fact able to be followed. And so I believe we received the name from the CDC around 3:30 in the afternoon and by 5:30 the Deputy Administrator had made the decision. At 7:30 or so the electrons



began to flow out from the Office of Intelligence to all of the airlines and all of the points of information sharing that TSA has.”¹²⁹

When asked again why it took two hours for “the electrons to flow,” Dr. Runge stated that while TSA reached the decision within two hours, “it took the confab of lawyers from the other departments a while to become comfortable with that, and in fact he was added at about 7:30.”¹³⁰ Though Mr. Speaker’s name was added to the list at 7:35 P.M., the addendum was not distributed to recipients until 8:31 P.M.¹³¹

Though careful deliberation should be a hallmark of government decision-making, the Committee finds it hard to understand why the Department’s attorneys either failed to understand their authority or were unable to convince other entities of their authority in a more timely fashion. In responding to the Committee’s questions in July 2007, the TSA insists that there was no delay in determining authorities; the record, however, suggests otherwise. Furthermore, the internal delays at the Department were never communicated to the CDC, whose officials still believe that Mr. Speaker’s name was placed on the “no-fly” list at 3:15 P.M.¹³²

- **Why did the CDC cite confidentiality concerns in their delay in providing Mr. Speaker’s information to the TSA? What is the relationship between the Department’s OHA and the CDC, and how can this relationship improve?**

The Committee is troubled by the confused and ineffective communications between the CDC and the Department of Homeland Security. When the CDC contacted OHA in the early afternoon to request assistance in preventing Mr. Speaker from traveling via commercial air, they did not provide his name due to confidentiality issues.¹³³ It was not until two hours later that the CDC gave Mr. Speaker’s name to TSA for inclusion on the “no-fly” list. The rationale for this delay is difficult to understand, given the fact that the CDC already disclosed information about Mr. Speaker to the CBP days earlier. The Committee expects that the CDC, CBP, and TSA will continue to improve their information-sharing decisions.

The Committee advises OHA to improve their relationship with the CDC. In response to Committee questions about the incident, OHA plans to continue to improve the efficiency and effectiveness of communications between it and the CDC in two ways. First, OHA assigned the responsibility of establishing and maintaining a relationship with the CDC to one of the associate chief medical officers, thereby elevating the importance of these activities and this relationship to a level just short of the Chief Medical Officer himself. The associate chief medical officer charged with this responsibility (among others, including but not limited to oversight over the Department’s health components, and liaison with other health agencies) travels frequently to Atlanta to take meetings at the CDC, and continues to do so now. However, challenges in building this relationship remain. While the responsibility for liaison has been institutionalized, the requirements for face-to-face meetings, periods of significant interaction, and other methods of building this alliance have not.¹³⁴

Furthermore, OHA continues to operationalize the broad and general requirements contained in memoranda of understanding/agreement entered into with other agencies. Soon



after the incident, a four-day meeting occurred in June 2007, to operationalize the requirements of the Department of Homeland Security-CDC Memorandum of Understanding. Although this Memorandum largely concerns routine data requests to support CDC contact-tracing efforts, and the provision of CDC assistance with the training of Department border forces, this meeting was an important first step in establishing an ongoing working relationship that exists before, during, and after emergency situations. Other such meetings are planned but have not yet been scheduled. While none of these processes have been institutionalized, OHA and CDC plan to continue their efforts in this regard.¹³⁵

MAY 25-28, 2007

On May 25, the National Targeting Center sends automatic notification at 12:30 A.M. that Mr. Speaker was encountered at the Champlain, N.Y. port of entry but that he was not detained.¹³⁶

Department of Homeland Security notifies Dr. David Kim at 2:00 A.M. of this situation.¹³⁷

Dr. Julie Gerberding asserts that the CDC “made contact” with Mr. Speaker as he was traveling between Albany and New York City.¹³⁸

Mr. Speaker drives himself voluntarily to an isolation hospital (Bellevue) in New York City for evaluation.¹³⁹ He is admitted and serves a provisional quarantine order that lasts 72 hours while he is being assessed.¹⁴⁰

Event is discussed at the morning WHO outbreak coordination meeting. Because of implication for European countries, WHO/HQ informs WHO/EURO.¹⁴¹

On May 28, CDC uses one of its planes to fly Speaker to a hospital in Atlanta.¹⁴² WHO/Stop TB receives further information about the status from CDC. WHO/Stop TB contacts TB focal points in Italy and Stockholm, and provides advice to Canada TB health authorities on the WHO “Guidelines for Air Travel and TB Control.”¹⁴³

MAY 29, 2007

Dr. Julie Gerberding holds a press conference announcing that the CDC had taken the rare action of issuing a federal public health isolation order for Mr. Speaker.¹⁴⁴

CDC recommends that those passengers who were seated close to Mr. Speaker on the two trans-Atlantic flights notify the health officials in their respective states or countries, and that such persons should then be tested for TB.¹⁴⁵ CDC also recommends that other passengers be notified and offered the opportunity to be evaluated and tested, if desired.¹⁴⁶

Conference call occurs between U.S., Canada, WHO/HQ, WHO/EURO, France, and Italy discussing public health rationale for contact tracing.¹⁴⁷



- **How does an isolation order differ from a provisional quarantine order?**

Based on authority contained in the Public Health Service Act, CDC may apprehend, detain, or conditionally release individuals arriving into the U.S. from a foreign country or moving from one state into another who are reasonably believed to be infected with or exposed to certain specified communicable diseases.¹⁴⁸ On November 30, 2005, HHS published a Notice of Proposed Rulemaking proposing updates to communicable disease regulations found at 42 CFR parts 70 and 71.¹⁴⁹ As part of this process, HHS proposed new procedures for the issuance of a “provisional quarantine order” and a “quarantine order.”¹⁵⁰ While these efforts are not yet finalized, CDC followed administrative procedures similar to those in the proposed rule during this incident. A provisional quarantine order imposes a public health restriction that may include isolation, quarantine, medical monitoring and reporting, or some other form of public health intervention. Such an order is temporary in nature and may be superseded by a permanent order that continues the public health restriction until the individual is no longer considered to be infectious.¹⁵¹

MAY 30, 2007

Department of Homeland Security spokesman Russ Knocke states that investigators are looking into how Mr. Speaker and his wife entered the U.S. when all border crossings had been given his name and told to hold him if he appeared.¹⁵²

CDC begins contact tracing.¹⁵³ CDC asks the Department of Homeland Security to provide passenger manifests.¹⁵⁴ CDC elects to share publicly the names of the flights, and information about specific seats in order to have those persons that occupied those seats self-identify in order to receive specific medical advice in terms of managing the risk.¹⁵⁵

Conference call occurs between U.S., Canada, WHO/HQ, WHO/EURO, the Pan American Health Organization (PAHO), the European Commission, the European Center for Disease Prevention and Control, France, Italy, Greece, and the Czech Republic. Further discussions of the details of the investigations occur.¹⁵⁶

- **What is contract tracing? How is it currently performed, and how can it be improved?**

Contact tracing is a public health tool used by the CDC (including DGMQ) to notify travelers of their exposure to communicable disease threats during commercial flights or on other conveyances. It is a time-intensive and laborious process. The process is challenging, in that CDC does not have direct access to passenger manifests or traveler contact information and must rely on the cooperation of airlines, federal partners, and other ministries of health to obtain this passenger information.¹⁵⁷

When the CDC is notified (usually by a state department of health) that a person with a communicable disease entered the U.S. or traveled between states, the CDC initiates a contact



tracing investigation so that passengers and crew believed to be at risk of infection are notified, and appropriate public health measures are implemented. Initial steps in this process are to verify the disease diagnosis and the risk of communicability, and to verify the patient's travel information (e.g., travel dates, carrier name, flight number, departure date and city, arrival date and city).¹⁵⁸

Once the CDC has confirmation of the disease and the flight information, protocols to obtain passenger data are followed. No federal mandate requires that airlines collect, store, and provide passenger contact information to the CDC in case of a public health event. Therefore, the CDC reaches out to many different potential sources of passenger contact data and compiles relevant information.¹⁵⁹ The CDC must issue an order requesting the manifest from the airlines for international flights arriving in the U.S. To do this, the CDC has developed a formal Manifest Order and a protocol that is followed when requesting passenger data from the air industry. The formal Manifest Order, signed by the CDC Director, requires the airline to provide the CDC with passenger names and seat numbers. It allows both the airline and the CDC to share personal data while respecting patient privacy.¹⁶⁰

The CDC also relies on an MOU signed between HHS and the Department of Homeland Security,¹⁶¹ and supplemental SOPs between the CDC and CBP,¹⁶² which allow for the sharing of passenger data held by homeland security agencies. Steps to obtain passenger contact data from CDC partners include: (1) notifying the air carrier that they should begin to compile necessary data and informing them that a formal Manifest Order from CDC will be forthcoming; and (2) serving the air carrier the formal Manifest Order that states the carrier is obligated to provide data (that it has available) to the CDC.¹⁶³

Often manifests only contain the name of the passenger and the seat number, so CDC also requests Customs Declaration Forms from CBP (inbound international flights only), on which passengers are required to provide a U.S. destination or residence.¹⁶⁴ It is important to note that the Customs Declaration Forms request only the address while in the U.S., not telephone numbers, so contacting individuals by using this information remains a challenge. The CDC also requests that CBP provide additional passenger data from its Advanced Passenger Information System (APIS) and Passenger Name Records (PNR) databases.¹⁶⁵

In addition to these steps, and primarily through its collaborative response to the Polonium incident in the United Kingdom, the CDC has also begun to work with the Department of State to obtain additional contact information for passengers who are U.S. citizens. A protocol for obtaining such information is being formalized.¹⁶⁶

The CDC manually reviews the information it receives from various sources to determine the passenger's contact information. This information is then compiled and entered into an electronic database and reviewed for quality assurance (e.g., frequently the address and phone number provided by airlines refer to the booking or billing agencies and not the passenger). Data is then imported into the CDC's secure eManifest data system, which automatically sorts passengers by states and sends a secure notification and passenger contact information to the state public health agencies. Each state is then responsible for notifying passengers identified as living in their jurisdiction. For passengers who are foreign nationals, CDC notifies the foreign



embassies, consulates or ministries of health and provides whatever contact information is available. The outcomes of these notifications and actions taken are then reported back to the CDC.¹⁶⁷

For this case, the contact tracing investigation began May 25 when CDC obtained Mr. Speaker's full itinerary. The CDC learned on May 18 that Mr. Speaker traveled internationally; however, his exact itinerary was not known. The CDC learned of his return to the U.S. on May 25, and contact tracing was initiated that day.¹⁶⁸

The process for requesting manifests noted above is used when flights are U.S. carriers. In this situation, none of the flights were U.S. carriers or had landed in the U.S., so the CDC had to rely on foreign governments to obtain names of passengers on those flights. On May 25, CDC requested that the Public Health Agency of Canada initiate efforts to obtain the manifest of the patient's inbound flight to Montreal. Canada received the manifest from Czech Air and began matching manifest names with their customs declarations. On May 30, they confirmed that no U.S. citizens or residents were on board Czech flight 0104 other than Mr. Speaker and his wife.¹⁶⁹

When the CDC contacted the Public Health Agency of Canada to request the manifest be obtained for Mr. Speaker's inbound flight to North America on May 25, the CDC also spoke directly with French health authorities, alerting them to the situation, and requesting assistance in obtaining the manifest from Air France for the previous outbound flight from Atlanta to Paris.¹⁷⁰ The CDC also requested assistance from TSA in obtaining the manifest information for those flights. TSA offered to work with their French counterparts to obtain the manifest and passenger contact information for Air France.¹⁷¹

Recognizing that the process of the CDC's reaching out to passengers can be time consuming and ineffective, information regarding the flights of concern was released publicly through a Health Alert Notice and press conference on May 29.¹⁷² These notices included CDC phone numbers for affected passengers to call so they could be directed to evaluation and testing.¹⁷³ On May 31, the CDC received manifest and passenger information from several flights. However, due to poor data quality and lack of completeness, the CDC requested assistance from the Department of State to obtain additional contact information for U.S. citizens and residents. CDC also contacted foreign embassies and consulates located in the U.S. for assistance in obtaining additional contact information for foreign nationals residing in the U.S.

The CDC is undertaking a variety of activities to improve its ability to request and receive timely passenger contact information. These include:

1. Operationalization of the MOU with the Department of Homeland Security – An MOU between the Department of Homeland Security and HHS,¹⁷⁴ and SOPs between CDC and CBP¹⁷⁵ are in place to ensure rapid sharing of information between government agencies to facilitate contact tracing on international flights. The Department of Homeland Security and CDC have had a series of meetings to discuss and draft guidance by which to operationalize this MOU and further operationalize these SOPs. Further operationalization will ensure the quick exchange of information



and will address when and who to contact in case of a public health threat on an international flight.

2. Quarantine Regulations – In 2005, CDC proposed changes to 42 CFR Parts 70 and 71 that would update and clarify interstate and foreign quarantine regulations. Included in the proposed changes are requirements for airlines to collect passenger contact information and to transmit it to the Federal government.¹⁷⁶ CDC is currently finalizing this rule.
3. eManifest – In response to the Severe Acute Respiratory System outbreak, the CDC developed the eManifest system, a web-based secure system that can rapidly access passenger contact information provided by airlines to facilitate emergency public health investigations by state, territorial, tribal, and local health departments. In 2004, CDC signed an MOU with Delta Airlines to develop and pilot-test strategies that might later be shared with all U.S. carriers in three areas: airline passenger/crew data capture and contact tracing, emergency response, and communications and education. Currently, only a few airlines submit electronic manifest data, which are often incomplete; therefore CDC still relies on other sources of data to obtain reliable contact information and manual entry of these data into an electronic database, which can then be imported into eManifest.¹⁷⁷
4. Passenger Locator Forms – CDC uses Passenger Locator Forms when illnesses are identified during travel. These forms are distributed to passengers who have been potentially exposed to a communicable disease, allowing CDC to contact them to provide relevant public health messages and/or coordinate necessary treatment and care. These forms can be scanned to allow rapid conversion of paper forms to electronic data which can be imported into the eManifest system.¹⁷⁸



MAY 31, 2007

Mr. Speaker is discharged from Atlanta Grady Memorial Hospital and transported to Denver by private plane.¹⁷⁹ He is instructed to wear a mask along with all who come into contact with him.¹⁸⁰ He arrives at National Jewish Medical and Research Center in Denver.¹⁸¹ There, he will go through a series of tests and be given two antibiotics, one oral and one intravenous.¹⁸²

Authorities in the U.S. and several European countries begin tracking down about 50 people who sat near Mr. Speaker on his Atlanta-to-Paris flight on May 12, and 30 people on his Prague-to-Montreal return on May 24. They will be offered testing to see if they are infected.¹⁸³

CDC initiates evaluation of Mr. Speaker's activities prior to his development of XDR-TB in hopes of learning the source of exposure.¹⁸⁴

CDC establishes a webpage providing further information to airline travelers and other members of the public who are interested in this issue: <http://www.cdc.gov/tb/xdr/tb/>.¹⁸⁵

The CBP officer who processed Mr. Speaker's entry on May 24 is placed on administrative duties while the investigation continues.¹⁸⁶ CBP Internal Affairs begins interviewing the officer.¹⁸⁷

News reports reveal that Mr. Speaker's father-in-law works for the CDC in Atlanta. The father-in-law, Robert C. Cooksey, is a microbiologist who has conducted research on TB for the National Center for Infectious Diseases.¹⁸⁸

- **Was the secondary screener ever disciplined for this incident?**

Though the CBP officer who allowed Mr. Speaker to enter the U.S. has since retired, the Committee continues to have questions about the supervisory (secondary) officer in this case. According to CBP Commissioner Ralph Basham, when an alert appears on a CBP officer's screen in primary inspection, the notification also goes to a screen in secondary referral. At the time of the incident, CBP procedures allowed the primary officer to determine what action to take with the individual.¹⁸⁹ Clearly, though, the secondary officer would have seen the same message that the primary officer saw on his screen. During the June 2007 Committee hearing, questions were posed to Commissioner Basham and Assistant Commissioner Jayson Ahern about the employment status of the secondary screener. Neither provided answers to the Committee at the time, stating that CBP was "looking at all of the actions on that day and who failed to perform or who did perform and how they performed."¹⁹⁰

The Committee notes that CBP has changed its procedures, no longer granting officers the discretion to overrule a TECS subject record without the approval of a supervisor.¹⁹¹ However, the Committee awaits an official report from the Department of Homeland Security for explanation about what disciplinary action was taken against the secondary, supervisory officer in this case.



JUNE 1-6, 2007

On June 1, Department of Homeland Security officials promise to examine systems for detaining sickened travelers, acknowledging “there will always be holes in the system.”¹⁹²

Dr. Julie Gerberding states that Mr. Speaker “still does not appear to be highly infectious,” and there is “no indication that his infectiousness has changed in the past few months.”¹⁹³

WHO/EURO informs WHO/HQ about non-European Union passengers to be traced. WHO/HQ contacts the WHO Regional Office for Africa, the WHO Office for the Eastern Mediterranean, and PAHO to communicate names of passengers to be traced.¹⁹⁴

On June 2, CDC withdraws the federal isolation order for Mr. Speaker because the state order to detain him at the Denver hospital is legally sufficient to protect the public’s health.¹⁹⁵

CDC officials state they have contacted 160 of the 292 U.S. citizens who were on the same Atlanta-to-Paris flight as Mr. Speaker.¹⁹⁶

CDC says that the father-in-law of Mr. Speaker will be investigated to see how he was involved with the case.¹⁹⁷

On June 4, CBP announces policy updates to Committee staff: 1) supervisors will receive the same warnings that CBP agents receive on their screens; and 2) agents will no longer be able to clear an “exact match” on identification (where a person’s name, date of birth, and passport number identically match a TECS warning). CBP states that “Exact matches” will always be referred to secondary screening.¹⁹⁸

On June 6, the House Committee on Homeland Security holds a full Committee hearing entitled “The Extensively Drug Resistant – Tuberculosis Incident: A Poorly Coordinated Federal Response.” Witnesses include CBP Commissioner Ralph Basham, Homeland Security Chief Medical Officer Dr. Jeffrey Runge, CBP Assistant Commissioner Jayson Ahern, and CDC Director Dr. Julie Gerberding.



Conclusion

Although there were certain circumstances in which U.S. federal departments and agencies worked well together, the 2007 XDR-TB incident was handled ineffectively and inefficiently. As is always the case with events for which we are poorly prepared, the situation cast a harsh light on the gaps in communication, coordination, response, patient management, implementation of quarantine and isolation laws, public messaging, information management, training, awareness, and professionalism. Though it is clear that all parties involved in this situation are aware of these shortfalls, it is not as clear to the Committee that they are being addressed with the urgency and attention necessary to prevent a similar series of events from occurring again today. The twin specters of diseases that are increasingly resistant or completely without current treatments and antimicrobials, and the ability of diseases to spread more quickly than ever before due to rapid transit and other enablers, place public health concerns squarely on the homeland, national, and transnational security agendas. How we address these gaps now will serve as a direct predictor of how well we will handle future events, especially those involving emerging, reemerging, and pandemic infectious diseases.



Endnotes

¹ MDR-TB, or multidrug-resistant TB, is a specific form of drug-resistant TB. It occurs when the TB bacteria are resistant to at least isoniazid and rifampin, the two most powerful anti-TB drugs.

² XDR-TB is TB that is resistant to any fluoroquinolone, and at least one of three injectable second-line drugs (capreomycin, kanamycin, and amikacin), in addition to those antimicrobials to which MDR-TB is resistant. This definition of XDR-TB was agreed by the WHO Global Task Force on XDR-TB in October 2006.

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¹⁶ Electronic communication between Rosemary Humes, Senior Science Advisor, Association of Public Health Laboratories, and Committee on Homeland Security staff, U.S. House of Representatives, on July 6, 2007. Email on file with Committee on Homeland Security.

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