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## FOREWORD

# BIOTERRORISM: A POTENTIAL EXISTENTIAL THREAT

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In 2005, former United States Senate Majority Leader William Frist claimed that "[t]he greatest existential threat we have in the world today is biological."[1] Years later, bioterrorism remains a serious threat, creating a challenging public health, medical, economic, and national security issue for the United States and other countries across the globe.

Bioterrorism is a form of asymmetrical warfare in which a terrorist, with biological expertise and modest means, could inflict great harm upon millions of innocent victims. Asymmetric warfare is a conflict between opponents whose relative power significantly differs, which compels the weaker opponent to employ unconventional strategies or tactics.[2] The Minutemen's strategy against the Redcoats—shooting at the superior British forces from behind trees instead of confronting them in the open—is a classic early-American example of asymmetric warfare.

The September 11, 2001, attacks on the World Trade Center and the Pentagon are another example of asymmetric warfare. Nineteen young Arab men—armed only with knives, box cutters, and pepper spray or Mace—hijacked four planes, "turned them into deadly guided missiles," and killed about three thousand innocent office workers, passengers, and aircraft

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1. MILTON LEITENBERG, ASSESSING THE BIOLOGICAL WEAPONS AND BIOTERRORISM THREAT 1 (2005).

2. *See* Andrew J. R. Mack, *Why Big Nations Lose Small Wars: The Politics of Asymmetric Conflict*, WORLD POL., Jan. 1975, at 175–200.

crew.[3] In addition, one publicly-supported nonprofit organization estimated that the economic loss from property damage, lost production of goods and services, and loss in stock market wealth approached $2 trillion.[4]

What would be the impact if terrorists employed biological agents instead of hijacked aircraft? On October 15, 2001, a letter containing anthrax spores was opened in the Hart Senate Office Building in Washington, D.C. The one letter impacted staff (about thirty congressional employees tested positive for anthrax exposure) and caused the closure of the Hart Building and several other government buildings along the mail delivery route and elsewhere. The cleanup costs to the Environmental Protection Agency were $27 million.[5] The Hart Building did not reopen until January 23, 2002.

Instead of a non-contagious biological agent such as anthrax, what if terrorists employed a contagious biological agent? An article in the *New England Journal of Medicine* explains how quickly the SARS epidemic raced around the globe in 2003:

> In terms of sheer drama, the emergence of the severe acute respiratory syndrome (SARS) rivaled the most exotic Michael Crichton thriller. A novel viral strain spread in "wet markets" from an obscure animal to food handlers; through a rural province in southern China; to Hong Kong by way of an ill Chinese physician who had traveled to attend a wedding; and in one night at a Hong Kong hotel, from that man to at least 12 other people. These 12 returned to their five home countries and created multiple chains of transmissions that, over the course of the next four months, led to more than 8000 cases of SARS, resulting in almost 800 deaths in 27 countries, representing every continent.[6]

Toronto provides an example of the devastating impacts of even a brief epidemic on a city. A 14-week epidemic in the city triggered quarantine measures for 30,000 persons who may have been exposed, closure of facilities, and the issuance of international travel advisories by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC). Ontario identified 375 probable SARS cases, and 44 ultimately died. Toronto also suffered an estimated $1 billion economic loss due to

3. The 9/11 Commission Report: Final Report of the National Commission on Terrorist Attacks Upon the United States, http://www.911commission.gov/report/911Report_Exec.htm (last visited Dec. 2, 2009).

4. Institute for the Analysis of Global Security, *How Much Did the September 11 Terrorist Attack Cost America?*, http://www.iags.org/costof911.html (last visited Dec. 2, 2009).

5. U.S. GEN. ACCT. OFF. REP. TO THE CHAIRMAN, COMMITTEE ON FIN., U.S. SENATE, CAPITOL HILL ANTHRAX INCIDENT: EPA'S CLEANUP WAS SUCCESSFUL; OPPORTUNITIES EXIST TO ENHANCE CONTRACT OVERSIGHT 2 (2003).

6. Robert A. Weinstein, *Planning for Epidemics—The Lessons of SARS*, NEW ENG. J. MED., June 3, 2004, at 2332.

lost jobs, the cancellation of nine city-wide conventions, and travel advisories.[7]

Bioterrorism clearly creates an extremely complicated public health, medical, and legal environment. Lethal, contagious pathogens could be released in a city without warning, which would overtax the public health and medical infrastructure, create local panic, involve law enforcement to detect and prosecute the perpetrators, and possibly trigger national and international restrictions to limit the spread of the epidemic.

The articles in this symposium publication illustrate the interconnected and complex nature of the issues surrounding a bioterrorist attack. Representing legal, scientific, and military backgrounds, the authors collectively offer a comprehensive picture of what is—or at least should be—involved in preparing for and responding to such attacks.

Keynote speaker Dr. Victoria Sutton, director of the Center for Biodefense, Law and Public Policy at Texas Tech University School of Law, analyzes the regulatory system governing biodefense research. Professor Sutton examines the historical development of the select agent rules, the legal consequences for violating them, and how they have affected the biodefense research community. Specifically, she discusses how biological agent regulation in the United States has increased over the past two decades in response to incidents like the anthrax attacks in 2001, closing the gap between the criminal intent to use or attempt to use biological weapons and mere possession of select agents.[8] Noting that this heavily regulated environment can overburden scientific researchers and, in turn, thwart biodefense advancements, she observes a resulting tension between two legitimate concerns: "The culture of the research scientist and the implementation of [select agent] regulatory mechanisms have led to a clash of interests—those of research for humankind and those of national security."[9] She argues that the United States can arrive at a more balanced regulatory system if it shifts away from focusing primarily on select agents and how to control them through performance- or standards-based regulation—i.e., its current normative approach, riddled with loose guidance and dangerous exceptions—and instead focuses on other players, like the facilities that host the select agents and the individuals who handle them. Public health and safety and national security, she maintains, should be the regulatory driving forces.[10] While she admits that these dual goals give rise to an unavoidable

7. GENE MATTHEWS, THE PUBLIC/PRIVATE RESPONSE TO SUDDEN DISEASE OUTBREAK 4 (2005).

8. Victoria Sutton, *The Culture of Science and the Regulation and Litigation of Biodefense Research*, 6 U. ST. THOMAS L.J. 523, 526–27 (2009).

9. *Id.* at 525.

10. *Id.* at 547.

tension, she also points out that careful consideration of this tension can provide useful insights to lawmakers, regulators, and legal academicians.[11]

Professor Barry Kellman and Zachary Clopton, president and former research fellow of the International Security & Biopolicy Institute, respectively, consider international anti-bioviolence initiatives to promote medical counter-measure (MCM) preparedness. Their decision to focus on MCM preparedness stems from the notion that the ready availability and proper dissemination of MCMs can help contain the negative effects of bioterrorist incidents and, in turn, deter attacks.[12] In addition, MCM preparedness engages the international community, which, Kellman and Clopton contend, is critical to successful response efforts since bioviolence is a global concern that demands global cooperation and collaboration.[13] They highlight some of the major legal challenges implicated in developing an effective international MCM preparedness strategy and suggest ways to address them. Kellman and Clopton identify risk assessment and management as the first hurdle to overcome in the MCM planning process and discuss the possibility of creating an international task force to handle such preparedness efforts.[14] Next, they explore the current lack of incentive to conduct MCM research and development. Recognizing that the costly, time-consuming, and risky nature of MCM research and development discourages drug manufacturers from engaging in it, they consider liability protection and patent right clarification as mechanisms to counter this reality.[15] Kellman and Clopton then turn to MCM licensing and emergency approval, arguing that this legal roadblock can be averted if national and international licensing standards and regulations are determined *before* a bioviolence crisis occurs.[16] Finally, they consider MCM stockpiling and delivery planning; they posit that MCMs will only be valuable if rapidly delivered to bioviolence victims when needed and outline ways to make this possible.[17]

Professors R. Gregory Evans and Rachel D. Schwartz of Saint Louis University School of Public Health's Institute for Biosecurity, discuss "preparedness and response paralysis"—what they define as "the point many planners reach where they find themselves lacking the resources, support, information, and leadership necessary to continue developing a concrete and actionable plan that can be implemented in the face of a particular type of disaster"—and the factors that contribute to it, in the context of the

11. *Id.* at 548.

12. Barry Kellman & Zachary D. Clopton, *A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence*, 6 U. ST. THOMAS L.J. 550, 554–55 (2009).

13. *Id.* at 555, 558–59.

14. *Id.* at 563–66.

15. *Id.* at 566–72.

16. *Id.* at 573–81.

17. *Id.* at 582–91.

U.S. public health system.[18] They claim that bioterrorism is an area of particular concern to the nation's public health system when it comes to preparedness, owing in part to the accessibility of biological agents and the devastating harm they can inflict.[19] Because the consequences of being underprepared are so grave, they argue that it is critical to develop a planning mechanism that overcomes the obstacles bioterrorism planners and responders (and pandemic planners and responders in general) presently encounter.[20] They see the current structure of the U.S. public health system as one of the primary obstacles to effective preparedness efforts and suggest ways to develop a more streamlined system.[21] They also view the lack of a process for decision-making in the public health sphere as a significant roadblock to successful response planning; a fair and transparent process, they contend, will facilitate critical decision-making and circumvent the paralysis that currently plagues preparation efforts.[22]

Professor Kavita M. Berger of the Center for Science, Technology and Security Policy at the American Association of the Advancement of Science, describes the role of science and scientists in bioterrorism preparedness and response efforts. Berger points out that scientists are responsible for accurately recognizing the symptoms of a disease, identifying the causative agents, and helping mount appropriate and timely public health responses to biological incidents.[23] She also notes that scientists' development of medical countermeasures (e.g., vaccines) is a critical component of biodefense preparedness and response efforts, while touching on the legal and ethical challenges inherent in the research and development and dissemination processes. On the international security and biosafety front, Berger states that scientists throughout the world participate in important policy discussions about oversight and education regarding dual-use research—research that is generally legitimate and beneficial but which could be misapplied for malicious purposes.[24] While she recognizes the concerns that gave rise to U.S. programs and policies intended to combat nefarious uses, she warns that such protective efforts can, in fact, greatly hamper our nation's ability to help identify and respond to global public health threats.[25] Echoing Professor Sutton, Berger argues that U.S. bioterrorism planning efforts should involve examining the impact of U.S. security policies on national security, scientific advancement, and public health,

18. R. Gregory Evans & Rachel D. Schwartz, *Preparedness and Response Paralysis: Ramifications for Pandemic Planning*, 6 U. ST. THOMAS L.J. 594, 595 (2009).

19. *Id.* at 596–604.

20. *Id.* at 604–06, 609–15.

21. *Id.* at 615–20.

22. *Id.* at 620–21.

23. Kavita Marfatia Berger, *The Role of Science in Preparedness and Response*, 6 U. ST. THOMAS L.J. 622, 623–26 (2009).

24. *Id.* at 626–33, 644–45.

25. *Id.* at 634–45.

as well as attempt to build an effective working relationship between the security and scientific communities.[26]

Lieutenant Colonel Larry A. Shireley, Commander of the 81st National Guard Civil Support Team (CST) based out of North Dakota, discusses the role CSTs play in preparing for and responding to bioterrorist attacks. Shireley underscores the importance of CSTs in the bioterrorism landscape by noting that they are designed specifically to supply 24/7 support to civilian first responders reacting to WMD terrorist attacks.[27] If a state is attacked by a bioterrorist, for example, and the state's first responders' assessment reveals that they need more assistance, the state's coordinating official can deploy a CST. Once deployed, Shireley explains, CSTs can further assess suspected biological events, help identify the biological agents, advise civilian responders about proper response actions, and facilitate requests for additional state and federal assistance through the coordination of their command, operations, administration/logistics, communications, medical, and survey sections.[28] Shireley concludes that if the United States is subject to a biological terrorist attack in the future, CSTs will be prepared to effectively respond to it.[29]

Though biological agents are literally microscopic in size, the reality that terrorists could use them to inflict harm far greater in magnitude makes bioterrorism a topic worthy of reflection. The following collection of articles will assist the reader with this endeavor, as it considers the subject from a variety of angles. Just as our society is multifaceted, so too should be our approach to an issue that could affect it so profoundly. So, one might reflect, *are* we ready for a bioterrorist attack? While historical experience and recent reports suggest that, as a nation, we still have work to do, engaging in serious discussions about the legal, ethical, and practical issues surrounding bioterrorism preparation and response efforts is certainly an important step in the right direction.

26. *Id.* at 646.

27. Lt. Col. Larry A. Shireley, *National Guard Civil Support Teams: A 24/7 Response to Weapons of Mass Destruction*, 6 U. ST. THOMAS L.J. 647, 648–50 (2009).

28. *Id.* at 650–57.

29. *See id.* at 657.