THE DUAL USE DILEMMA: CRYING OUT FOR LEADERSHIP

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I. INTRODUCTION

Between October 2011 and March 2012, a controversy regarding the publication of results of H5N1 influenza virus research by two scientists led to additional oversight of a relatively broad segment of the infectious disease research enterprise in the U.S.[1] The episode has been described as an example of the "dual use dilemma," legitimate and open research that could be exploited for harm by others. Why is *leadership* important in the context of the dual use dilemma? Is not dual use about technology and knowledge being misused for harm? Can we not just control the knowledge and technologies? How is the dual use dilemma related to the *insider threat* in research and clinical laboratories? What is our interest in these low likelihood events in twenty-first century America? The recent concern regarding Dual Use Research (DUR) is focused on the traditional agents of biological warfare and the influenza viruses. Yet, these *Select Agents* are but a small part of the spectrum of biological threats and risks we humans, our animals, and plants face today. Therefore, Dual Use Research of Concern (DURC) cannot be understood in isolation. What follows is a short history of the misuse — and use — of biology in what will always be a dangerous world. We cannot reduce risk to zero, but we can increase safety, security, and productivity in our laboratories without layering another set of

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1. Ron A.M. Fouchier et al., *Transmission Studies Resume for Avian Flu,* 339 SCI. 520, 520 (2013). H5N1 is a subtype of the influenza A virus, known as "bird flu" or "highly-pathogenic avian influenza." It is sometimes designated "A/H5N1" or "A(H5N1)." It can cause illness in humans and many animal species.

regulations over the enterprise each time an individual scientist does something thoughtless or even malevolent.

II. DURC BACKGROUND

A. A Short History of Laboratory Biosafety — 1940s Onward

The U.S. conducted offensive biological warfare research, development, and field-testing from mid-1942 until late 1969, when President Nixon traveled to Fort Detrick, Maryland, to announce that the U.S. would end its biological weapons program.[2] In two National Security memoranda, the first dated November 25, 1969, and the second February 20, 1970, the U.S. Government renounced development, production, and stockpiling of biological weapons.[3] Further, the U.S. declared its intent to maintain only quantities of agents necessary for the development of vaccines, drugs, and diagnostics.[4] While I am convinced the weapons testing during the more than 25 years of the offensive program demonstrated *nuclear equivalence* of biological weapons, the real legacy of this program is the development and implementation of the foundational principles of modern laboratory biological *safety*.

During the 1960s, Dr. Arnold G. Wedum, M.D., Ph.D,[5] Director of Industrial Health and Safety at Fort Detrick, was the principal proponent and leader of a system of containment facilities, equipment, and procedures developed to greatly enhance the safety of the employees of the offensive program and the rural community in which the core laboratories were operated. Many of Dr. Wedum's principles of biological safety served as the basis for the U.S. Centers for Disease Control and Prevention's (CDC) publication called *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).[6] The BMBL is now updated regularly and has become the biosafety *bible* in laboratories around the globe. Thus, in what we might today call a reverse dual use model, some very important good has ultimately come from a program that was designed to do harm.

2. David R. Franz et al., *The U.S. Biological Warfare and Biological Defense Programs*, *in* TEXTBOOK OF MILITARY MEDICINE: MEDICAL ASPECTS OF CHEMICAL AND BIOLOGICAL WARFARE 425, 431 (Russ Zatjchuk ed., 1997).

3. U.S. Nat'l Sec. Council, National Security Decision Memorandum 44 (Feb. 20, 1970) (on file with the National Security Archive); U.S. Nat'l Sec. Council, National Security Decision Memorandum 35 (Nov. 25, 1969) (on file with the National Security Archive).

4. National Security Decision Memorandum 35, *supra* note 3.

5. Franz et al., *supra* note 2, at 430.

6. U.S. DEP'T OF HEALTH & HUMAN SERVS., HHS PUB. NO. 21-1112, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES 3 (5th ed. 2009).

By the end of the twentieth century, the principles of biosafety — facilities, equipment, and procedures — were codified, enhanced, respected, and followed by the scientists in the relatively few high-containment labs in the U.S. The original U.S. high-containment labs were commissioned from 1971 to 1972 at Fort Detrick within the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID),[7] and in Atlanta at the CDC just a few years later.[8]

I served as Deputy Commander (1993–1995) and Commander (1995–1998) of USAMRIID. My command briefings during the mid-90s often listed three top priorities — "biosafety, biosafety, and biosafety." We had good people in harm's way during peacetime and in war in Biosafety Level-4 (BSL-4)[9] labs where one needle stick, one bone fragment through a surgical glove, or even the bite of an infected laboratory animal could mean almost certain death to a scientist or technician. While the institute was located on a fenced and guarded military installation with twenty-four hour unarmed guards, as well as redundant locking systems with personal identification number codes for laboratory suite entry, my focus was on the safety of the employees and the community, as well as the productivity of our laboratory. I learned in those six years that the same leadership approach that makes people safe, makes an organization productive, and gives a community a sense of well being, is based on nurturing a culture of responsibility and trust.

B. Laboratory Biosecurity — Mid-90s and Beyond

In 1995, Mr. Larry Wayne Harris mailed a letter requesting an isolate of *Yersinia pestis (Y. pestis)*, the plague bacillus, from the American Type Culture Collection (ATCC) in Manassas, Virginia.[10] It was eventually

7. U.S. ARMY MED. RESEARCH INST. OF INFECTIOUS DISEASES, FACT SHEET (2012), *available at* http://www.usamriid.army.mil/aboutpage.cfm.

8. Personal communication with Dr. Thomas Ksiazak, University of Texas, Galveston National Labs (July 2013).

9. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 6, at 4. Biosafety Levels (1 – 4) are used to describe combinations of facilities, equipment, and procedures that allow safe handling of pathogens within a laboratory. The highest level (BSL-4) is used for the most dangerous pathogens. In it, the air moving in and out is filtered to contain the viruses being studies; scientists are protected by 'space suits' or special sealed hood lines. To the lay public, I often describe BSL-1 as a high school science room, BSL-2 as a hospital clinical lab, BSL-3 as a containment lab for microbes for which we have vaccines or other effective medical countermeasures, and BSL-4 as a similar lab but in which physical systems (space suits and hood lines) are used to protect the people from bugs for which there are no or less effective countermeasures.

10. TOXIC TERROR: ASSESSING TERRORIST USE OF CHEMICAL AND BIOLOGICAL WEAPONS (Jonathan B. Tucker ed., 2000).

discovered that the letterhead he used — "Small Animal Microbiology Laboratory, 266 Cleveland Avenue, Lancaster, Ohio" and the "Ohio Environmental Protection Agency approval number 890" — were fraudulent.[11] While the ATCC ultimately shipped the vials of *Y. pestis*, Mr. Harris became impatient and called to follow up on his order. In doing so, he alerted authorities and the Federal Bureau of Investigation (FBI) became involved. While other incidents — Aum Shinrikyo sarin attack in Tokyo on March 20, 1995[12] and the B'nai B'rith incident in Washington D.C. involving a petri dish of *B. cereus* in 1997[13] — contributed to our increased concern about both the illicit acquisition and malevolent use of biological agents, it was the Harris incident that most greatly influenced our thinking regarding laboratory biological *security* in the U.S.

The Select Agent Rule became law and was implemented in 1997.[14] This new rule made the transfer between laboratories illegal for designated bacteria, viruses, or toxins without CDC approval.[15] Initially, the rule only affected agent transfers,[16] which meant that many academic and clinical labs with select agent pathogens could maintain them without breaking the law. Only after an inspection by the CDC (or, for some pathogens, the U.S. Department of Agriculture) could a laboratory be certified to transfer pathogens on the list, and then once certified, transfer only to a similarly certified laboratory. The era of laboratory biosecurity had begun. As a result of his actions, Harris, the individual most directly responsible for the Select Agent Rule, was required to complete 200 hours of community service. Legitimate research with the listed agents would forever be more costly and probably less productive in government, academic, and industrial labs where the new rules were promulgated.

C. DURC — 2003 and Beyond

The World Trade Center attacks on September 11, 2001 (9/11), and the first case of inhalational anthrax concerning the anthrax letters discovered on October 4, 2001 (10/4), changed everything. The U.S. biosecurity budget went from $137 million in 1997, to $14.5 billion spent

11. *Id.*
12. U.S. DEP'T. OF STATE, 2010 COUNTRY REP. ON TERRORISM, at 209.
13. Matthew L. Wald, *Suspicious Package Prompts 8-Hour Vigil at B'nai B'rith*, N.Y. TIMES, Apr. 5, 1997, at A12.
14. 42 C.F.R. § 73.16 (2012).
15. *Id.*
16. *Id.*

on biodefense from 2001 to 2004.[17] Soon many more laboratories sought and received Select Agent certification.[18]

Today, it is almost impossible to put one's mind back into the state of infectious disease research before 2002, when thousands of new scientists began working with this short list of threat agents. After 9/11, 10/4, and the increased funding for new high-containment labs and Select Agent research, the next layer of DURC regulation in the life sciences was beginning to unfold. It would take another legitimate, even respected scientist,[19] this time not trying to do harm, but possibly for personal or professional gain, to drive the U.S. Government to further regulate the traditional select agents and influenza viruses.

About ten years before the 2012 controversy regarding the publication of information on the intentional development of a recombinant H5N1 influenza virus transmissible between mammals, there was the reasonable observation by the U.S. biological sciences community that it should "think about policing itself" before the government intervened with undue regulation. The now well-known Fink Report by the National Academies of Science, *Biotechnology Research in an Age of Terrorism: The Dual-Use Dilemma,* was a direct result.[20] At that time, factors that triggered the perceived need for the study and subsequent report included: (1) a surprise result of Australian attempts to design a rodent sterilization virus,[21] (2) the second *de novo* synthesis of poliovirus from a "web recipe,"[22] and (3) a new understanding of the implications of the Smallpox Inhibitor of Complement Enzymes "SPICE gene" in orthopox viruses.[23]

17. Ari Schuler, *Billions for Biodefense: Federal Agency Biodefense Funding: FY2001-FY2005*, 2 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 86, 86 (2004).

18. *See* James W. Blaine, *Establishing a National Biological Laboratory Safety and Security Monitoring Program*, 10 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 396, 397 (2012) (explaining that from 2002-2012, 400 laboratories were registered in U.S.).

19. *See, e.g.*, Sander Herfst et al., *Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets*, 336 SCI. 1534, 1538 (2012).

20. *See* COMMITTEE ON RESEARCH STANDARDS & PRACTICES TO PREVENT THE DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM vii (2004) [hereinafter FINK REPORT].

21. *See* Ronald J. Jackson et al., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, 75 J. VIROLOGY 1205, 1206 (2001).

22. *See* Eckard Wimmer, *The Test-Tube Synthesis of a Chemical Called Poliovirus: The Simple Synthesis of a Virus Has Far-Reaching Societal Implications,* 7 EUROPEAN MOLECULAR BIOLOGY ORG. REP. (SPECIAL ISSUE) S3, S8 (2006).

23. *See* Ariella M. Rosengard et al., *Variola Virus Immune Evasion Design: Expression of a Highly Efficient Inhibitor of Human Complement*, 99 PROCEEDING OF THE NAT'L ACAD. OF SCI. OF THE U.S. 8809, 8813 (2002).

The nation was now working in a backdrop of 9/11 and 10/4,[24] so misuse of biology was on our minds. Although the term "dual use" had been used in other settings, it was the Fink Report that really codified the term in this context.[25] The Fink Report also suggested that a national-level committee be formed and composed of equal numbers of biology and security experts to help the government cope with the dual use dilemma.[26] The eventual response from the U.S. Government was the formation of the National Science Advisory Board for Biosecurity (NSABB) in 2004.[27] Initially, the NSABB described DUR as "research yielding new technologies or information with the potential for both benevolent and malevolent applications . . . ."[28] Later, after realizing that a significant percentage of the technology and knowledge in the life sciences enterprise could be used for good or harm, the NSABB chose the term DURC to define a subset of dual use knowledge and technologies. The NSABB described DURC as "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment or materiel."[29]

III. DURC DISCUSSION

A. DURC Has Always Existed — Just By Other Names

DURC is nothing new; it is not a product of the twenty-first century. It has been around for tens or hundreds, maybe even thousands of years. Remember fire? What about nuclear fission? I have a personal example. During the mid to late-90s, a perfectly legitimate test of a potential antibody therapy against a virus in a high-containment laboratory at USAMRIID resulted in the natural development of resistance to the candidate therapy

24. *See* Gina Kolata, *Florida Man Is Hospitalized With Pulmonary Anthrax*, N.Y. TIMES, Oct. 5, 2001, at A16 (discussing Oct. 4, 2001, the day Mr. Stevens, a Florida man, was diagnosed with inhalational anthrax).

25. *See* FINK REPORT, *supra* note 20, at vii-viii.

26. Dana A. Shea, CONG. RESEARCH SERV., RL33342 OVERSIGHT OF DUAL-USE BIOLOGICAL RESEARCH: THE NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY 2, 4 (2007), *available at* http://www.fas.org/sgp/crs/natsec/RL33342.pdf.

27. NAT'L SCI. ADVISORY BD. ON BIOSECURITY, ENHANCING RESPONSIBLE SCIENCE CONSIDERATIONS FOR THE DEVELOPMENT AND DISSEMINATION OF CODES OF CONDUCT FOR DUAL USE RESEARCH, 1, 30 (2012), *available at* http://oba.od.nih.gov/oba/biosecurity/documents/COMBINED_Codes_PDFs.pdf.

28. *NSABB Frequently Asked Questions, What is "Dual Use Research" and "Dual Use Research of Concern"?,* OFFICE OF SCI. POLICY-NIH, http://oba.od.nih.gov/biosecurity/nsabb_faq.html (last visited Aug.17, 2013).

29. *Id.*

being studied.[30] The scientist, in whose laboratory it occurred, came to my office and explained the finding. We simply pulled a small group of experts together, examined the data, talked about the potential consequences, and decided to put the entire experiment into the autoclave. That was it. We did not hear anyone say, "Wow! We could get a paper in *Science* or *Nature*."

The scientists involved had a personal sense of responsibility and I, accepting the corporate responsibility, did not think twice about announcing it at a scientific meeting or hyping it to the media. It was not called DURC, but just another *surprise* from biology. These unexpected outcomes are part of what makes our professional experience so rewarding. I have often said, "It is why we call it biology after all." There are many more benign surprises in biology than potentially malignant ones. Many scientists have spent the greater part of their lives trying to do *good* things with biology, and it is hard. My experience talking with former biological weapons scientists suggests that doing really *bad* things with biology is not that easy either.

In the past, when surprises occurred in biology or any of the sciences, responsible scientists typically acted responsibly, neither trying to gain undue attention for themselves nor seeking to misuse the new information. There have been, and will always be, irresponsible or even criminal minds in all professions and societies, but the vast majority of humans involved in the life sciences will continue to contribute positively for the good of mankind.

B. What Has Changed in the U.S. and the World?

Dartmouth Professor Kendall Hoyt, Ph.D., in her book, *Long Shot,* asked the questions: "Why was the U.S. Government so successful in developing and fielding vaccines from the 1940s through the 1950s, and why has it been so difficult in recent years?"[31] It cannot be the technologies, which have been greatly improved during the period in which progress in fielding has slowed. One would expect us to be better and faster today than 50 years ago. It turns out there may be several factors that explain the earlier successes and difficulties today. For example, simpler technologies and less complex approval protocols. However, Dr. Hoyt made two other important conclusions, which suggest more behavioral than technical explanations. First, she learned that "champion-led research," in which a single, dedicated individual shepherds a vaccine candidate from the bench all the way through development, clinical trials, and licensure, was much more common.[32] Second, Dr. Hoyt learned that those champions were working

30. This passage is my personal recollection. It occurred between 1995 and 1998.

31. *See* KENDALL HOYT, LONG SHOT VACCINES FOR NATIONAL DEFENSE 2, 4 (Harvard Univ. Press 2012).

32. *Id*. at 5.

within "collaborative communities."[33] In these communities, scientists worked in teams and openly shared helpful information within and between those teams, even if this information might help make competitors successful.

A likely major contributor to both the motivation of the *champions* and the formation of *communities* was the patriotism and sense of urgency of a nation at war during World War II (WWII). Many of the scientists who had served their country in military laboratories, such as the Walter Reed Army Institute of Research, then moved to commercial enterprise. The motivation and cultural norm in the workplace that was learned under excellent leadership in a time of great national struggle likely contributed to the burst of commercial productivity after the war. It is my belief that leadership and communities of trust not only lead to more productivity, but also reduce the potential impact of DURC and even the threat of insider misconduct or criminality.

Possibly the most troubling development in some of our government laboratories in the last ten to fifteen years has been the separation of responsibility and authority. Individuals in the laboratory are powerfully motivated and have increased productivity levels when authority and responsibility are balanced. We are losing this balance and the kind of supercharging that results. Beginning in the Department of Defense (DOD) before 9/11 and spreading to other government *security* laboratories, this authority to make decisions locally has been pulled to within the beltway, while responsibility has stayed with the laboratories. Relatively inexperienced managers are now often assigned to *manage* research project portfolios within the laboratories from afar. In the past, laboratory directors or commanders were selected from a vibrant pool of scientists all considered to be technical, subject-matter experts and tested or potential leaders. They knew their programs, were dedicated to their missions and loved their people. Today, good people hold some of those positions with leadership experience from other military sectors, but lack technical credibility. In other cases, qualified leaders are given responsibility, but adequate authority to do their jobs is withheld.

C. We are No Longer Alone

The *biological playing field*, both with regard to disease and progress toward controlling disease, is enormous, complex, extremely dynamic, competitive, and global. Like the rest of the sciences, technical advances in biology are incremental, but cumulative, and generally not reversible.[34] One

33. *Id.* at 6.

34. The general concept drawn from discussions with Roger Brent (Feb 2013).

cannot put the *toothpaste* of the global life sciences enterprise *back in the tube*. Like physical and chemical phenomena in nature, biological ones challenge us as a human race and exact a toll on health and life. More than nine million of the fifty million plus people who die globally each year die of infectious diseases.[35] Plant losses from pests and pathogens alone are believed to result in monetary losses of approximately $20 to 33 billion annually in the U.S., so the challenges of disease are not only related directly to humans.[36]

1. Natural and Intentional Disease

Our experience with *intentional disease* — biological warfare, terrorism, and crime — is much more limited than our experience with naturally occurring disease. Historians believe at least 10,000 to 12,000 Chinese died from biological warfare attacks by the Japanese during WWII.[37] We know that five humans died as a result of the anthrax letters sent through the U.S. mail system in 2001.[38] Biological agents have also been used to kill humans in what most would consider biocrimes. The majority of those crimes involved contamination of food with biological toxins or replicating agents.[39] The relative emphasis the government placed on these health risks varied with the perception of them; the perception held by politicians and the news media are particularly powerful.

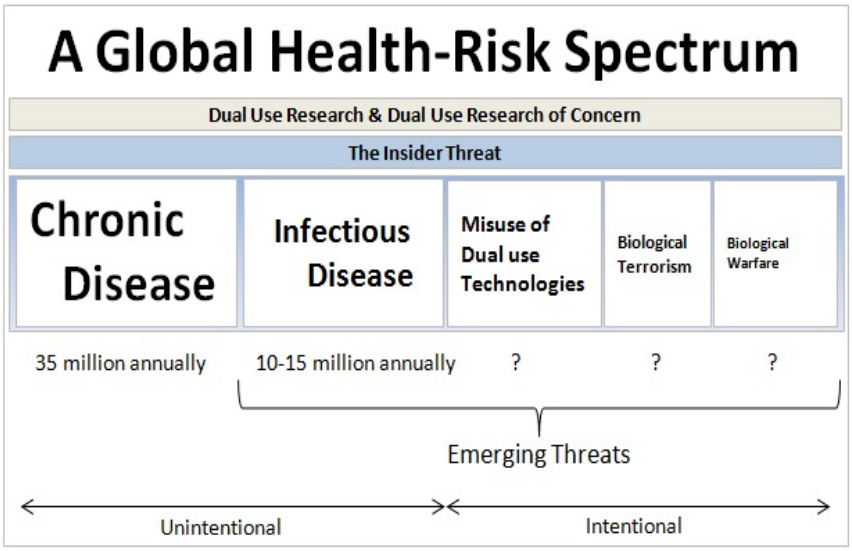
35. WORLD HEALTH ORG., WORLD HEALTH REPORT 1996: FIGHTING DISEASE FOSTERING DEVELOPMENT 1 (1996).

36. CALVIN O. QUALSET & HENRY L. SHANDS, SAFEGUARDING THE FUTURE OF U.S. AGRICULTURE: THE NEED TO CONSERVE THREATENED COLLECTIONS OF CROP DIVERSITY WORLDWIDE 7 (2005).

37. Judith Miller, *When Germ Warfare Happened,* 20 CITY JOURNAL 86, 86 (Spring 2010).

38. JEANNE GUILLEMIN, AMERICAN ANTHRAX: FEAR, CRIME, AND THE INVESTIGATION OF THE NATION'S DEADLIEST BIOTERROR ATTACK, xx-xxi (Henry Holt & Co. 2011).

39. W. SETH CARUS, BIOTERRORISM AND BIOCRIMES: THE ILLICIT USE OF BIOLOGICAL AGENTS SINCE 1900, 19-20 (Minerva Grp. 2002) (1998).



The above figure represents the relative impact in lives lost from unintentional disease and the intentional misuse of biology. Regardless of how you define the anthrax letter attacks, whether as misuse or terrorism, there were five deaths as a result of that intentional event. DURC examples can be found across most of this space, as can insider threat potential. The risk-threat spectrum, as shown above, is ever changing, making the analysis of requirements for preparedness, response, recovery, and policy very difficult. Understanding what to do about intentional health threats is even more difficult than planning for natural risks and threats.

2. Health and Security

Both health and security are of interest to government decision makers and decision influencers. The funding they provide to protect the population depends on their perception of the threat or risk. It also appears that in biology, government decision makers often prefer funding response measures rather than preventive measures, regardless of whether they are seeking health or security. When HIV and AIDS were discovered, Congress called for huge increases in funding for health. When 9/11 and 10/4 occurred, massive increases in funding occurred, this time for security. The National Institute of Allergy and Infectious Disease's (NIAID) annual budget for biosecurity was increased from essentially zero dollars to $1.7 billion

after the anthrax letters in 2001.[40] But when no further attacks occurred in the next five to ten years, the program's emphasis changed from traditional threat agents toward emerging infectious diseases.[41]

3. The Advance of Technologies

Biotechnology, and the knowledge that derives from it, has been increasing at a phenomenal rate for the past 20 years.[42] Rob Carlson, a biotechnology futurist, has calculated that *genetically modified systems* generated more than $300 billion, or two percent Gross Domestic Product for the U.S economy in 2010.[43] Just as new biological knowledge builds on previous knowledge, so too, the biotech revolution was built on previous revolutions in transportation and communication. In 1999, Harvard Professor Matthew Messelsen, Ph.D., a major influence on President Nixon who renounced biological weapons, said, "Every major technology — metallurgy, explosives, internal combustion, aviation, electronics, nuclear energy — has been intensively exploited, not only for peaceful purposes but also for hostile ones. Must this also happen with biotechnology, certain to be a dominant technology of the [twenty-first] century?"[44] His concerns were as much prophetic as they were a warning. Dr. Messelsen made the statement in the very early days of molecular biology; our capabilities and knowledge have now caught up with his concerns. This is particularly true in the twenty-first century, but there has not been a massive loss of life as a result of intentional misuse of these powerful tools.

D. Biological Warfare, Terrorism, and Crimes

While relatively few humans or animals have died of intentional misuse of biology in modern times, several governments, non-government groups,

40. *See* Anthony S. Fauci et al., *Emerging Infectious Diseases: A 10-Year Perspective from the National Institute of Allergy and Infectious Diseases*, 17 INT'L J. RISK & SAFETY 157, 159, 164 (2005).

41. *See* David R. Franz, *Preparedness for an Anthrax Attack,* 30 MOLECULAR ASPECT MED. 503, 504. This was not necessarily a bad thing. In fact, it might have been wiser to fund both the traditional threat agent countermeasures and those for the emerging diseases from the outset. *See id.* at 504-07.

42. *See* ROBERT H. CARLSON, BIOLOGY IS TECHNOLOGY: THE PROMISE, PERIL, AND NEW BUSINESS OF ENGINEERING LIFE, 233 (Harvard Univ. Press 2010).

43. Robert H. Carlson, *Biodesic 2011 Bioeconomy Update: U.S. Revenues from Genetically Modified Systems Now $300 Billion, or Greater than 2% of GDP,* SYNTHESIS (Aug. 15, 2011, 11:18 AM), http://www.synthesis.cc/2011/08/biodesic-2011-bioeconomy-update-us-revenues-from-genetically-modified-systems-now-300-billion-or-gre.html.

44. Matthew Meselson, Professor, Harvard Univ., Presentation on The Problem of Biological Weapons at the 1818th Stated Meeting of the American Academy of Arts and Sciences (Jan. 13, 1999), *available at* http://www.pugwash.org/reports/cbw/cbw5.htm.

and even individuals have developed biological weapons or conducted research toward that end.

1. Enormous State-Sponsored Biological Warfare Programs But Little Actual Use

Evidence shows that during WWII the Japanese conducted wide-ranging human experiments with biological agents and also conducted focal attacks on a number of Chinese villages. These activities are chronicled in a book that takes the name of the Japanese military unit involved, *Unit 731*.[45] The records of this secret unit, then headquartered near Harbin, China, were handed over to American forces in exchange for leniency toward the perpetrators.[46] While the U.S. may have hoped to apply lessons learned from the unit's reports to bolster its own biological warfare program, the consensus is that Japan's research was of little value, as it was far from scientific.[47] In many cases, the number of test subjects per study group was one or just a few, making the data analysis impossible.[48] Describing what appeared to be more of a random torture campaign against Chinese and allied prisoners than a research program, the records were soon filed in the U.S. archives where they remain today.[49] The Japanese attacks themselves, the most famous of which involved clay pots filled with rice and *Y. pestis* infected fleas dropped on Chinese villages from the air, were described in 2005, by a young officer of the Peoples Liberation Army.[50] Until very recently, the Chinese sought reparations from the Japanese for these attacks. The Japanese government has apparently now acknowledged that they did occur.[51] Many find it surprising to learn that these poorly understood attacks on Chinese villages over 70 years ago are the largest biological attacks undertaken by a state in the modern era.

In April 1942, Secretary of War Henry L. Stimson recommended the creation of a U.S. civilian advisory group to coordinate government and non-governmental organizations in a biological warfare effort to President

45. *See* PETER WILLIAMS & DAVID WALLACE, UNIT 731: JAPAN'S SECRET BIOLOGICAL WARFARE IN WORLD WAR II (Free Press, 1st ed. 1989).

46. *See id.* at 202-219, 235.

47. *See id.* at 257-266.

48. Personal communication with William C. Patrick, III, expert in germ and biological warfare (late 1990s).

49. *See* U.S. NAT'L ARCHIVES & RECORDS ADMIN., SELECT DOCUMENTS ON JAPANESE WAR CRIMES AND JAPANESE BIOLOGICAL WARFARE 3, 1934-2006, *available at* http://archives.gov/iwg/japanese-war-crimes/select-documents.pdf.

50. *Id.* at 5. *See also* LI XIAOFANG, BLOOD-WEEPING ACCUSATIONS: RECORDS OF ANTHRAX VICTIMS (2005).

51. Personal Communication with Wang Xuan, a Chinese activist, in Beijing (Sept. 2012).

Franklin Roosevelt.[52] The War Reserve Service, headed by George W. Merck, was established under the Federal Security Agency, part of the Department of Agriculture at the time. Secret work, under Mr. Merck's direction in 1942, involved 28 U.S. universities including, Harvard and Stanford, with a budget of $200,000.[53] What President Roosevelt did not know was that the U.S. Army Chemical Corps had already begun exploring biological weapons in 1941.[54] Eventually, it was the Army that became the larger part of the nation's offensive program with millions of dollars in funding and several geographic sites at locations including, a research facility at Camp Detrick in Frederick, Maryland, a manufacturing plant at Terre Haute, Indiana, and a 2,000-acre field test site at Horn Island, Mississippi.[55] The U.S. build-up was in response to concerns over a biological weapons program in Germany in WWII, yet it was the Japanese that should have been the main concern.

By 1943, the programs at Camp Detrick employed "3,800 military and 100 civilian personnel."[56] During WWII, the U.S. exchanged technical information with Canada and Great Britain, both of which had their own offensive programs. In 1944, Dugway Proving Ground, Utah, replaced the Mississippi test site (the Utah site is used today to test environmental sensors, decontamination techniques and equipment as countermeasures to biological weapons).[57] "In January 1946, the [U.S. Government] made public for the first time the fact that [it] had been conducting biological warfare research, [development], and testing."[58] In 1953, an agreement was signed between the Army Chemical Corps and the U.S. Army Medical Department to collaborate on the development of medical countermeasures for the military force in parallel with the offensive program.[59] By the mid-1950s, the large weapons complex at Camp Detrick included a pilot plant and a special operations division.[60] Until the offensive program ended in 1969, the medical department continued its work, and the Chemical Corps worked on developing biological weapons and conducting large-scale field tests in the continental U.S., Alaska, and the Pacific.[61]

In retrospect, we knew that the offensive program demonstrated that biological warfare was truly feasible, and a more recent analysis of original

52. Franz et al., *supra* note 2, at 426.
53. *Id.*
54. *Id.*
55. *Id.*
56. *Id.* at 427.
57. Franz et al., *supra* note 2, at 427.
58. *Id.*
59. *Id.* at 428.
60. *Id.*
61. *See id.* at 431.

documents supports the argument that the biological program achieved *nuclear equivalence* in killing power.[62] "In response to President Nixon's decision in 1969, all [agent] stocks were destroyed within a year, between May 1971 to May 1972."[63] The Terre Haute plant was sold to the Pfizer Company, the Pine Bluff, Arkansas facility was converted to the National Center for Toxicological Research,[64] and most of Fort Detrick's facilities were eventually turned over to the National Institutes of Health's (NIH) National Cancer Institute. In 1967, the Army broke ground at Fort Detrick for a new medical defense research facility, which would become USAMRIID.[65] USAMRIID's new mission was to "conduct studies related to medical defensive aspects of biological agents of military importance and develop appropriate biological protective measures, diagnostic procedures, and therapeutic methods."[66] After 9/11, USAMRIID would come to national prominence. First, for its exceptional and unique role in analyzing samples in support of response and recovery from the anthrax letters attacks, and second, as the home laboratory of Bruce Ivins, Ph.D., the *person of interest* who took his own life as the FBI was about to charge him as the mailer of those letters.[67]

The former Soviet Union also had an offensive biological weapons (BW) program that was the largest and most comprehensive in history, and almost certainly the largest the world will ever know. Its size and level of funding greatly increased throughout the 1970s and 1980s, just after the Soviet Union, like the U.S., signed and ratified the Biological Weapons Convention (BWC) in 1972 and 1975, respectively.[68] While intelligence communities in

62. Personal communication with William C. Patrick, III, expert in germ and biological warfare (Fall 2010) and Dr. Robert P. Kadlec (Sep. 2013).

63. *Id.*

64. *About Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/FacilitiesServices/ucm121463.htm (last updated Sept. 9, 2012) (explaining the location of the Arkansas facility).

65. Franz et al., *supra* note 2, at 431. The current USAMRIID facility broke ground in 1967 and opened in phases in 1971 and 1972. It is currently scheduled to be replaced by a new facility on the same campus at Fort Detrick, MD and the move to the new facility is scheduled to begin in 2014. *Id. See also* U.S. DEP'T OF THE ARMY, ENVIRONMENTAL ASSESSMENT: REAL PROPERTY MASTER PLAN FOR ARMY-CONTROLLED LAND AT AREAS A AND C OF FORT DETRICK IN FREDERICK COUNTY, MARYLAND 30 (2010), http://www.detrick.army.mil/emo/ea/AreasACMP EA.pdf.

66. Franz et al., *supra* note 2, at 431.

67. Guillemin, *supra* note 39, at 2-3, 106.

68. *Biological Weapons Convention Signatories and States-Parties*, ARMS CONTROL ASS'N, http://www.armscontrol.org/factsheets/bwcsig (last updated April 2013). *See also* Raymond A. Zilinskas, *The Anti-Plague System and the Soviet Biological Warfare Program*, 32 CRITICAL REVIEWS IN MICROBIOLOGY 47, 49 (2006).

the free world were aware of the program, the public knew little until February 13, 1980.[69] Public awareness occurred globally when a German magazine, *Bild-Zeitung,* carried the story of an accident at a military facility in Sverdlovsk, Russia.[70] The story was confirmed, and it soon became clear, that there had been at least 64 deaths from anthrax[71] and a massive cover-up by Soviet military and political authorities. It was at this point that Dr. Messelson led a team to Sverdlovsk to attempt to better understand what had happened.[72]

We would later learn from defectors, Vladimir Pasechnik, who sought asylum in the United Kingdom (U.K.) in 1989, and Ken Alibek in the U.S. in 1992,[73] that the Soviet enterprise was massive, far larger, and more advanced than that of the U.S. A strategic turning point in the Western search for evidence of a Soviet program came with the discovery of an enormous *B. anthracis* spore production capability in Stepnagorsk, Kazakhstan.[74] It was Alibek, through a popular book, *Biohazard,* who first described the Soviet program in great detail.[75] We learned of several military biological warfare facilities and a network of at least 18 generally non-military research institutes and plants called Biopreparat.[76] Biopreparat was created in 1973, just after the Soviet Union signed the BWC.[77] Alibek, Biopreparat's Deputy Director in 1992, estimated there were 30,000 scientists, engineers, and technicians in the whole program.[78]

69. TOM MANGOLD & JEFF GOLDBERG, PLAGUE WARS: THE TERRIFYING REALITY OF BIOLOGICAL WARFARE 73, 406 (2001).

70. JUDITH MILLER ET AL., GERMS: BIOLOGICAL WEAPONS AND AMERICA'S SECRET WAR 76 (2001).

71. MANGOLD & GOLDBERG, *supra* note 70, at 70.

72. *See* Matthew Meselson et al., *The Sverdlovsk Anthrax Outbreak of 1979*, 266 SCI. 1202 (1994).

73. *See* Linda Kozaryn, *Former Soveits' Bio-War Expert Details Threat*, U.S. DEP'T OF DEFENSE (Nov. 3, 1999), http://www.defense.gov/News/NewsArticle.aspx?ID=42946 (the U.S. production capacity was on the order of one ton of a given agent per year, while the Soviet capacity was 100 to 1,000 tons per year). *See also Vladimir Pasechnik,* TEL., Nov. 29, 2011, *available at* http://www.telegraph.co.uk/news/obituaries/1363752/Vladimir-Pasechnik.html.

74. *See* DAVID E. HOFFMAN, THE DEAD HAND: THE UNTOLD STORY OF THE COLD WAR ARMS RACE AND ITS DANGEROUS LEGACY 463-64 (2009) (describing the discovery of the Soviet anthrax plant at Stepnogorsk, Kazachstan, negotiations for entry, and ultimate destruction of the facility).

75. *See* KEN ALIBEK, BIOHAZARD: THE CHILLING TRUE STORY OF THE LARGEST COVERT BIOLOGICAL WEAPONS PROGRAM IN THE WORLD — TOLD FROM INSIDE BY THE MAN WHO RAN IT (1999) (Random House NY).

76. *See id.*

77. Jonathan B. Tucker, *Biological Weapons in the Former Soviet Union: An Interview with Dr. Kenneth Alibek*. 4 THE NONPROLIFERATION REVIEW 5 (1999).

78. *Id.* at 6.

After the 1991 collapse of the former Soviet Union, Ministry of Defense funding for biological warfare programs diminished to almost nothing. In April 1992, President Yeltsin publicly outlawed biological weapons in Russia.[79] On October 5, 1993, the day after Yeltsin's constitutional crisis and the attacks on the Russian White House, the first team of joint U.S./U.K. inspectors, in support of the Trilateral Agreement, began their visits to Biopreparat facilities.[80] It was my first of what would be many trips to Russia over the next ten years.

I see the following anecdote as unique and one of the most impactful experiences in my career with regard to the way I think about arms control and international engagement.

It was January 1994, in the Ministry of Foreign Affairs (MFA) building in Moscow. I was involved as a technical expert in the ongoing Trilateral Agreement discussions and negotiations. The Russians faced us from across a large table while our U.S./U.K. delegation worked from the side with the sun in our eyes. Much of the discussion addressed ground rules for the visits: how many sites, what could be covered with a tarp or screen and called proprietary, how many members of each team would be allowed, could samples be taken, and what was the protocol for sampling? We got to a part of the bracketed text that was mostly technical. The head of our delegation turned to me and said, "Colonel Franz, you and Colonel Pickavich go into the next room and work on this part of the text — it is only science." My partner was a uniformed M.D., Ph.D. from the Russian Army. We went to the next room, reconciled our texts, and returned to the delegation that was still debating the mechanics. Our brackets were gone and it had been easy because it was only science. *At the next break, my new friend and I wandered toward each other and were soon talking about our scientific interests and even about our families. That experience, so brief yet so powerful, changed the way I thought about international engagement and biological security. I realized that science and public health provide a common language and that working toward trust can tear down superficial, but sometimes very resilient, political barriers. I had not heard of DURC at the time, and had only given minimal thought to the insider threat, but my experience at the MFA would impact my thinking on how to deal with the more subtle challenges we face today.*[81]

79. THE GATHERING BIOLOGICAL WARFARE STORM 170 (Jim A. Davis & Barry R. Schneider eds., 2004).

80. *See* Serge Schmemann, *Revolt in Moscow: How Yeltsin Turned the Tide, Hour by Hour*, N.Y. TIMES, Oct. 11, 1993, at A1, A6; MANGOLD & GOLDBERG, *supra* note 70, at 197.

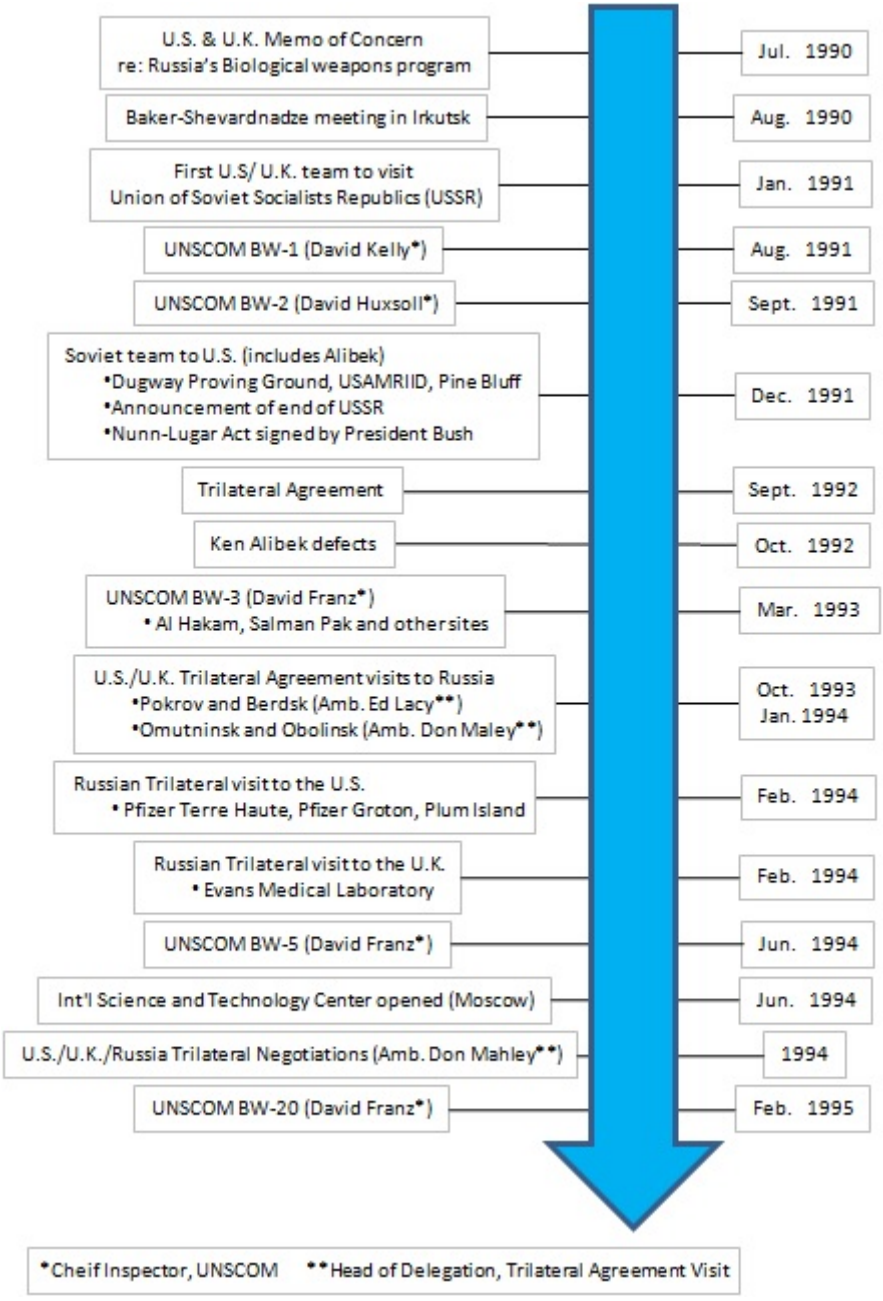
81. Names were changed for confidentially.

When the Trilateral Agreement visits and negotiations eventually ground to a halt, collapsing under the weight of mistrust on both sides, U.S. Senators Sam Nunn and Richard Lugar demonstrated visionary leadership by stepping into the gap with a most thoughtful, and at that time, politically risky idea: The Nunn-Lugar Cooperative Threat Reduction Program of 1991.[82] Actually, the establishment of this program predates the failure of the Trilateral Agreement. Did the Senators anticipate the Trilateral's failure or just realize there was not a mandate to try to force the Russians to admit they had been conducting an illicit BW program for 20 years? Whatever their motivations, it was the right response at the right time in history.

Multi-national UNSCOM BW-5 team staging in Bahrain in June of 1994. William C. Patrick III, former US "bioweaponeer" is standing fourth from left. The author, who served as Chief Inspector, is standing second from left.

The following timeline summarizes major events of the five-year period during which both the Soviet Union and Iraqi BW programs were under great scrutiny by the West. The U.S. and U.K. were involved in the Trilateral Agreement visits and were key players in the United Nations Special Commission on Iraq (UNSCOM) visits.

82. *See Nunn-Lugar Global Cooperation Initiative*, DEFENSE THREAT REDUCTION AGENCY & USSTRATCOM CENTER FOR COMBATING WMD & STANDING JOINT FORCE HEADQUARTERS-ELIMINATION, *available at* http://www.dtra.mil/Missions/nunn-lugar/nunn-lugar-home.aspx (last visited Sep. 17, 2013).


U.S. & U.K. Memo of Concern re: Russia's Biological weapons program
Jul. 1990
Baker-Shevardnadze meeting in Irkutsk
Aug. 1990
First U.S/ U.K. team to visit Union of Soviet Socialists Republics (USSR)
Jan. 1991
UNSCOM BW-1 (David Kelly*)
Aug. 1991
UNSCOM BW-2 (David Huxsoll*)
Sept. 1991
Soviet team to U.S. (includes Alibek)
•Dugway Proving Ground, USAMRIID, Pine Bluff
•Announcement of end of USSR
•Nunn-Lugar Act signed by President Bush
Dec. 1991
Trilateral Agreement
Sept. 1992
Ken Alibek defects
Oct. 1992
UNSCOM BW-3 (David Franz*)
• Al Hakam, Salman Pak and other sites
Mar. 1993
U.S./U.K. Trilateral Agreement visits to Russia
•Pokrov and Berdsk (Amb. Ed Lacy**)
•Omutninsk and Obolinsk (Amb. Don Maley**)
Oct. 1993
Jan. 1994
Russian Trilateral visit to the U.S.
• Pfizer Terre Haute, Pfizer Groton, Plum Island
Feb. 1994
Russian Trilateral visit to the U.K.
• Evans Medical Laboratory
Feb. 1994
UNSCOM BW-5 (David Franz*)
Jun. 1994
Int'l Science and Technology Center opened (Moscow)
Jun. 1994
U.S./U.K./Russia Trilateral Negotiations (Amb. Don Mahley**)
1994
UNSCOM BW-20 (David Franz*)
Feb. 1995
*Cheif Inspector, UNSCOM
**Head of Delegation, Trilateral Agreement Visit

The early 1990s was a time of winding down state-sponsored weapons programs. Interspersed between trips to Russia and London for the Trilateral Agreement related negotiations, I traveled to Baghdad where I served as Chief Inspector for three UNSCOM's biological warfare missions. The purpose of these inspection missions was to implement United Nations Security Council Resolution (UNSCR) 687, an effort to assure the uncovering and removal of Saddam Hussein's offensive biological warfare program.[83] It turns out that the Iraqi program probably began in the early 1980s when equipment was purchased from Germany, and pathogen strains from France and the U.S.[84] Some of the strains were used for legitimate medical countermeasure development and others, notably *B. anthracis* and *C. botulinum*, for weapons development.[85] The Iraqis worked with other bacterial and viral strains, but in the end, they weaponized just anthrax, botulinum toxin, and aflatoxin.[86]

The program was discovered during the First Gulf War, but production of agents had been ramped up before the war, probably beginning in 1989.[87] The main research center, Salman Pak, was destroyed during early bombing. The production site at Al Hakam, unknown to the West during the bombing raids, was later destroyed by the United Nations (U.N.). The other key facility, Al Manal Foot and Mouth Disease Center, was preserved because of its potential value to the country for legitimate agricultural use. Tim Trevan, an individual actively involved in many of the early inspections, wrote the first comprehensive popular account of the program and the activities of UNSCOM.[88] In Mr. Trevan's book, *Saddam's Hidden Secrets*, published in 1999, he provides an on-the-ground, inspector's eye-view of the very difficult task of definitively identifying small-scale offensive biological developments by a nation state.[89]

E. Non-State Misuse of Biology

While states planned and prepared for biological warfare, they almost never used the weapons they developed. We learned of non-state plans and programs only after the rather primitive *weapons* were used. Three major non-state crimes, none causing loss of life like that seen with chemical

83. *See* S.C. Res. 687, ¶¶ 8(a), 10, U.N. SCOR, U.N. Doc. A/RES/687 (April 3, 1991), *available at* http://www.un.org/docs/scres/1991/scres91.htm.

84. *See* TIM TREVAN, SADDAM'S SECRETS: THE HUNT FOR IRAQ'S HIDDEN WEAPONS 341, 343 (1999).

85. *See id.*

86. *See id.* (describing types of chemical weapons the Iraqi worked with).

87. *See id.* at 341 (describing the timeline of production of agents).

88. *See id.* at i, 1.

89. *See* TREVAN, *supra* note 84, at ix-x.

crimes, influenced our thinking about threats and risks near the end of the twentieth century. The first, in 1984, resulted in the food poisoning of more than 700 individuals in The Dalles, Oregon.[90] The fact that it took the CDC a year to discover that it was not a natural foodborne outbreak is a significant measure of how we perceived risk from intentional misuse of biology just 30 years ago. While there had been previous criminal biological activity in the U.S. and other countries, particularly Japan, the Oregon attack was by far the largest with the contamination of at least ten restaurant salad bars with salmonella bacteria.[91]

It turns out that the followers of Bhagwan Shree Rajneesh, an eccentric philosopher and modern-day interpreter of mysticism and religions, conducted the attack for political reasons.[92] They hoped to incapacitate part of the largest voting block in the county to give themselves an advantage in an election for members of a county court.[93] It appears that up to one dozen people were involved in either planning or executing the plot.[94] The contamination of salad bars was a trial run, as they were also planning to contaminate the water supply, but apparently never did.[95] The fact that so many people were involved and the perpetrators were not discovered for many months underscores the extremely poor awareness of biological crimes among our political leaders, health officials, citizens, and even the media. It is also interesting to note that after the adulteration of salad bars by the Rajneesh cult, the U.S. Government did not respond with new policies or legislation.

Fearing copycat attacks, federal and state investigators requested that the *Journal of the American Medical Association* not publish a record of the incident, and the journal complied.[96] Judith Miller, a former *New York Times* correspondent and Pulitzer Prize winning author, and her colleagues published the story of the above attacks years later in the book *Germs*.[97] This forgotten incident occurred long before the Fink Report, before NSABB discussions occurred regarding DURC, and before we seriously considered the implications of the publication of threat techniques or public vulnerabilities. By standards of today, there was little media attention given.

90. Joseph E. McDade & David Franz, *Bioterrorism as a Public Health Threat*, 4 EMERGING INFECTIOUS DISEASES 493, 493 (1998).

91. *Id. See also* CARUS, *supra* note 40.

92. *See* CARUS, *supra* note 40, at 50.

93. *Id.* at 52.

94. *Id.* at 53.

95. *See id.* at 56-57.

96. LAURIE GARRETT, BETRAYAL OF TRUST: THE COLLAPSE OF GLOBAL PUBLIC HEALTH 535 (2000).

97. *See* MILLER ET AL., *supra* note 71, at 19 (describing the food poisoning attacks by the Rajneesh cult).

The second incident before 9/11, which had a significant impact on our thinking and awareness of the risks of biological attacks, was a chemical attack. In 1995, ten years after the incident in Oregon, followers of Shoko Asahara, called the Aum Shinrikyo (Aum), an eccentric and powerful group, carried out a gas attack on Tokyo's subway system.[98] The attack used crude sarin gas that was delivered by a very simple, improvised device.[99] This attack killed 13 commuters, seriously injured more than 50, and affected nearly 1,000.[100] It followed an earlier sarin attack, in mid-1994, in which seven people died and two hundred became ill.[101]

The cult's religious organizational status, gained in 1989, may have offered some protection in Japanese society.[102] The Aum's broader activities demonstrated behavior even more bizarre than the Rajneehes had displayed ten years prior in the Oregon attacks. In addition to several kidnappings and assassinations conducted by members, the cult traveled to Australia to field-test their sarin on animals.[103] They also traveled to Russia to acquire military equipment, reportedly even seeking components for a nuclear weapon.[104] The illicit biological activity for which they are best known is the release of a bacillus species in July 1993, from the top of a Tokyo building.[105] It was later learned that the *anthrax* was not virulent, and that the steam device used was not an effective means of dissemination. While the Aum's signature attack was with a chemical, not a biological agent, it clearly had a wake up effect on U.S. policymakers, public health community leaders, and the media.

The third incident in this series, while much less impactful than the two previously mentioned, had a galvanizing impact on U.S. law enforcement and legislative communities. No one died, no pathogens were used, but Mr.

98. CARUS, *supra* note 40, at 49-50.

99. Holly Fletcher, *Aum Shinrikyo (Japan, Cultists, Aleph, Aum Supreme Truth)*, COUNCIL ON FOREIGN RELATIONS, June 19, 2012, at 3, http://www.cfr.org/japan/aum-shinrikyo/p9238. Sarin is one of the more volatile organophosphate chemical warfare agents, previously weaponized by several governments. *Id*.

100. *See* Hiroko Tabuchi, *Suspect in '95 Tokyo Attack is Said to be Caught*, N.Y. TIMES, June 15, 2012, at A10.

101. Nicholas D. Kristof, *Terror in Tokyo: The Overview, Hundreds in Japan Hunt Gas Attackers after 8 Die, Security Tight – Rider Seen as Suspect*, N.Y. TIMES, March 21, 2005, http://www.nytimes.com/learning/general/onthisday/big/0320.html.

102. AMY E. SMITHSON & LESLIE-ANNE LEVY, THE HENRY L. STIMSON CTR., ATAXIA: THE CHEMICAL AND BIOLOGICAL TERRORISM THREAT AND THE US RESPONSE 110 (2000), *available at* http://www.stimson.org/images/uploads/research-pdfs/atxchapter3.pdf.

103. RICHARD DANZIG ET AL., AUM SHINRIKYO: INSIGHTS INTO HOW TERRORISTS DEVELOP BIOLOGICAL AND CHEMICAL WEAPONS, CTR. FOR A NEW AM. SECURITY, 47 (2011), *available at* http://www.cnas.org/files/documents/publications/CNAS_AumShinrikyo_Danzig_0.pdf.

104. *Id.* at 18, 27.

105. *Id.* at 56, 18 n.112.

Harris'[106] request to the ATCC for an isolate of *Y. pestis* led to new legislation.[107] This new legislation made the act of transferring certain pathogens between laboratories a crime, and made work more difficult for the scientists and laboratories who conducted research with these agents.[108] Harris was required to complete 200 hours of community service and laboratories were *given* the Select Agent Rule, the law prohibiting transfer of a defined group of biological agents between laboratories not certified for such actions by the U.S. Government. The rules would continue and become more onerous for years after the 200 hours of service served by Mr. Harris passed.

Why the need for the Select Agent Rule, a regulatory response that seemed at the time too far-reaching for the crime, or actually, no-crime? Probably because we were primed. We had seen the enormity of the Soviet program in significant detail, now understood the Rajneesh salad bar attack and the terror impact of the Aum's sarin attacks, had learned of the Iraqi offensive program, and were in the midst of planning for the Summer Olympics in Atlanta. Still on active duty and commanding USARMIID, I recall this as the time that our own thinking expanded and, in a sense, shifted from a focus on protecting our forces on a distant European battlefield to protecting our citizens at home. We made it through the Olympics Games in Atlanta mostly unscathed, at least biologically, but we continued to think about the domestic threat and to enhance our preparations.

1. And then Everything Changed Forever

We all know where we stood gazing at a television screen as the second plane slammed into the World Trade Center on that clear September morning. The next few minutes wrung some innocence out of the American culture that will likely never return. In the memories of those who have dedicated their lives to the security of the nation, there is a bright line through the events of 9/11.[109]

106. *See generally Beyond Anthrax: Extremists and the Bioterrorism Threat: The Harris Hoax*, ANTI-DEFAMATION LEAGUE (2001) (describing background information on Larry Wayne Harris as a biological extremist) *available at* http://archive.adl.org/learn/anthrax/Harris.Asp?xpicked=3&item=5.

107. GERALD L. MANDELL ET AL., PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES 3965 (Gerald L. Mandell et al. eds., 7th ed. 2010).

108. *See* Select Agent Regulations 42 CFR § 73 (1997) (relating to public health).

109. I sat next to Barbara Hatch-Rosenberg in a meeting in Washington D.C. all day on the 10th of September, the day before the WTC attacks. Oddly, Dr. Hatch-Rosenberg would later speculate on the Federation of American Scientists website that "Col. David R. Franz and his cronies, if they weren't involved in the anthrax letters, would very likely know who was." [paraphrased]. *See* Barbara Hatch Rosenberg, *Analysis of the Anthrax Attacks*, FED'N OF AM.

Just three weeks after 9/11, I was in New York City preparing for a taping of CBS's *60 Minutes* with Mike Osterholm, Matthew Messelson, and Richard Butler. As I sat in a makeup chair, Mike Wallace walked up behind me holding, as I recall, several linked, perforated pages that looked like they came from a telex machine. He said, "Dr. Franz, there's a wire report of a case of inhalational anthrax in a Florida man. What do you think?" My response was too quick, "No way! We haven't had a case of inhalational anthrax in this country since 1978!" I have often relived that moment and thought to myself, "Wow! If I wasn't prepared for that at that very time in history, who was? For Pete's sake, it was my job!"

Later that evening, I left John F. Kennedy International Airport for Moscow. When I connected with my wife by email a few days later, she informed me that our friend, Judy Miller, had called to talk with me. Judy had received a letter containing some granular powder in her office at the *New York Times*. By the time I returned to the U.S., we were in the midst of a response to the biological event that would further change our lives and our life sciences enterprise forever.

2. The Anthrax Letters

The so-called *anthrax letters* changed much of the world I had come to know so well over the previous 14 years. Life at USAMRIID had been very different in the 1990s. We had come through some really hard times together. The Clinton peace-dividend *right-sizing* of the military force had resulted in salami-slicing cuts of personnel and funding. We had been forced to reduce our military and civilian workforce by 31% from 1991 through 1997.[110] We were able to cut many staff by attrition, as well as offering early retirement packages,[111] but I was forced to fire the last 17 people, many my personal friends, due to a reduction in force. That had been a nightmare for me, but also a lesson regarding the basic goodness of people. Some told me on the spot, almost apologetically, that they knew how hard it was for me. Others later wrote letters saying they had landed on their feet and not to worry.

We were also constantly strapped for funds. Just one year before I was to finish my tour as commander of USAMRIID, our initial funding for fiscal year 1997 had been $18 million. It took about $16 million to run the very

SCIENTISTS (January 17-31, 2002), http://www.911review.org/Wget/www.fas.org/bwc/news/anthraxreport.htm (commenting on the FBI's knowledge of the anthrax killer).

110. This information comes from my personal recollection.

111. *See, e.g.*, U.S. OFFICE OF PERSONNEL MGMT., GUIDE TO VOLUNTARY EARLY RETIREMENT REGULATIONS (2006); U.S. OFFICE OF PERSONNEL MGMT., GUIDE TO VOLUNTARY SEPARATION INCENTIVE PAYMENTS (2006) (stating the guidelines to follow when offering early retirement and separation incentive payments).

complex and unique high-containment infectious disease laboratories and to pay civilian salaries, leaving only $2 million for research. I wrote a formal request to my higher command asking to furlough one-half of the civilian workforce to free up funds for research. In response, we received another $1.5 to $2 million for research.[112] Those lean times were good for us, and good for me as the commander, I had a great boss who gave me authority commensurate with my responsibility, and supported me. There was a sense that we, the military and civilian employees, were *in this together*; we were *a team, a family*. We not only survived, but also prospered. The patriotic, hard-working employees made enormous strides in diagnostics for biological warfare agents, education of healthcare providers, and amazing advances in basic and preclinical research supporting the development of vaccines for the force.

I walked out of the USAMRIID late one Sunday night in the summer of 1998, with the last box of books from my office in my arms and tears dripping from my chin. I loved the USAMRIID, the mission, and the people. I still have a homemade bumper sticker that I placed on my command suite bulletin board during the most difficult times: "Someday, we'll look back and say it was fun." And I have many, many times. As my wife and I formally said goodbye in the Dalrymple Conference Room, I told my friends, "It is not the science, but you people I will remember." I was right.

When the anthrax letters arrived at the various media and government offices, the frenzy began. At this point, I still knew the leadership and most of the staff at USAMRIID very well. In addition to receiving some of the actual letters for analysis, suddenly my friends were inundated with samples of unknown white powders from all over the country. They worked in round-the-clock shifts to handle the increased workload and processed more anthrax samples than any other laboratory in the nation. As a result of the tragic death of five innocent Americans from the anthrax letters, there was an immediate response in Washington with the administration of antibiotics and vaccines for exposed victims, an enormously expensive cleanup at the Senate and Post Office buildings, and the development of forensics tools in contractor labs. Lastly, time and resources were expended for the nearly seven-year FBI investigation with the "person of interest" lawsuit.[113] This long ordeal ended with the death of Dr. Ivins. As I have stated on the back cover of the book, "*American Anthrax* is a gripping story of a series of human tragedies at the collision of behavior, biology, and bureaucracy. It

112. The above information comes from my personal recollections.

113. *See, e.g.*, GUILLEMIN, *supra* note 39; LEONARD A. COLE, THE ANTHRAX LETTERS: A MEDICAL DETECTIVE STORY (Joseph Henry Press 2003); DAVID WILLMAN, THE MIRAGE MAN: BRUCE IVINS, THE ANTHRAX ATTACKS, AND AMERICA'S RUSH TO WAR (Bantam Books 2011) (stating that many resources were used during the seven-year FBI investigation of Bruce Ivins).

underscores the crucial importance not only of public health readiness but of basic science in controlling dangerous disease outbreaks, however they emerge."[114]

The failure of the government to allow a proper closure to the story makes it even more tragic. While the circumstantial evidence against Dr. Ivins was convincing, many technical questions about the investigation still remain.[115] The last opportunity for an open court trial of the case evaporated when the Department of Justice settled out of court with Mrs. Maureen Stevens, the rightfully distraught wife of Robert Stevens, the Florida man whose illness and death resulted from inhalation of anthrax spores.[116]

IV. DOMESTIC RESPONSE

A. The U.S. Biosecurity Build Up

In response to the anthrax letters, Congress quickly went beyond the 1997 Select Agent Rule. Under the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, registration was required of individual scientists with laboratory access to the Select Agents.[117] For the first time, we were licensing scientists to work with a defined set of pathogens. However, this license was not meant to protect public *safety*, dependent on competence like a driver's license, it was about public *security* and included background checks much like the one the FBI had conducted when they cleared Dr. Ivins long before he became a suspect in the anthrax letters investigation. One person had apparently sent the anthrax letters, but all scientists in a class were subject to these new laws. We may never know how much safer the laws have made us, but many

114. GUILLEMIN, *supra* note 39.

115. *See* REVIEW OF THE SCIENTIFIC APPROACHES USED DURING THE FBI'S INVESTIGATION OF THE 2001 ANTHRAX LETTERS, COMM. ON SCI., TECH., & LAW, POLICY & GLOBAL AFFAIRS DIV., NAT'L RESEARCH COUNSEL OF THE NAT'L ACADS. (2011) (stating that many technical questions remain regarding the FBI's investigation of the 2001 anthrax letters).

116. Scott Shane, *U.S. Settles Suit Over Anthrax Attacks*, N.Y. TIMES, November 29, 2011, at A19.

117. Kunal J. Rambhia et al., *Everywhere You Look: Select Agent Pathogens*, 9 BIOSECUIRTY & BIOTERROISM: BIODEFENSE STRATEGY, PRACTICE & SCI. 70 (2011), *available at* http://www.upmc-biosecurity.org/website/resources/publications/2011/pdf/2011-03-03-select_agent_pathogens.pdf. Other than variola virus, the etiologic agent of smallpox, the select agents were all widely available in nature, and continue to be. *See id.* at 70. Note that SARS Corona virus has been added to the list as well as some of the influenza viruses, not necessarily available in nature. *Id.* at 69-70.

believe they have had a negative impact on scientific progress, and even biosecurity.[118]

The DOD borrowed a term and an approach from our nuclear weapons labs in drafting Army Regulation 50-1,[119] which was implemented in draft form in 2004, the approved regulation signed on July 28, 2008, ironically one day before Dr. Ivins' suicide.[120] The new regulation overlaid on infectious disease research what had been the government's approach to safety and security in laboratories with nuclear weapons and chemical warfare agents. While the nuclear and chemical programs were conducted primarily in what might be called *government security labs*, biological surety would eventually impact public health, academic, and industrial labs as well.

"Biological Surety," a system of regulations and practices used for years in nuclear weapons labs and chemical defense labs, includes: (1) Biological Safety, (2) Biological Security, (3) Agent Accountability, and (4) Personnel Reliability.[121] The principles of Biological Safety were developed at Camp Detrick and have been embraced by infectious disease scientists for many years. Biological Security, often affectionately called "Guns, Gates, and Guards," sometimes poses minor inefficiencies for the laboratory scientists, but for the most part they do not mind those inconveniences or the closed circuit cameras in their labs. Agent Accountability, like other *good ideas* in the nuclear model, turned out to be impossible to implement in biology. The requirements to account for the quantity of organisms in one's lab day to day was scaled back somewhat after essentially shutting down the lab for several months. Finally, Personnel Reliability involves interviews, reporting, medical history checks, and other personally invasive actions.[122]

118. Arturo Casadevall & David A. Relman, *Microbial Threat Lists: Obstacles in the Quest for Biosecurity?*, 8 NATURE REVIEWS: MICROBIOLOGY 83, 153 (2010), *available at* http://www.ncbi.nlm.nih.gov/pubmed/20065941.

119. *See* DEPT. OF THE ARMY, ARMY REGULATION 50-1, BIOLOGICAL SURETY: NUCLEAR AND CHEMICAL WEAPONS AND MATERIAL (2008), *available at* http://www.fas.org/irp/doddir/army/ar50-1.pdf [hereinafter AR 50-1].

120. *See* David Willman, *Senators Question FBI's Handling of Anthrax Probe*, L.A. TIMES, September 18, 2008, http://articles.latimes.com/2008/sep/18/nation/na-anthrax18.

121. ARMY BIOSURETY PROGRAM, U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, 1-2 (2000), *available at* http://mrmc.amedd.army.mil/assets/docs/media/biosuretyCommPlan.pdf. Biological Safety is protecting the scientists and the community around a laboratory from the microbes. Biological Security is protecting the microbes from those who might misuse them. Agent Accountability is keeping a "real time" account of quantities of microbes. Personal Reliability is attempting to assure that no laboratory worker or other individual with access to the microbes is the kind of person who might use microbes to cause harm. *Id*.

122. *See* AR 50-1, *supra* note 121, at 5.

But our response as a government was not over; we were primed by the horrific events of 9/11. We will never know how we would have responded to the anthrax letters in isolation of these events. In 1997, the entire U.S. Government's budget for biodefense was $137 million, and this was all within the DOD.[123] In 1998, the CDC received $148 million for diagnostics and public health lab upgrades, education of healthcare responders, and the stockpiling of medical countermeasures in the Strategic National Stockpile.[124] By 2002, the U.S. Government was spending $4.1 billion total for biosecurity.[125] While the DOD's budget for medical countermeasures research remained flat after doubling in 1998, the Department of Health and Human Services (HHS), previously only collaborating at the periphery of medical biological defense, received a significant plus-up, mostly within the NIH's National Institute of Allergy and Infectious Disease (NIAID). A few years later, the NIAID would announce the award of grants to academic consortia for basic research to develop countermeasures.[126] The initiative would include the construction of two BSL-4 labs and, planned at the time, 13 BSL-3 labs,[127] mostly on campuses located regionally across the U.S. The media and fellow scientists from other disciplines asked many questions during those years. The most common was, "Do we really need all these new high-containment labs?" It was at this time that a group of more than 700 scientists formally protested the massive spending at the expense of *more important research*.[128]

B. Surprises in Biology

While the media was asking questions, the science community was also watching the greatly increased number of scientists who were working with the agents formerly limited to USAMRIID, the CDC labs in Atlanta, and a handful of contractor labs. We, the biological science community, began

123. DAVID R. FRANZ, THREATS AND RISKS TO U.S. AGRICULTURE: AN OVERVIEW 1 (2005), *available at* http://fss.k-state.edu/featuredContent/PDF/Franz20050219.pdf.

124. This information comes from my personal recollection.

125. Crystal Franco & Tara Kirk Sell, *Federal Agency Biodefense Funding, FY2010-FY2011*, 8 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, & SCI. 129, 130 (2010), *available at* http://www.upmchealthsecurity.org/website/resources/publications/2010/2010-06-14-biodefensefunding.html. *See also* Schuler, *supra* note 17, at 87, 90.

126. *Biocontainment Laboratories,* FED'N OF AM. SCIENTISTS, http://www.fas.org/biosecurity/resource/research.htm (last visited Sept. 20, 2013). *See also* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 6, at 4.

127. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 6, at 4 (explaining information regarding containment labs and Biosafety Levels).

128. Sidney Altman et al., *An Open Letter to Elias Zerhouni*, 307 SCI., Mar. 4, 2005, at 1409-10, *available at* http://www.sciencemag.org/content/307/5714/1396.summary?sid=f942d78a-7e22-4748-8047-a0d14d67c18e.

wondering aloud where all this was headed. Further, considering new risks, we began to wonder if we should take issues upon ourselves before someone with a poorer understanding of the complex challenges and the possible outcomes did it for us. The Fink Committee of the National Academies of Science considered this issue from April 2002 – January 2003.[129] The resulting report, *Biotechnology Research in an Age of Terrorism: The Dual Use Dilemma*, released to the public in 2004, became a signpost in the discussion between biological science and security, and in addition to the findings and recommendations, the Report's "Experiments of Concern"[130] live on as stated below. This list of experiments has become the legacy of the Fink Report and should be given special attention before they are begun, as they are seven examples of research that might be misused:

1) Would demonstrate how to render a vaccine ineffective.
2) Would confer resistance to therapeutically useful antibiotics or antiviral drugs.
3) Would enhance the virulence of a pathogen or render a non-pathogen virulent.
4) Would increase transmissibility of a pathogen.
5) Would alter the host range of a pathogen.
6) Would enable the evasion of diagnostic and detection modalities.
7) Would enable the weaponization of a biological agent or toxin.[131]

Finally, the committee's recommendation that the U.S. Government form a national-level board bringing together biological scientists and security professionals to report to HHS became a reality when the NSABB was chartered in 2004.[132] The stated mission of the NSABB, a Federal Advisory Committee,[133] was to "provide advice, guidance, and leadership

129. *See* FINK REPORT, *supra* note 20, at vii- viii (2004).

130. *Id.* at viii, 5. These are also sometimes referred to as the "Fink Seven Deadly Sins."

131. *Id.* Experiment #7 regarding facilitating weaponization might be considered one which should not be done, although the BWC might allow it in small quantities for "prophylactic, protective or other peaceful purposes." Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, art. 1, ¶1, Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163, *available at* http://disarmament.un.org/treaties/t/bwc/text [hereinafter BWC]. The point is that the Committee did not intend to automatically ban all seven of the experiments listed, but to ask the community of scientists to consider them carefully before undertaking such research. *See* FINK REPORT, *supra* note 20, at 36.

132. FINK REPORT, *supra* note 20, at 9. *See also* DANA A. SHEA, CONG. RESEARCH SERV., *supra* note 26, at 4.

133. *See* WENDY R. GINSBERG, CONG. RESEARCH SVC., FEDERAL ADVISORY COMMITTEES: AN OVERVIEW 1 (2009), *available at* http://www.fas.org/sgp/crs/misc/R40520.pdf. Often called a "FACA," it is a type of committee assembled by a government agency to allow non-

regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security."[134]

C. *The NSABB and DUR*

The NSABB held public meetings from its inception. Several internal subgroups were formed initially to focus on particular topics such as, *criteria* for identifying DUR, *codes of conduct* for life sciences researchers, responsible *communication* of dual use life sciences research, biosecurity issues raised by *synthetic genomics* and *international collaboration* for oversight of DUR.[135] Some of these were dissolved and new ones established as needs changed or new questions arose over the years. The NSABB met as needed in plenary and the subcommittees met more often. Typically, the subcommittees drafted recommendations and then the full board edited and formally approved each before sending them from the NIH to HHS. From HHS, the approved recommendations were sent to the White House, where the real customer was the National Security Staff.

The International Engagement Subcommittee, which I co-chaired from the beginning, held a series of international meetings in Washington, D.C. The largest meeting, in November 2008, involved representatives from 37 countries.[136] At each meeting, we introduced the NSABB and explained the challenges concerning DURC as we understood them, then sought to gain perspective regarding perceptions of the DURC issues, common challenges, and potential solutions from our partners.[137] The reports of the early meetings are available on the NSABB's website.[138] In recent years, after the face-to-face international meetings became too large and too expensive, we held a series of webinars with local experts from major global regions.

governmental Subject Matter Experts to advise the government without conflict. The law establishing the process is called The Federal Advisory Committee Act.

134. *About NSABB*, OFFICE OF BIOTECHNOLOGY ACTIVITIES, http://oba.od.nih.gov/biosecurity/about_nsabb.html (last visited Aug. 18, 2013).

135. Italicized words illustrate the topics of the NSABB's Working Groups and ultimate early reports. Meeting Agenda from NSABB Meeting July 13, 2006, NAT'L SCI. ADVISORY BD. FOR BIOSECURITY (July 13, 2006), *available at* http://oba.od.nih.gov/biosecurity/meetings/200607/Criteria%20Working%20Group.pdf.

136. NAT'L SCI. ADVISORY BOARD FOR BIOSECURITY, SUSTAINING PROGRESS IN THE LIFE SCIENCES: STRATEGIES FOR MANAGING DUAL USE RESEARCH OF CONCERN 1 (2008), *available at* http://oba.od.nih.gov/biosecurity/PDF/Report%20from%203rd%20Rt_Final_18%20May%2009.pdf.

137. *See id.* at 2.

138. *See Office of Biotechnology Activities*, NAT'L INST. OF HEALTH, http://oba.od.nih.gov/biosecurity/biosecurity_documents.html (last visited Aug. 15, 2013).

Recordings of these broadcasts are also available on the NSABB's website.[139]

The most relevant and comprehensive document produced by the NSABB was the June 2007 report entitled, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*.[140] This end-to-end roadmap overlaid the concept and awareness of DURC on the life sciences' fundamental research. Further, this report gave the U.S. Government and NIH the first and best globally available *guidebook* for dealing with the complexities pertaining to discovery and responsibility in the life sciences and technical security related surprises.

D. Back to the Letters

In August 2002, not long after Barbara Hatch Rosenberg, a scientist at the State University of New York at Purchase, and closely affiliated with the Federation of American Scientists, published and discussed with the media her numerous and varied hypotheses mostly proposing U.S. Government employees as the perpetrators,[141] Attorney General John Ashcroft stated in a press conference that Dr. Steven Hatfill was a "person of interest" in the anthrax letters case.[142] While Dr. Hatfill vehemently denied involvement, the FBI continued to pursue him. At one point in 2003, the FBI even drove over Dr. Hatfill's foot[143] and agents also showed up at his significant other's home and "trashed" it, apparently searching for evidence.[144] In 2003, Dr. Hatfill filed a lawsuit against Ashcroft, the Department of Justice (DOJ), and several media outlets.[145] The negotiations went on for more than five years,

139. *U.S. Dept. of Health & Human Servs.*, NAT'L INST. OF HEALTH, http://videocast.nih.gov/summary.asp?Live=10326 (last visited Oct. 11, 2013).

140. *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, PROPOSED FRAMEWORK FOR THE OVERSIGHT OF DUAL USE LIFE SCIENCES RESEARCH: STRATEGIES FOR MINIMIZING THE POTENTIAL MISUSE OF RESEARCH INFORMATION (2007).

141. *Projects and Initiatives*, FED'N OF AM. SCIENTISTS (Aug. 15, 2013), http://www.fas.org/projects.htm. *See also* Barbara Hatch Rosenberg, Op-Ed., *Anthrax Attacks Pushed Open an Ominous Door*, L. A. TIMES (Sept. 22, 2002), http://articles.latimes.com/2002/sep/22/opinion/op-rosenberg22.

142. Complaint at 19-20, Hatfill v. Ashcroft, 404 F.Supp. 2d 104 (D.D.C. 2005) (No. Civ.A. 03-1793(RBW)).

143. Kelli Arena, *Hatfill Ticketed in Altercation with FBI Agent*, CNN.COM (May 19, 2003, 4:40 PM), http://www.cnn.com/2003/US/05/19/hatfill/.

144. Robert D. Novak, *Novak: Hatfill Affair Tells of FBI's Esteem Dip*, HOUSTON CHRONICLE (Aug. 31, 2002), http://www.chron.com/opinion/editorials/article/Novak-Hatfill-affair-tells-of-FBI-s-esteem-dip-2103560.php.

145. *See* Complaint, *supra* note 144. *See also* Hatfill v. New York Times Company, 416 F.3d 320 (4th Cir. 2005).

but in June 2008, the U.S. Government exonerated Dr. Hatfill and announced a settlement of $4.6 million.[146]

In July 2005, Dr. Hatfill filed a lawsuit against the *New York Times* and Nicholas D Kristof, a *New York Times* reporter, for statements Kristof published suggesting that Hatfill was the "likely culprit."[147] This case was dismissed on summary judgment on January 12, 2007, based on the fact that Dr. Hatfill was a public figure and had not proven malice on the part of the *New York Times*.[148] Dr. Hatfill also filed a lawsuit against Donald Foster,[149] a forensic linguist who had stated in a 2003 *Reader's Digest* article that Hatfill's travels and the postmarks on certain anthrax hoax letters closely correlated.[150] That suit was apparently settled out of court. Soon after the 2003 lawsuit that Hatfill filed against the DOJ, the FBI began to focus its attention on Dr. Ivins, an anthrax vaccine specialist at USAMRIID.[151] As the questioning and surveillance of Dr. Ivins' family and himself continued, the pressure on the FBI to solve the nearly seven-year-old case intensified. During this time, we learned much more about the life of the hard-working and selfless, but quirky scientist so many of us knew. On the morning of August 2, 2008, the *Frederick News Post* opened with the headline: "Anthrax Case Turns."[152] Dr. Ivins had committed suicide.

V. THEY ARE RELATED

A. DURC and the Insider Threat

The anthrax letters were not an example of DURC. However, they are believed by many to have been the result of a lone insider's action — whether that insider was from USAMRIID or another legitimate government or non-government laboratory. The best approaches to preventing either the

146. Shane Scott & Eric Lichtblau, *Scientist is Paid Millions by U.S. in Anthrax Suit*, N.Y. TIMES, June 28, 2008, http://www.nytimes.com/2008/06/28/washington/28hatfill.html?_r=1&.

147. *Hatfill*, 416 F.3d at 325.

148. Michael Sung, *Federal Judge Dismisses Anthrax Defamation Suit against New York Times*, JURIST (January 13, 2007, 9:13 AM), http://jurist.law.pitt.edu/paperchase/2007/01/federal-judge-dismisses-anthrax.php.

149. *See* Brief for Petitioner, Hatfill v. Foster, No. 1:04-cv-01001 (E.D. Va. Aug 23, 2004).

150. John Gerstein, *Hatfill Settles $10M Libel Lawsuit*, N.Y. SUN, Feb. 27, 2007, http://www.nysun.com/national/hatfill-settles-10m-libel-lawsuit/49333/.

151. Scott Shane & Eric Lichtblau, *Scientist's Suicide Linked to Anthrax Inquiry*, N.Y. TIMES, Aug. 2, 2008, http://www.nytimes.com/2008/08/02/washington/02anthrax.html?ref=bruceeivins&_r=0.

152. Gina Galluci-White & Justin Palk, *Anthrax Case Turns*, FREDERICK NEWS-POST, Aug. 2, 2008, http://www.fredericknewspost.com/archive/article_00d56ca2-f6f1-58b9-a5b6-d7a938ee9b77.html?mode=story.

DURC release or insider attack are likely very similar. Tighter regulation of an entire class of individuals, whatever their knowledge, experience, or access to technical tools, is unlikely to prevent another similar act by an unethical, uncaring, unstable, or criminal mind. Yet, new regulation has been the dominant response by the U.S. Government.

Within ten days after Dr. Ivins' death, U.S. House of Representatives John Dingell and Bart Stupak wrote to President George W. Bush:

> If these allegations are true, the FBI has identified serious weaknesses in the security at one of our Nation's premier laboratories for the study of some of the most deadly pathogens in the world. Their allegations also raise equally troubling security concerns about the thousands of other scientists and technicians who work at hundreds of labs across our country with 'select biological agents' such as anthrax.[153]

1. Washington Studies the Problem

During 2009, four national-level studies would be undertaken to consider the insider threat with each of the studies funded by the U.S. Government.[154] Three of the committees were made up of senior non-government advisors, and the fourth, of civilian and uniformed government employees.

The Defense Science Board's study, *Department of Defense Biological Safety and Security Program,* published in May 2009, acknowledged the difficulty of preventing the insider threat.[155] It suggested, first, to use a red teaming approach to understand the vulnerabilities and assure security of laboratory computer systems.[156] Second, to monitor activities without undue impact on the research process and to conduct "periodic meetings with laboratory personnel to reinforce values, moral obligations, and observations that should be reported."[157] Third, to tailor any Personnel Reliability Program (PRP) for biological research, rather than simply overlay the nuclear model.[158] Fourth, to use DOD background investigations for host country personnel working in high-containment U.S. Government labs outside the U.S.[159] Fifth, to combine the many current compliance inspections with a single, independent inspection team made up of

153. Letter from John Dingell, Chairman, Comm. on Energy and Commerce, to George Bush, President of the United States (Aug. 8, 2008), *available at* http://www.nobio.org/html/dingell_press_release.html.

154. *See* text accompanying notes 157, 166, 173, and 176.

155. *See* DEF. SCI. BD., DEPARTMENT OF DEFENSE BIOLOGICAL SAFETY AND SECURITY PROGRAM 19-20 (2009), *available at* http://www.acq.osd.mil/dsb/reports/ADA499977.pdf.

156. *Id.* at 41.

157. *Id.* (from memorandum of Chairman).

158. *Id.*

159. *Id.*

experienced individuals.[160] Sixth, to review the usefulness of the current "two-person rule" for insider threats,[161] and to use the "lost in the crowd rule" for shipping Biological Select Agent and Toxins between labs.[162] Lastly, to keep the public involved and informed by communicating regularly, particularly regarding mission, safety measures, and emergency response plans.[163]

Also, in May 2009, the NSABB released a study, *Enhancing the Personnel Reliability of Persons with Select Agent Access*.[164] The Board addressed PRPs, which are programs traditionally focused on insider threat. The report made five key recommendations. First, to enhance extant PRP, but stated that a national PRP is unnecessary at this time.[165] Second, to strengthen the current FBI Security Risk Assessment (SRA),[166] but to do so efficiently so as not to impede the recruitment of researchers.[167] Third, to enhance the culture of responsibility and accountability, which it noted as the best defense against the insider threat.[168] Fourth, to encourage professional societies to get involved, continue the dialogue, and "foster community-based solutions."[169] Fifth, to reduce or stratify the list of Select Agents and Toxins, thereby focusing on the most important agents.[170]

In July 2009, HHS released *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*.[171] The task force recommended improved coordination of oversight activities, "encourage[d]

160. DEF. SCI. BD., *supra* note 157, at 45.

161. *Id. See* JAMES LEDUC ET AL., POTENTIAL IMPACT OF A 2-PERSON SECURITY RULE ON BIOSAFETY LEVEL 4 LABORATORY WORKERS 15(7) (July 2009), *available at* http://wwwnc.cdc.gov/eid/article/15/7/08-1523_article.htm ("two-person rule" requires that no single individual work in a laboratory alone).

162. DEF. SCI. BD., *supra* note 157, at 40. ("lost in the crowd" is the concept of using plain or routine packaging for mailing valuable, or in this case potentially amusable, materials, so that the package will not be identifiable as usual or different).

163. *Id.*

164. NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, ENHANCING PERSONNEL RELIABILITY AMONG INDIVIDUALS WITH ACCESS TO SELECT AGENTS 1 (May 2009), *available at* http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.

165. *Id.* at 6.

166. FED. BUREAU OF INVESTIGATION, BIOTERRORISM SECURITY RISK ASSESSMENT FORM (FD-961), *available at* http://www.fbi.gov/about-us/cjis/bioterrorism-security-risk-assessment-form/bioterrorism-security-risk-assessment-form-fd-961.

167. *Id.* at 12.

168. *Id.* at 13.

169. *Id.* at 15.

170. *Id.* at 16.

171. ASS'T SEC'Y OF PREPAREDNESS & REPSONSE, U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT OF THE TRANS-FEDERAL TASK FORCE ON OPTIMIZING BIOSAFETY AND BIOCONTAINMENT OVERSIGHT (July 2009) *available at* https://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Documents/transfedbiocontainmentrpt092009.pdf.

a robust culture of accountability characterized by individual and institutional compliance" with policies, development of a national strategy for training and technical competence in containment lab research, obtaining and analyzing data from laboratory accidents and incidents, and assuring that biosafety and biocontainment regulations were current.[172] The taskforce also recommended the development of an "agricultural equivalent of the [Biosafety in Microbiological and Biomedical Laboratories] BMBL," development of a "national research agenda for applied biosafety and biocontainment," and, finally, "improve[d] sharing of strategies to ensure effective public communication and outreach."[173]

Finally, in September 2009, the U.S. National Academies of Science released the report, *Responsible Research with Biological Select Agents and Toxins*.[174] Like the other three reports above, it made recommendations for improving the security within our laboratories.[175] First, laboratory leadership and the Select Agent Program should foster a "culture of trust and responsibility."[176] Second, a biological select agents and toxins advisory committee should be formed to provide continual oversight of the list of related regulations.[177] Third, the Select Agents list should be stratified and provisions developed for timely inclusion or removal of an agent from the list.[178] Fourth, *accountability* for agent materials should focus on archived stocks, but not working materials, and counting of vials should not be employed for agents that replicate.[179] Fifth, the FBI's Security Risk Assessment requirement should be maintained, but with an appeals process.[180] Sixth, regulatory obligations should be clarified by defining "minimum cross-agency physical security requirements."[181] Seventh, an "independent evaluation of the Select Agent Program should be undertaken" and, lastly, inspectors should be mandated to have scientific and laboratory knowledge and experience, and training and inspections should be harmonized.[182]

172. *Id.* at 87, 94, 103.

173. *Id.* at 109, 122, 125.

174. *See* NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., RESPONSIBLE RESEARCH WITH BIOLOGICAL SELECT AGENTS AND TOXINS (2009), *available at* http://www.ncbi.nlm.nih.gov/books/NBK44956/pdf/TOC.pdf.

175. *Id.* at 89.

176. *Id.*

177. *Id.* at 107.

178. *Id.* at 112.

179. NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., *supra* note 176, at 115.

180. *Id.* at 83.

181. *Id.* at 123.

182. *Id.* at 127, 130.

2. Much Has Been Accomplished

In addition to clarifying the challenges and formulating alternative strategies, the NSABB quickly engaged the science and policy communities both domestically and internationally. Academic centers and traditional non-governmental organizations began training. International outreach programs were begun and the U.S. Departments of State, Defense and Energy, and the FBI funded efforts to do the same. The focus of most of the outreach programs was on training of laboratory risk assessment and risk reduction, DURC, biosafety, and biosecurity. In recent years, as some of our international colleagues have pushed back against suggestions for DURC training and biological security training, the U.S. training teams have emphasized the better accepted term, "responsible life sciences research." Where ambassadors of DURC have engaged their international colleagues as equals and worked jointly to address the issues, positive relationships of understanding and trust have often resulted.

3. An Incomplete Response

Although much has been accomplished, domestically there has been little emphasis on the role of healthy cultures within laboratories to counter the potential for accidental misapplications or intentional misuses of biological technologies by those possessing relevant knowledge. The broad positive, prophylactic impact that enlightened leadership can play is apparently either not fully appreciated or assumed away, which has led to a continued lack of emphasis on the role of leadership.

Note that each of the 2009 reports made some mention of the importance of leadership, cultures of responsibility, accountability and trust, and values and moral obligations.[183] Yet to date, government laws, regulations, and even guidelines show little attention or investment in improving or even encouraging the kind of leadership that fosters such values.[184] Regulatory solutions, increased oversight, and assignment of responsibility without commensurate authority remain the norm. Regulations that lend themselves to check-box management by contractors have proliferated. Enlightened leadership fostering cultural change is difficult to scale and its impact difficult to measure. Busy regulators typically move on to other things after a single vote. The approaches recently taken by the government are much more likely to result in disgruntled, rather than happy

183. *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 166, at v; ASS'T SEC'Y OF PREPAREDNESS & REPSONSE, *supra* note 173, at 10-11; NAT'L RESEARCH COUNCIL OF THE NAT'L ACAD., *supra* note 176, at 89.

184. David R. Franz & James W. LeDuc, *Balancing our Approach to the Insider Threat*, 9 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 205, 206 (2011).

employees. These solutions are also less likely to contribute to a culture of trust and openness. There is no convincing evidence that these approaches make our citizens safer.

In an example of another extremely complex challenge, protecting New York City from terrorists, a data set appears to be developing that suggests behavioral approaches and community policing with much less disruption to the lives of law-abiding citizens is working. The system has interrupted a number of terrorist plots in recent years.[185] By building human relationships of trust, or at least respect, law enforcement can improve both its situational awareness as well as interdict would-be malevolent actors before they can bring harm to the community.

VI. TECHNICAL SURPRISE OR ETHICAL LAPSE?

A. H5N1

In September 2011, Dr. Ron Fouchier, Ph.D., of the Erasmus University Medical Center in Rotterdam, Netherlands, described his NIH-funded work with the H5N1 influenza virus.[186] The NIH funded similar research in the laboratory of Dr. Yoshihiro Kawaoka, Ph.D., at the University of Wisconsin-Madison. Both grants were financed to develop mutant strains of the H5N1 influenza virus that would be transmissible to mammals.[187] During a meeting of the European Scientific Working Group on Influenza in Malta,[188] Dr. Fouchier described his successful development as "very bad news"[189] and the viral product as "efficiently transmitted as seasonal [flu] virus."[190] In the November 2011, publication of *Science*, Dr. Fouchier described what he had developed as "probably one of the most dangerous viruses you can make."[191] Shortly thereafter, Dr. Fouchier and Dr. Kawaoka submitted

185. Judith Miller, Op-Ed., *How to Stop Terrorists before They Kill*, WALL ST. J., Apr. 25, 2013, at A15.

186. INFLUENZA TIMES, (European Scientific Working Group on Influenza (ESWI), Malta), Sep. 11-14, 2011, http://labs.fhcrc.org/cbf/Papers/H5N1_docs/FEIC_news_from_Malta.pdf.

187. Bryan Walsh, *H5N1 Paper Published: Deadly, Transmissible Bird Flu Could Be Closer than Thought,* TIME HEALTHLAND BLOG (May 3, 2012), http://healthland.time.com/2012/05/03/h5n1-paper-published-deadly-transmissible-bird-flu-could-be-closer-than-thought/.

188. INFLUENZA TIMES, *supra* note 188.

189. Katherine Harmon, *What Really Happened in Malta This September When Contagious Bird Flu Was First Announced*, SCIENTIFIC AM. (Dec. 30, 2011), http://blogs.Scientificamerican.com/observations/2011/12/30/what-really-happened-in-malta-this-september-when-contagious-bird-flu-was-first-announced/.

190. INFLUENZA TIMES, *supra* note 188.

191. Martin Enserink, *Controversial Studies Give a Deadly Flu Virus Wings*, 334 SCI. 1192, 1192 (2011).

manuscripts describing their findings to *Science* and *Nature*.[192] Concerned that the papers contained DURC relevant information, the editors asked the NSABB to review them.[193] The NSABB met in plenary while sub-group sessions spent tens of hours discussing the papers.[194] In addition, influenza experts from government laboratories were consulted and safety and security implications concerning the draft manuscripts were considered.[195]

Finally, in late December of 2011, the NSABB made recommendations that a small amount of key information regarding the sequences that were used and/or discovered should be redacted from the publications, that the redacted information be made available to the global science community on a need-to-know basis, and that the manuscripts and implications of publication be discussed with key experts in the international science community.[196] In addition, the NSABB proposed a three-month moratorium on further publication and/or presentation of work with these viruses.[197]

In February 2012, in response to the NSABB, the U.S. Government helped organize a meeting with the World Health Organization (WHO) at its headquarters in Geneva.[198] Attendance included NSABB chair, U.S. Government science leaders, the authors of the two papers in question, and representatives from other countries (Indonesia, China, The Netherlands, France, Australia, Vietnam, U.K., Hong Kong, and South Africa).[199] At this meeting, new data was presented and Dr. Fouchier described the results with more modest interpretation than he had in the prior months.[200] The meeting ended with the following consensus: the findings contribute to our ability to conduct surveillance and to understand pathogenesis, and they highlight safety and security concerns.[201] Further, the group concluded that

192. Lauren Neergaard, *U.S.: Don't Publish Lab-Bred Bird Flu Recipe,* NBCNEWS.COM (Dec. 20, 2011, 1:48 PM), http://www.nbcnews.com/id/45738690/ns/health-cold_and_flu/t/us-don't-publish-lab-bred-bird-flu-recipe/#.UlglEs0ZLUk.

193. *See id.*

194. *See id.*

195. Press Release, Nat'l Inst. of Health, Press Statement on the NSABB Review of H1N1 Research (Dec. 20, 2011), http://www.nih.gov/news/health/dec2011/od-20.htm.

196. *Id.*

197. Martin Enserink, *U.S. Biosecurity Panel May Call for Asilomar-Style Moratorium on H5N1 Papers*, SCI. INSIDER, (Dec. 23, 2011, 1:10 PM), http://news.sciencemag.org/2011/12/u.s.-biosecurity-panel-may-call-asilomar-style-moratorium-h5n1-papers.

198. News Release, World Health Org., Public Health, Influenza Experts Agree H5N1Research Critical, But Extend Delay (Feb. 17, 2012), http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/.

199. *List of Participants, Technical Consultation on H5N1 Research Issues*, WORLD HEALTH ORG. (Feb. 16-17, 2012), http://www.who.int/influenza/human_animal_interface/list_participants/en/index.html.

200. *See* News Release, World Health Org., *supra* note 200.

201. *See id.*

redaction and limited distribution is not feasible, the mutant viruses should be kept in the labs, the moratorium should continue in effect, and work of this type should be supported in the future.[202]

In March 2012, the two authors and their journal editors then met with the NSABB and the Directors of the NIH and the National Institute of Allergy and Infectious Disease (NIAID).[203] The NSABB was allowed to read the latest versions of Dr. Fouchier's and Dr. Kawaoka's manuscripts and hear oral presentations from the authors as well.[204] After a period of discussion, the NSABB voted unanimously in support of the publication of Kawaoka's paper and with simple majority to publish Fouchier's.[205] Although both authors' works were eventually published, the long-term solutions to this complex DURC issue are far from clear.[206]

B. Thoughts on the H5N1 Episode

Earlier, I described DURC as a *technical surprise*. Actually, the Fink Report's experiments concerning the seven deadly sins could be undertaken intentionally or discovered by surprise. Historically, what we call DURC today probably occurred more by surprise than by plan. In this age of biotechnology, it is likely that DURC experiments may result more from plan than surprise; although our knowledge in this field is still relatively primitive, we know a lot more now than we did in the 1960s. The H5N1 studies were intentionally conducted with the goal to accomplish what was in fact done, and were funded by HHS, the same U.S. Government department that produced the 2007, NSABB Report, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*.[207] The U.S. Government received and funded the research that it requested.

Dr. Fouchier's and Dr. Kawaoka's flu manuscripts were a *tactical challenge*, and I believe we learned a lot in the process of dealing with

202. *Id.*

203. Statement of the NSABB, Nat'l Sci. Advisory Bd. for Biosecurity, Meeting of the National Science Advisory Board for Biosecurity to Review Revised Manuscripts on Transmissibility of A/H5N1 Influenza Virus (Mar. 29-30, 2012), http://oba.od.nih.gov/oba/biosecurity/PDF/NSABB_Statement_March_2012_Meeting.pdf.

204. *See* Ron Fouchier et al., *The Fight Over Flu*, 481 NATURE 257, 257 (2012). *See also* Martin Enserink & David Malakoff, *Will Flu Papers Lead to New Research Oversight?* 335 SCI. 20, 20 (2012).

205. *See* Press Release, Nat'l Insts. of Health, *supra* note 197.

206. Brendan Maher, *Bird-Flu Research: The Biosecurity Oversight*, 485 NATURE 431, 434 (2012).

207. *See* NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *supra* note 142.

them. But our future safety and security depends on us.[208] My notes, jotted down during the early deliberations, show that I believed the ferret was a good model of the human for *transmission* studies; it was not clear what the ferret model in these experiments told us about virulence or pathogenicity in humans following aerosol exposure; my concern was more about safety than security; we were playing Russian roulette, potentially releasing a mammal transmissible H5 subtype virus into the global *petri dish* where pigs, chickens, ducks, and humans live together; it was important to share these findings with the international science community, and the U.S. Government could never censor global science communication. Jim LeDuc, Ph.D., Director of the National Biocontainment Laboratory at the University of Texas Medical Branch in Galveston, and I described our concerns about safety in a subsequent commentary.[209]

If the two manuscripts were a tactical challenge, we all share the *strategic challenge* as well. The U.S. Government responded to this incident with new draft guidelines in an attempt to reduce the likelihood of government departments and agencies knowingly funding research with a significant DURC outcome as we did this time, or at least doing it more thoughtfully next time.[210] After a period of public debate, the guidelines were approved and published by NIH in August of 2013.[211] There remains little doubt that we will see future surprises in biological research, some of which might pose significant safety risks to humans, animals, or the environment, and some that might even be exploited by those who would do harm. Future DURC *surprises* will be ever more likely to come from outside the U.S. because of the global proliferation of capabilities and knowledge. Therefore, it is critical we work closely with our international colleagues to help them learn from our mistakes. In addition, it is important to learn from their experience and to increase the likelihood that we quickly learn of any *surprises* when they occur around the globe.

208. *See* David A. Relman, Editorial Commentary, *"Inconvenient Truths" in the Public Pursuit of Scientific Knowledge and Public Health*, J. INFECTIOUS DISEASES (published online Oct. 7, 2013).

209. James W. LeDuc & David R. Franz, *Genetically Engineered Transmissible Influenza A/H5N1: A Call for Laboratory Safety and Security*, 10 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 153, 154 (2012).

210. OFFICE OF BIOTECHNOLOGY ACTIVITIES, NAT'L INST. OF HEALTH, A PATH FORWARD: FRAMEWORK FOR GUIDING UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDING DECISIONS ABOUT HIGHLY PATHOGENIC AVIAN INFLUENZA H5N1 GAIN-OF FUNCTION RESEARCH (2012), *available at* http://oba.od.nih.gov/oba/biosecurity/meetings/Dec2012/Proposed_Framework_for_Guiding_HHS_Funding_Decisions_about_HPAI_H5N1_GOF-12-11-12.pdf.

211. NAT'L INST. OF HEALTH, NIH POLICY ON MITIGATING RISKS OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (2012), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-107.html.

VII. REGULATORY AND BEHAVIORAL RESPONSES

A. *No Technical Solution*

Noble laureate, Joshua Lederberg, Ph.D., long-time thought leader and advisor to the government on matters of biological defense, said to Richard Preston in a 1998 *New Yorker* interview, "There is *no* technical solution to the problem of biological weapons. It needs an ethical, human, and moral solution if it's going to happen at all. Don't ask me what the odds are for an ethical solution, but there is no other solution."[212] Then Dr. Lederberg paused and said, "But would an ethical solution appeal to a sociopath?"[213]

Dr. Lederberg was talking about biological weapons at the time, but the concept applies as well to DURC and the insider threat. I consider regulatory fixes, such as those we have seen, and check-box management to be *technical solutions*. No one questions the importance of management and regulations or dependence on regulatory schemes, which help make us safer. However, overlooking or back-shelving the behavioral ones is done at our peril. We have put in place numerous legal and regulatory systems, both internationally and domestically, over the years. Some target biological warfare by nation states, some target terrorism, some the insider threat, and more recently, DURC. Some academic centers and non-governmental organizations have underscored ethics in the course of biosafety-biosecurity training, but the value of leadership in the context of organizational culture has been terribly underappreciated by our government.

VIII. INTERNATIONAL

The following is a list of relevant international laws, agreements, norms, and regulations related to biological security. Included is a brief description of the intention of the drafters and the content of the regulatory tool relevant to this discussion. With the exception of the Biological Weapons Convention (BWC) of 1972, most were put in place in the last 30 years, roughly the period addressed by this article.

A. *The BWC of 1972*

The BWC was signed in 1972, and ratified in 1975.[214] Currently, it is signed by 170 states and serves as a supplement to the 1925 Geneva Convention, which prohibited the *use* of biological and chemical

212. Richard Preston, *Annals of Warfare: Bioweaponeers*, NEW YORKER 65 (Mar. 9, 1998).
213. *Id.*
214. *See* BWC, *supra* note 135.

weapons.[215] The BWC prohibits the development, production, and stockpiling of biological and toxin weapons.[216] Article I of the BWC allows research with weapons agents, but prohibits production and stockpiling agents "of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes."[217] Article III prohibits assisting another nation in the acquisition of biological weapons, and Article X exhorts the signatories to encourage the "peaceful uses of biological science and technology."[218]

B. United Nations Security Council Resolution (UNSCR) 687 on Iraq

Adopted in April 1991, this resolution was the basis and legal authority for the U.N. Special Commission on Iraq (UNSCOM) to govern inspections of biological, chemical, nuclear, and missiles/weapons sites in the country.[219] It authorized the removal and destruction of all chemical and biological weapons and all ballistic missiles with a range greater than 150 kilometers.[220] The resolution represented the terms Iraq was required to comply with after the First Gulf War.[221]

C. The Trilateral Agreement

This agreement, signed in 1992, by the U.S., U.K., and Russia, was an attempt by the U.S. and U.K. to gain information regarding the Union of Soviet Socialists Republics (USSR) massive biological weapons program and to assure that subsequent biological weapons activities did not continue.[222] Implementation of this agreement is considered to have been a failure, primarily because Russia was unwilling to acknowledge their former biological weapons activities. The process demonstrated the extreme

215. *Id.*; *Membership of the Biological Weapons Convention*, UNITED NATIONS OFFICE AT GENEVA, http://www.unog.ch/80256EE600585943/%28httpPages%29/7BE6CBBEA0477B52C12571860035FD5C?OpenDocument (last visited Aug. 15, 2013).

216. BWC, *supra* note 135.

217. *Id.*

218. *Id.*, *Background Information on the Biological Weapons Convention and Oversight of the Life Sciences*, UNITED NATIONS OFFICE AT GENEVA, http://www.unog.ch/80256EDD006B8954/(httpAssets)/C838E9BF09C31A3DC1257505003249B4/$file/BWC+backgrounder+-+BWC+&+science+oversight.pdf (last visited Aug. 24, 2013).

219. *See Chronology of Main Events*, UNITED NATIONS (last updated Dec. 1999), http://www.un.org/Depts/unscom/Chronology/chronologyframe.htm.

220. S.C. Res. 687, ¶ 1, U.N. SCOR, 46th Sess, at 1, U.N. Doc. S/RES/687 (Apr. 3, 1991).

221. Laura Edgerton, Note, *Eco-Terrorist Acts During the Persian Gulf War: Is International Law Sufficient to Hold Iraq Liable?,* 22 GA. J. INT'L & COMP. L. 151, 155-56 (1992).

222. David C. Kelley, *The Trilateral Agreement: Lessons for Biological Weapons Verification*, 2002 VERIFICATION Y.B. (Verification Research, Training & Info. Ctr.), 93, 96-97.

difficulty in using traditional arms control procedures and methods in biological facilities, many of which can be used for either legitimate or malevolent purposes.

D. UNSCR 1540

Published in April 2004, this resolution obligates states to "develop and enforce appropriate legal and regulatory measures against the proliferation of chemical, biological, radiological, and nuclear weapons and their means of delivery" with particular attention given to avoiding proliferation of weapons capabilities to non-state actors.[223] It also requires states to establish criminal penalties for involvement in weapons by certain non-state actors.[224] Of special interest therefore, and in contrast to the BWC, UNSCR 1540 places emphasis on reducing the likelihood that non-state actors will acquire weapons of mass destruction.[225]

E. International Health Regulations (IHR) of 2005

Entered into force in 2007, as a legal instrument binding on more than 190 countries, the IHR requires countries to report certain disease outbreaks and public health events to the WHO.[226] In addition, countries are required to strengthen their existing capacities for disease surveillance.[227] While the IHRs are not directed at biological warfare or terrorism, it is believed that this global *early warning system* will make all nations more secure by increasing the likelihood that outbreaks or biological attacks will be discovered as quickly as possible so intervention can begin, thus saving lives.

IX. U.S. DOMESTIC

The following is a list of relevant U.S. domestic laws, agreements, norms, and regulations related to biological security. Included is a brief

223. U.N. News Centre, *Ban Reiterates Necessity of Political Solution to Syrian Conflict in Meetings with Oartners, Envoy* (Apr. 22, 2013), http://www.un.org/apps/news/story.Asp?NewsID=44725#.Uh5CCz7Xh4E. *See also United Nations Security Council 1540 Committee,* UNITED NATIONS, http://www.un.org/en/sc/1540/ (last visited Aug. 17, 2013).

224. S.C. Res. 1540, ¶ 2, U.N. Doc. S/RES/1540 (Apr. 28, 2004). *See also* Peter Crail, *Implementing UN Security Council Resolution 1540: A Risk-Based Approach*, 13 NONPROLIFERATION REV. 355, 365 (2006) (explaining the impact and enforcement of the 1540 resolution).

225. S.C. Res. 1540, *supra* note 225, ¶ 1. See *also* Crail, *supra* note 225, at 368.

226. *International Health Regulations (IHR): Ten Things You Need to do to Implement the IHR*, WORLD HEALTH ORG., http://www.who.int/ihr/about/10things/en/ (last visited September 18, 2013).

227. *Id.*

description of the intention of the drafters and the content of the regulatory tool relevant to this discussion.

A. Antiterrorism and Effective Death Penalty Act of 1996

Effective June 1996, Title V, Subtitle B, Section 511 addresses biological weapons.[228] It makes it a federal crime to threaten, conspire, or use a biological weapon, it expands on definitions of the categories of agents, modifies, and adds definitions regarding biological weapons, and directs the Secretary of HHS to develop and implement what became the Select Agent Rule of 1997.[229]

B. Select Agent Rule of 1997

This first iteration of the rule in 1997, made it illegal to transfer certain listed bacteria, viruses, or toxins between laboratories without the CDC's approval.[230] The agents could be held and used within the lab without permit.[231]

C. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Title II, *Enhancing Controls on Dangerous Biological Agents and Toxins*, gave the CDC regulatory control, regulation of transfer and possession over the Biological Select Agents and Toxins (BSAT).[232] It called for registration of persons who work with BSAT, laboratory inspections, mandated disclosure of information, civil penalties, and certain reporting requirements, including the requirement for notification in the case of an incident involving BSAT.[233] It codified the Select Agent Program of 2001.[234]

228. Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-132, 110 Stat. 1214. (codified as amended at 42 U.S.C. 262 § 511(2006)).

229. *Id*. *See also Select Agents and Toxins*, WASH. STATE UNIV., (Aug. 16, 2013), http://www.bio-safety.wsu.edu/biosafety/toxins.asp.

230. 42 C.F.R. § 72.6(a)(1) (1997). *See also Additional Requirements for Facilities Transferring or Receiving Select Agents*, Centers of Disease Control and Prevention, (Nov. 23, 2005), http://grants.nih.gov/grants/policy/select_agent/42CFR_Additional_Requirements.pdf [hereinafter *CDC*].

231. 42 C.F.R § 72.6(a)(1) (1997). *See also* CDC, *supra* note 231, at 15.

232. WASH. STATE UNIV., *supra* note 230. *See also* Ali S. Khan, *Public Health Preparedness and Response in the USA since 9/11: A National Health Security Imperative*, 378 THE LANCET 953, 954 (2011) *available at* http://www.cdc.gov/phpr/documents/Lancet_Article_Sept 2011.pdf.

233. *General FAQ's about Select Agents and Toxins*, THE FED. SELECT AGENT PROGRAM, (Aug. 16, 2013), http://www.selectagents.gov/FAQ_General.html#sec1q2.

234. *Id*.; 42 C.F.R. § 73 (2013). *See also Biosafety Policy*, UNIV. OF ALA., (Aug. 16, 2013), http://bama.ua.edu/~ehs/Web%20Redo/BiolSaf.htm, 3.

D. The USA PATRIOT Act

Effective February 2002, the full title of the act is *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001*.[235] The act is wide-ranging, but with regard to biology, it has established a ten-year imprisonment and fine for anyone who cannot prove they are using a biological agent for "prophylactic, protective, bona fide research, or other peaceful purposes."[236]

E. Army Regulation 50-1

The regulation entitled *Biological Surety* was enacted in draft form at USAMRIID in 2004, signed on July 28, 2008, and became effective on October 28, 2008.[237] "Th[e] regulation prescribes policies, procedures, and responsibilities for the Army Biological Surety Program."[238] Initially, the regulation brought together Biological Safety, Biological Security, Agent Accountability, and Personnel Reliability in U.S. Army laboratories.[239] The regulation was later applied to certain contractors and the Army Biological Defense Research Program.[240]

F. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern

Released in draft form on March 29, 2012, the policy proposed to establish regular review of U.S. Government-funded or conducted research with a list of 15 selected pathogens including, highly pathogenic avian influenza, and/or seven categories of experiments of concern, very similar, but not identical to those listed in the Fink Report.[241] The policy outlines

235. Uniting and Strenghtening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (Patriot Act) Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001) (codified in various sections of the United States Code).

236. 18 U.S.C. § 175(b) (2012).

237. AR 50-1, *supra* note 121; Gretchen L. Demmin, *Biosurety*, *in* MEDICAL ASPECTS OF BIOLOGICAL WARFARE 543, 549, *available at* http://www.cs.amedd.army.mil/borden/Portlet.aspx?ID=66cffe45-c1b8-4453-91e0-9275007fd157. *See also* JOHN P. SKVORAK, BIOSURETY OVERVIEW FOR THE FREDERICK COUNTY CONTAINMENT LABORATORY COMMUNITY ADVISORY COMMITTEE (2013), http://www.cityoffrederick.com/DocumentCenter/Home/View/1089 (last visited September 18, 2013).

238. AR 50-1, *supra* note 121, at i, 1.

239. *Id.* § 9-4e at 30.

240. *Id.* §§ 1-5(7)b at 4, B-3(b)3 at 36.

241. U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 1, 2 (2012), *available at* http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf [hereinafter DURC DRAFT POLICY]; COMM. ON RESEARCH STANDARDS & PRACS. TO PREVENT THE DESTRUCTIVE

department and agency responsibilities regarding review, risk assessment, risk mitigation, and reporting.[242] This was the first formal document to bring together the Select Agent List and the Fink Report's "Seven Deadly Sins."[243]

G. *A Framework for Guiding U.S. HHS Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets*

Released on February 21, 2013, by HHS, the framework calls for individual agencies, as well as HHS to perform robust reviews of proposals to determine risks and benefits for HHS-funded research anticipated to produce Highly-Pathogenic Avian Influenza H5N1 viruses.[244] It lists seven *criteria* to be used in the review and establishes a review process.[245]

H. *U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*

A draft policy document was released for public comment on February 22, 2013, to establish regular review of U.S. Government-funded or conducted research with a list of 15 selected pathogens including, highly pathogenic avian influenza, and/or seven categories of experiments similar to those listed in the Fink Report.[246] This policy would require DURC oversight by institutions defined as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity involved in

APPLICATION OF BIOTECHNOLOGY, NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM: CONFRONTING THE DUAL USE DILEMMA 4 (2003).

242. DURC DRAFT POLICY, *supra* note 242, at 3-4.

243. An interesting regulatory approach and outcome, since the select agent list was developed for security reasons and the 'seven deadly sins' for DUR reasons.

244. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., A FRAMEWORK FOR GUIDING UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDING DECISIONS ABOUT RESEARCH PROPOSALS WITH THE POTENTIAL FOR GENERATING HIGHLY PATHOGENIC AVIAN INFLUENZA H5N1 VIRUSES THAT ARE TRANSMISSIBLE AMONG MAMMALS BY RESPIRATORY DROPLETS 2 (2013).

245. *Id.* at 5.

246. A copy of the proposed Policy is available on the U.S. Department of Health and Human Services (HHS) Science Safety Security (S3) web site. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, 78 Fed. Reg. 12369, 12371 (Feb. 22, 2013).

funding, conducting, or sponsoring research."[247] NIH released the policy in final form on August 28, 2013.[248]

X. REGULATORY APPROACHES: VALUE AND COST

It is interesting to note, particularly on the domestic front, that the actions of a few have historically impacted the work of many. Mr. Harris, the anthrax letter mailer, and scientist communication of the H5N1 research have stimulated responses from our government in its effort to protect us. Actions to protect us have taken place in the name of public safety and security. The Antiterrorism and Effective Death Penalty Act of 1996, the Select Agent Rule, Army Regulation 50-1, and the new DURC policies are all domestic U.S. Government actions. These regulations are wide nets cast, rather than leadership-based approaches, to deal with troubled or frustrated personnel more broadly. Due to the nature of the dual use dilemma (technical surprise or ethical lapse) and insider threat (individual or small group sociopathic behavior), these wide cast, but superficial regulatory nets are, at best, very blunt instruments. Very few studies have looked at the productivity of the enterprise before and after 2001, but the subject deserves our attention.[249] At least anecdotally, compliance with these regulatory approaches has forced laboratories to hire additional contractors to manage the programs, which has diverted funds from legitimate research, subsequently slowing progress.[250] Even with these regulations in place, the U.S. Government cannot assure increased security.

Possibly the greatest value in the international laws and resolutions is in their role as norms, tools of education, and awareness. Further, dialogues around international laws and resolutions have led to some increased understanding by bringing experts from many nations together to discuss them, as well as the visible boundary lines which they paint on the life sciences court. In other cases, the international laws have been barriers to communication and understanding. Regulations may do harm when they overburden the life sciences community or build walls internationally, instead of simply painting the boundary lines. Internationally, there have been more focused actions for nations who crossed the line: the Trilateral Agreements (because of Former Soviet Union behavior) and UNSCR 687 (in

247. *See id*. *See also* U.S. DEP'T OF HEALTH & HUMAN SERVS., UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN 3-4 (2013), https://www.phe.gov/s3/dualuse/documents/oversight-durc.pdf.

248. *See* NAT'L INST. OF HEALTH, *supra* note 211.

249. *See, e.g.*, Arturo Casadevall & David A. Relman, *Microbial Threat Lists: Obstacles in the Quest for Biosecurity?*, 8 NATURE REVIEWS: MICROBIOLOGY 149-154 (2010).

250. This information comes from my personal communications with Col John Skvorak, DVM, PhD, the commander of USAMRIID (early 2010).

response to Iraqi behavior). Domestically, the individual acts listed above have increased oversight,[251] and broad regulatory management has become the norm within the life sciences community.

XI. WHY SO LITTLE EMPHASIS ON LEADERSHIP?

A. Leadership Models

During the past 20 years, the role of leaders, particularly in U.S. Government laboratories where insider threats seem to be of greater concern than DURC, have changed dramatically. In this regard, the period before 9/11 can be clearly differentiated from the period after. In the past, laboratory leaders grew up within their organizations, took personal responsibility for their organizations, and molded laboratory cultures in a way that resulted in productivity and safety. Security was viewed differently before 9/11, but was appropriate for that day and time. Patriotism and teamwork were underlying principles, and the mission and focus on scientific ethics was the norm.

Leaders who knew their organizations well also knew their people well enough to practice preventive intervention in the rare case of outlier behavior. The troubled scientist would seek out the leader for help if trust was there or the leader would observe and intervene in time if the leader was enlightened and appropriately engaged. Outlier employees were counseled and helped or weeded from the organization. A self-centered, arrogant, or insensitive manager would miss the warning signs, and thus, be unable to avert disaster. Such poor leaders did not last in those days. Today, there is much less thought given to these issues. Rather, much more time is spent trying to assure compliance with regulations. The challenge of heavy-handed regulation is also facing academic researchers in this country today.[252]

B. Really Hard, but Rare Problems with No Perfect Solution

We are dealing with two very hard problems in a very complex, even messy, world today. The spectrum of natural disease kills millions of people globally each year. Our government has focused enormous energy and treasure on hopefully rare, but potentially high-impact intentional events.

251. For example, in 2012 the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) had an inspector in the building between 90 and 120 working days, not including additional FDA inspectors. Personal Communication with Col Ben DeKoning, MD, U.S. Army Commander, USAMRIID (May 2013).

252. *See* Tobin L. Smith et al., *Reforming Regulation of Research Universities: Regulatory and Reporting Requirements have become Excessively Burdensome. A More Balanced Approach is Needed*, NATURE REVIEWS: MICROBIOLOGY, Summer 2011, at 57.

Much of this is related to the *terror* factor and the vast unknowns. Most Americans do not notice the deaths of 50,000 humans from seasonal influenza complications, 30,000 from auto accidents, or even the 10,000 deaths associated with gun homicides annually, unless they involve one of our loved ones.[253] Yet, the unknowns frighten us. As we face fiscal constraints nationally, the challenge is to balance our preparations and resolve regarding those vast unknowns.

Dr. Lederberg told us "there is no technical solution."[254] He proposed ethical or moral solutions, but acknowledged that such personal controls would not appeal to an individual set on doing harm.[255] Just as epidemiologists tell us that protecting a percentage of a population with a vaccine will indirectly protect unvaccinated individuals within a population,[256] so too, establishing a corporate culture of responsibility will help reduce the likelihood that an individual within that culture will go astray.

Secretary of the Navy, Richard Danzig, Ph.D., has told us that "we are driving in the dark" with regard to understanding the risk in national security.[257] We cannot know what lies ahead. We have spent time and hundreds of millions of dollars trying to predict what is coming and for what to prepare.[258] The insider threat is a very hard case while the DURC challenge is also difficult, but more easily dealt with. Interestingly, both respond to a very similar set of behavioral tools. We are much more likely to divert, dissuade, deter, or just discover individuals prone to either course in a healthy corporate culture than in an unhealthy one. So we get two-for-one

253. CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL VITAL STATISTICS REPORT, VOL. 61, NO. 4, at 89-91 tbl.10 (May 8, 2013) (reporting the number of deaths from 113 selected causes in 2010, including 50,097 from influenza and pneumonia, 35,332 from motor vehicle accidents, and 11,078 from homicides by discharge of firearms).

254. Preston, *supra note* 213, at 65.

255. *See id.*

256. "Herd Immunity" is commonly explained as the phenomenon that occurs when a large enough percentage of a population is protected against a communicable disease (typically by a vaccine), thereby protecting the remaining unvaccinated individuals within the population because the disease cannot be sustained within that population. *Community Immunity ("Herd Immunity")*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES (NIAID), http://www.vaccines.gov/basics/protection (last updated July 23, 2013).

257. *See* RICHARD DANZIG, DRIVING IN THE DARK TEN PROPOSITIONS ABOUT PREDICTION AND NATIONAL SECURITY (2011).

258. *See generally* COMM. ON METHODOLOGICAL IMPROVEMENTS TO THE DEP'T OF HOMELAND SEC.'S BIOLOGICAL AGENT RISK ANALYSIS, NAT'L RESEARCH COUNCIL, DEPARTMENT OF HOMELAND SECURITY BIOTERRORISM RISK ASSESSMENT: A CALL FOR CHANGE (2008) (reviewing the methodology that led to the 2006 Department of Homeland Security report, Bioterrorism Risk Assessment (BTRA), as well as providing a foundation for future updates).

— DURC and the insider threat — protection in a healthy life sciences laboratory culture.

C. *Rethinking DURC: Did the Science Community Do the Right Thing?*

It's not surprising that we have focused our energies on the technologies, the science, and the microbiological agents rather than on the behavior of the scientists. At the national level, our elected officials seek to do something to make the public feel safer, so they regulate what they cannot directly control. For DUR, it started with the beloved Fink Report, so we must bear part of the responsibility. When we called it DUR and listed the seven examples of research that might be misused, we forced ourselves to look at the technologies, the knowledge, and the science. If we had instead called for "Responsible Life Science Research," the term now preferred by many of our international colleagues, we would have had to focus on human behavior. I believe more effective outcomes would have resulted if we had focused more on individual and corporate responsibility than on regulation to control technologies and knowledge. No matter if the individual scientist is armed with an oligonucleotide synthesizer or the organization with a freezer full of Select Agents, they are less likely to do harm with them in a healthy laboratory culture than an unhealthy one.

D. *Leadership and DURC or Actually "Responsible Life Sciences Research"*

Leadership is related only indirectly to DUR, but it is very much related to responsibility, which is the real problem. Leaders, by definition, demonstrate personal responsibility and they, by definition, develop cultures of responsibility in the organizations that they lead. Responsible organizations contribute, again with enormous influence by their leaders, to networks of responsibility. Responsible leaders, groups of responsible individuals, and networks of responsible groups provide *herd immunity* that protects the whole. It's simple, but it requires smart, caring, humble, and strong leaders throughout the organization.

John P. Kotter, in his book, *The Heart of Change,* makes reference to the U.S.'s success in WWII and underscores the need for leadership throughout the organization.[259] He writes, "[The war] . . . forced a bureaucratic military to miraculously produce a handful of great leaders, hundreds of good leaders, and tens of thousands of people who performed leadership acts." [260] Where have they gone?

259. *See* JOHN P. KOTTER, THE HEART OF CHANGE: REAL LIFE STORIES OF HOW PEOPLE CHANGE THEIR ORGANIZATIONS (2002).

260. *Id.* at 185.

Few would argue that Lee Iacocca, former chairman of Chrysler Corporation, did not demonstrate exceptional leadership qualities during his very successful career. In his book, *Where have all the Leaders Gone?,* he concludes that great leaders operate from the nine "C"s:

> Curiosity — a leader is a reader and listener.
>
> Creative — a leader thinks outside the box.
>
> Communicate — a leader tells the truth, even when it is painful.
>
> Character — a leader knows the difference between right and wrong and [has] the guts to do the right thing.
>
> Courage — a leader has 'the balls' and is committed to talk and negotiate.
>
> Conviction — a leader has fire in the belly passion.
>
> Charisma — a leader has the ability to inspire and people follow a leader because they trust him.
>
> Competent — a leader knows what he is doing, but more importantly surrounds himself with others who know what they are doing.
>
> Common Sense — a leader is a human, so has the 'ability to reason and use common sense and does it.'[261]

Stephen M.R. Covey expands on the enormous potential influence of leadership in *The Speed of Trust,* saying that high-trust organizations are characterized by increased value, accelerated growth, enhanced innovation, improved collaboration, stronger partnering, better execution, and heightened loyalty while low-trust organizations show redundancy, bureaucracy, politics, disengagement, turnover, churn, and fraud.[262] Where would you rather work and from which would you expect safety and security lapses?

Leaders come in all types and there is no single style or mold. Many have been uncharacteristically strong leaders and have inspired trust in their people and organizations. Others have been kind leaders and they too inspire trust. Personality type is less important than the fundamentals of character and integrity. William F. Baker, Ph.D., and Michael O'Malley, Ph.D., in their book, *Leading with Kindness,* equate kindness with a commitment to the welfare of your company.[263] Kindness, they state, is compassion rather than being distant, integrity is to think, say and act from

261. *See* LEE IACOCCA, WHERE HAVE ALL THE LEADERS GONE? 6-10 (2007).

262. STEPHEN M. R. COVEY, THE SPEED OF TRUST: THE ONE THING THAT CHANGES EVERYTHING 250-58 (2006).

263. WILLIAM F. BAKER & MICHAL O' MALLEY, LEADING WITH KINDNESS: HOW GOOD PEOPLE CONSISTENTLY GET SUPERIOR RESULTS 20 (2008).

the same set of values, gratitude is, therefore, considering employees as people rather than assets, authenticity rather than fraudulence, humility is to listen and learn from others, and, finally, humor.[264]

A powerful set of leadership principles comes from Robert J. Shoop's, Ph.D., book, entitled *A University Renaissance*.[265] Dr. Shoop describes the visionary leadership early in Jon Wefald's, Ph.D., presidency at Kansas State University and the principles on which it was based as listed below:

> 1) Have a Vision and Develop a Game Plan
>
> A leader must be able to provide a clear vision of a transformed future. Vision encompasses strategy and goal setting but is more than simply having a plan. Vision is a passionate commitment to creatively closing the gap between the present reality and the desired future.
>
> 2) Communicate Your Vision
>
> A vision is useless unless it can be shared with others. A leader must possess a wide-range of communication skills — articulating issues, listening to what others have to say, and understanding diverse perspectives.
>
> 3) Hire Excellent People and Delegate Authority and Responsibility
>
> Leaders develop the networks, relationships, and culture that form a community. In healthy communities, everyone can find meaning and motivation. A *team* attitude exists and individuals are eager to cooperate for the common good. Collaboration makes a community greater than the sum of its parts and enables a vision to be realized.
>
> 4) Make Decisions and Take Risks
>
> True leaders have the courage to act. They take risks and make tough decisions. Without risk, there is no progress. Leaders must be willing to make bold moves and embrace the seemingly impossible.
>
> 5) Admit Mistakes and Apologize When Necessary
>
> A leader who encourages risk-taking must allow mistakes to be made. A leader should quickly recognize mistakes, apologize, and remedy the situation. Accountable leaders learn from their mistakes and make changes. Being accountable means being in charge of your choices.
>
> 6) Be Trustworthy and Care About Others
>
> Visions are based on values. For good leaders, the means are just as important as the end. They make improvements with integrity, taking the

264. *Id.* at 41-71.

265. *See* ROBERT J. SHOOP, A UNIVERSITY RENAISSANCE: JON WEFALD'S PRESIDENCY AT KANSAS STATE (2001) (centering around eight characteristics of excellent leadership originally identified in Wefald's 1999 speech: "The Characteristics of Excellent Leadership Using Various American Presidents as Examples").

> right actions for the right reasons. They know that trust and credibility are central to the leadership process.
>
> 7) Never Give Up
>
> Never give up. Work hard. Those simple statements are at the heart of successful leadership. The best leaders love what they are doing and put everything they have into their efforts. Leaders make commitments and have the determination to see them through.
>
> 8) Have a Sense of Humor
>
> Good leaders are not afraid to laugh with others and at themselves. They maintain a healthy sense of balance and perspective and know that humor can sometimes diffuse a tense situation.[266]

Humility is not the first word that comes to mind when the average person thinks about leadership; it is probably power, authority, or even arrogance. But humility is absolutely essential to great leadership and what is sometimes perceived as arrogance is often simply confidence. Humility facilitates another characteristic of a great leader — appreciating employees who are smarter than you. Bo Peabody, in his book, *Lucky or Smart? Secrets to an Entrepreneurial Life,* tells would-be entrepreneurs to create an environment where smart people gather and then be smart enough to stay out of the way.[267] He goes on to say that managers are A-students and entrepreneurs are B-students.[268] Likewise, it is not unusual to find that the best leaders are very comfortable when surrounded by people who are smarter than they.

In industry and even in academia today, the great leaders rise to the top on merit. As the moral underpinnings of the electorate weaken, elected officials in a democracy can become more interested in their own position of authority than the good of their electorate or even their nation. When they do, their inclination is to try to *control* when the issues are too complex for them to resolve quickly and easily. As in the case with DURC and the insider threat, they often choose to regulate and in doing so, upset the balance between appropriate regulation and freedom. An over-regulated individual, organization, or nation will not attain its full potential.

XII. CONCLUSION

A. Our Place in the World

Exceptional leaders and thinkers drafted the intellectual and legal foundation of the U.S. We were made a free and powerful nation by great

266. *Id.* at xvi-xvii.
267. BO PEABODY, LUCKY OR SMART?: SECRETS TO AN ENTREPRENEURIAL LIFE 5 (2005).
268. *Id.* at 15.

leaders. Leaders in our most productive laboratories demonstrate personal responsibility and inculcate corporate responsibility. With the global proliferation of biological technologies and knowledge, we now face well-qualified and serious competition in the life sciences. Patrick Lencioni, in his book, *Healthy Organizations,* states "because of this global competition, it will become ever more difficult to have a competitive advantage based on knowledge and technologies,"[269] but a healthy organization can compete on this new, more level playing field. DURC issues and insider threat are rare, but potentially harmful outcomes of the life sciences enterprise. Both are outlier risks that are more likely to occur in an unhealthy or poorly led organization.

Personal and corporate responsibility provide herd immunity, which can protect, rehabilitate, or ferret out the outliers in an organization. Communities of trust characterize the kind of corporate responsibility typically orchestrated by enlightened leadership. Every organization needs regulation; we must know the boundaries of the playing field and the rules of the game. The greater the potential for injury in the game, the thicker the rulebook. The safety rulebook in a high-containment infectious disease laboratory is *thick* and applies to everyone. The DURC and the insider threat rulebooks are there for the outliers, but they impact all of us. When rules for the few become too disruptive to the work of the many, communities of trust can break down. Laboratories with exceptional leaders armed with well thought-out and *thin* DURC and insider threat rulebooks will always be safer, more secure, and far more productive than laboratories where the many are overregulated because of the few. It takes courage to do the right thing — to mentor, grow leaders, and then give them the responsibility, authority, and the freedom to succeed. Will we find leaders with the wisdom and the moral courage to rebalance our approach to DURC and the insider threat?

269. PATRICK LENCIONI, THE ADVANTAGE: WHY ORGANIZATIONAL HEALTH TRUMPS EVERYTHING ELSE IN BUSINESS 8 (2005). Lencioni goes on to say, an organization must be both smart and healthy. Smart organizations have strategy, marketing, finance and technology. Healthy organizations have minimal politics, minimal confusion, high morale, high productivity and low turnover. *Id.* at 5-6.