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WMD PREVENTION AND PREPAREDNESS  
ACT OF 2009

R E P O R T

OF THE

COMMITTEE ON HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS  
UNITED STATES SENATE

TO ACCOMPANY

S. 1649

together with  
MINORITY VIEWS

TO PREVENT THE PROLIFERATION OF WEAPONS OF MASS DE-  
STRUCTION, TO PREPARE FOR ATTACKS USING WEAPONS OF  
MASS DESTRUCTION, AND FOR OTHER PURPOSES



DECEMBER 17, 2010.—Ordered to be printed

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WEAPONS OF MASS DESTRUCTION PREVENTION AND  
PREPAREDNESS ACT OF 2009

DECEMBER 17, 2010.—Ordered to be printed

Mr. LIEBERMAN, from the Committee on Homeland Security and  
Governmental Affairs, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 1649]

The Committee on Homeland Security and Governmental Affairs, to which was referred the bill (S. 1649) to prevent the proliferation of weapons of mass destruction, to prepare for attacks using weapons of mass destruction, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

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I. PURPOSE AND SUMMARY OF THE LEGISLATION

The purpose of the Weapons of Mass Destruction (WMD) Prevention and Preparedness Act of 2010 is to provide a comprehensive framework for the United States to prevent and prepare for biologi-

cal and other WMD attacks. Key provisions of the Act include heightening U.S. and international laboratory security regarding the most dangerous pathogens, strengthening intelligence and bioforensics, improving the information provided to citizens, enhancing emergency responders' safety, and distributing countermeasures to victims.

## II. BACKGROUND AND NEED FOR THE LEGISLATION

### A. GENERAL NATURE OF THE WMD THREAT

A weapon of mass destruction can assume many forms. It can be a nuclear bomb that with a blinding flash can kill countless people and level buildings for miles around. It can be a biological pathogen released undetectably and spread quietly among the population until suddenly the disease emerges and overwhelms our hospitals' capacities to care for the sick. Or, it can be a chemical agent released in the close confines of a subway, striking down commuters in an instant. But whatever form a WMD takes, it can bring exactly what its name suggests—mass destruction—to our people, our infrastructure, and our economy.

Unfortunately, the threat of terrorists attacking us using WMDs is a real and near-term danger—in terms of both the potential for terrorists to acquire and use such weapons and the horrific consequences of an attack. In December 2008, then-Director of National Intelligence (DNI), Mike McConnell, warned publicly that a WMD terrorist attack is more likely than not to occur somewhere in the world by 2013 and that a biological attack is more likely than a nuclear attack.<sup>1</sup> The bipartisan Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism ("Prevent WMD Commission"), co-chaired by former Senators Bob Graham and Jim Talent, seconded DNI McConnell's warning concerning biological weapons in its December 2008 report, *World at Risk*.<sup>2</sup> The Prevent WMD Commission's report assessed the overall threat of WMD posed by terrorists to the United States and offered recommendations to close identified gaps in the nation's preparedness efforts.

A WMD terrorist attack is one of the most serious national security challenges faced by the United States. As President Barack Obama stated on the eve of an April 2010, Nuclear Security Summit, "we know that organizations like al Qaeda are in the process of trying to secure a nuclear weapon—a weapon of mass destruction that they have no compunction at using."<sup>3</sup> And as the President previously has said, "If an organization like al Qaeda got a weapon of mass destruction on its hands—a nuclear or a chemical or a biological weapon—and they used it in a city, whether it's in Shanghai or New York, just a few individuals could potentially kill

<sup>1</sup> See Remarks and Q&A by the Director of National Intelligence, Mike McConnell, at the John F. Kennedy, Jr. Forum at Harvard University, December 2, 2008, available at [http://www.odni.gov/speeches/20081202\\_speech.pdf](http://www.odni.gov/speeches/20081202_speech.pdf) (last accessed October 8, 2010), at 8.

<sup>2</sup> The Prevent WMD Commission was created by the Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53). *World at Risk: The Report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*. December 2008, available at <http://www.preventwmd.gov/report/> (last accessed October 8, 2010), at xv.

<sup>3</sup> CNN, "Political Punch," April 11, 2010, available at <http://blogs.abcnews.com/politicalpunch/2010/04/president-obama-al-qaeda-is-seeking-a-nuke-to-kill-innocents.html> (last accessed April 12, 2010).

tens of thousands of people, maybe hundreds of thousands.”<sup>4</sup> Similarly, President Obama’s Assistant to the President for National Security Affairs, General James Jones, USMC (ret.), stated publicly on October 4, 2009, that the most alarming threat facing the United States is the nexus of WMD proliferation and terrorism:

There are a lot of things that keep me up at night, but if I had to pick one that I—that I thought was most—most alarming, it’s the question of proliferation and weapons of mass destruction falling into terrorists’ hands. Generally, nation states, once they have the capability, can be controlled a little bit more. But if we—if we lost, you know, track of nuclear weapons or other weapons of mass destruction and [they] came into the hands of a radical terrorist group, they would use them. And that—and that bothers me a great deal. And that’s why this question of proliferation is probably central to how our children and grandchildren are going to live in this 21st century.<sup>5</sup>

WMDs are of particular interest to terrorist groups. As far back as 1998, Osama bin Laden called acquiring WMDs for the defense of Muslims a religious duty.<sup>6</sup> Islamist extremist religious leaders associated with al Qaeda have issued religious decrees, or fatwas, justifying mass murder and the use of WMD against their enemies.<sup>7</sup> Al Qaeda’s spokesman, Sulayman Abu Gayth al Libi, stated that al Qaeda would be justified in using WMDs to kill four million Americans.<sup>8</sup>

Although the term WMD has no universally agreed-upon definition, the term is used generally in U.S. statutes and government documents to refer to nuclear, chemical, and biological weapons.<sup>9</sup> Similarly, a report by the Department of Defense entitled *Proliferation Threat and Response 2001* refers to “capabilities to inflict mass casualties and destruction: nuclear, biological and chemical (NBC) weapons or the means to deliver them.”<sup>10</sup>

To be sure, conventional weapons also can inflict mass casualties and destruction—example, nuclear weapons can be more than one million times more powerful than the same. However, WMD are distinguished by their destructive force as compared to their small size. For weight of conventional explosives and also generate long-term radioactive fall-out as well as damage electronic instruments by producing an electromagnetic pulse.<sup>11</sup> A single nuclear weapon dropped on Hiroshima in 1945 killed approximately 68,000 people

<sup>4</sup> Quoted in Rolf Mowatt-Larssen, *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?*, Belfer Center for Science and International Affairs, Harvard Kennedy School (2010), at 3.

<sup>5</sup> CNN, “State of the Union,” October 4, 2009, available at <http://transcripts.cnn.com/TRANSCRIPTS/0910/04/sotu.05.html> (last accessed December 10, 2010).

<sup>6</sup> Rahimullah Yusufzai, “Conversations with Terror,” *TIME*, January 11, 1999.

<sup>7</sup> “A Treatise on the Legal Status of Using Weapons of Mass Destruction Against Infidels,” issued by radical cleric Nasir Bin Hamd al-Fahd in May 2003, available at <http://www.jihadspn.com/NuclearFatwa.pdf> (last accessed April 12, 2010).

<sup>8</sup> *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?*, at 23.

<sup>9</sup> See “WMD 411: Definitions of WMD,” Nuclear Threat Initiative, available at [http://www.nti.org/f\\_wmd411/fla1.html](http://www.nti.org/f_wmd411/fla1.html) (last accessed April 8, 2010).

<sup>10</sup> Department of Defense, *Proliferation Threat and Response 2001* (2001), available at <http://www.fas.org/irp/threat/prolif00.pdf>, at i.

<sup>11</sup> U.S. Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559 (U.S. Government Printing Office, 1993), available at <http://www.au.af.mil/au/awc/awcgate/ota/9341.pdf> (last accessed October 20, 2010), at 2–3 and n.1.

and injured another 76,000.<sup>12</sup> Producing a nuclear weapon requires access to uranium or plutonium, which the international community has attempted to control tightly. Chemical weapons have a long history of use in warfare and more recently have been employed by terrorists. For example, the Aum Shinrikyo cult killed 12 people in a sarin gas attack on the Tokyo subway system in 1995. Chemical weapons can be manufactured from a variety of substances that are used commercially, such as chlorine.

*The bioterrorism threat specifically*

Bacteria and viruses are used widely in the research and commercial sectors for purposes such as disease studies, drug delivery, sanitation or manufacturing. Some organisms that cause human or agricultural diseases, or pathogens, are also suitable for development into biological weapons because they contain the right characteristics of lethality, deliverability, and stability. In the wrong hands, a surprisingly small volume of such a biological weapon can cause a surprisingly large number of human casualties either directly or by “growing” the material to create additional weapons. In the “National Strategy for Countering Biological Threats,” released by President Obama on November 23, 2009, the National Security Council stated:

The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed one trillion dollars for each such incident. In addition, there could be significant societal and political consequences that would derive from the incident’s direct impact on our way of life and the public’s trust in government.<sup>13</sup>

In 2001, trace amounts of anthrax sent through the U.S. mail system sickened twenty-two people, killing five of them. According to the President’s Homeland Security Council, a single airborne attack using anthrax in one city with one truck could yield nearly 330,000 exposures and cause 13,000 fatalities.<sup>14</sup> Ultimately, a biological weapon can produce as many fatalities as a nuclear weapon.<sup>15</sup> Congress’s Office of Technology Assessment estimated that an airplane dispersing one hundred kilograms of anthrax over a city could kill between 420,000 and 1.4 million people.<sup>16</sup>

The development of nuclear weapons requires advanced equipment, a high and relatively scarce level of expertise, and access to tightly controlled materials. Biological weapons, in contrast, can be created by many members of the large global biological sciences workforce, using technology that is widely available for legitimate purposes and pathogens stored at institutions with varying levels

<sup>12</sup> *Id.* at 46.

<sup>13</sup> *National Strategy for Countering Biological Threats*, National Security Council, November 2009. Available at [http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf) (last accessed October 15, 2010), at 1.

<sup>14</sup> *World at Risk*, at 5–6.

<sup>15</sup> Nuclear Threat Initiative, “Effects of WMD,” updated August 2010, available at [http://www.nti.org/f\\_wmd411/fla2.html](http://www.nti.org/f_wmd411/fla2.html) (last accessed April 12, 2010).

<sup>16</sup> *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, at 54.

of security or directly from natural environmental sources. All of these factors make biological weapons considerably easier and cheaper to produce in facilities that are smaller and harder to detect than those required to create a nuclear device. Indeed, then-speaker of the Iranian Parliament, Hashemi Rafsanjani, stated in 1988 that biological and chemical weapons are “the poor man’s atomic bomb.”<sup>17</sup> Biological weapons using infectious pathogens such as smallpox can quickly spread beyond the point of release to other areas, putting an entire nation or region at risk without requiring multiple terrorists to attack in different areas. For biological weapons using pathogens that do not spread person to person readily, such as anthrax, the ability to easily replicate the pathogen in the laboratory means that little stands in the way of producing multiple or ever larger weapons. As with the 2001 anthrax attacks, bioterrorists would likely conduct a campaign of attacks because it is easy to field multiple weapons once the first one has been developed.

Al Qaeda’s interest in developing biological weapons is well documented.<sup>18</sup> The National Security Council confirmed in the Administration’s “National Strategy for Countering Biological Threats” that “in 2001, while engaging the Taliban in Afghanistan, coalition forces came into possession of a significant body of evidence that al-Qa’ida was seeking to develop the capability to conduct biological weapons attacks.”<sup>19</sup> And as the Secretary of Homeland Security, Janet Napolitano, has stated, biological and chemical weapons “are capacities al Qaeda has sought for years.”<sup>20</sup> In the late 1990’s, al Qaeda established a biological weapons program and a biological laboratory in Kandahar, Afghanistan, which included experiments on animals.<sup>21</sup> Among its members, al Qaeda had several individuals with advanced scientific expertise, including in the fields of chemistry and microbiology.<sup>22</sup> The most significant biological weapons program focused on developing an anthrax bioweapon but the group also pursued ricin and botulinum toxins. Al Qaeda explored dispersal methods for those biological weapons, and operatives were found to possess crop duster manuals and appeared to have tried to purchase a crop dusting airplane. In 2003, associates of the Jordanian extremist Abu Musab al Zarqawi, who headed Al-Qaeda in Iraq and received the title “Emir of Al Qaeda in the Country of Two Rivers,” were arrested as they prepared ricin attacks against

<sup>17</sup> North Atlantic Assembly, *Chemical and Biological Weapons: The Poor Man’s Bomb*, Draft General Report (1996), available at <http://ftp.fas.org/irp/threat/an253stc.htm>, (last accessed April 12, 2010). The North Atlantic Assembly report noted, “This phrase is as accurate as it is alarming. While nuclear weapons represent the zenith of mass destruction, their fabrication requires advanced industrial capabilities as well as access to rare, tightly controlled materials. Chemical and biological weapons, on the other hand, are cheap and easy to build using equipment and materials that are used extensively for a host of civilian purposes.” *Id.*

<sup>18</sup> For a discussion of the biological weapons threat from al Qaeda, see generally *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?*; see also George Tenet, *At the Center of the Storm* (New York: HarperCollins, 2007).

<sup>19</sup> *National Strategy for Countering Biological Threats* at 2.

<sup>20</sup> Janet Napolitano, “Common Threat, Collective Response: Protecting Against Terrorist Attacks in a Networked World,” speech before the Council on Foreign Relations, (July 29, 2009), available at [http://www.cfr.org/publication/19929/common\\_threat\\_collective\\_response.html](http://www.cfr.org/publication/19929/common_threat_collective_response.html) (last accessed April 12, 2010).

<sup>21</sup> *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?*, at 23.

<sup>22</sup> Ayman Zawahiri, Osama bin Laden’s deputy, had a master’s degree in surgery and reportedly oversaw al Qaeda’s efforts to establish a biological weapons laboratory by microbiologist Dr. Rauf Ahmed and to obtain a lethal strain of anthrax by biochemist Yazid Sufaat. Other operatives such as Mubarek al-Duri and Abu Rida Mohammed Bayazid had degrees in biology and physics, respectively. *Id.* at 12, 14, 21.

the London underground subway system.<sup>23</sup> The Administration's National Strategy concluded with respect to al Qaeda that "it is prudent to assume that its intent to pursue biological weapons still exists."<sup>24</sup>

However, the October 2001 anthrax attacks show that the threat of bioterrorism is not limited to al Qaeda. In February 2010, the Department of Justice concluded that Bruce Ivins, a researcher with the U.S. Army Medical Research Institute of Infectious Diseases, was the sole perpetrator of those five letter attacks.<sup>25</sup> The attacks demonstrated that a single researcher could prepare and carry out a biological attack without detection by his peers. Other notable examples of bioterrorism include the 1993 attack by a Japanese religious cult in which they sprayed a non-virulent strain of anthrax off their headquarters building. That attempt was not detected until years later when authorities investigated the cult's successful sarin gas attack on the Tokyo subway system. In 1984, another religious cult, the Rajneeshee sect in Oregon, launched a series of salmonella food poisoning attacks that sickened hundreds.

The President's National Strategy concluded: "[w]e are fortunate that biological threats have not yet resulted in a catastrophic attack or accidental release in the United States. However, we recognize that: (1) the risk is evolving in unpredictable ways; (2) advances in the enabling technologies will continue to be globally available; and (3) the ability to exploit such advances will become increasingly accessible to those with ill intent as the barriers of technical expertise and monetary costs decline."<sup>26</sup>

## B. THE BIOSECURITY RISK OF DANGEROUS PATHOGEN LABORATORIES

### B.1. Background

The Prevent WMD Commission's December 2008 final report gave particular focus to the threat of bioterrorism, finding that the nation's counter-WMD planners have not adequately prioritized addressing what is the most likely catastrophic WMD threat. The commissioners stated "the more that sophisticated capabilities, including genetic engineering and gene synthesis, spread around the globe, the greater the potential that terrorists will use them to develop biological weapons. *The challenge for U.S. policymakers is to prevent that potential from becoming a reality by keeping dangerous pathogens—and the equipment, technology and know-how needed to weaponize them—out of the hands of criminals, terrorists, and proliferant states.*"<sup>27</sup> Specifically the Commission offered its first recommendation on the issue of domestic biosecurity, urging a comprehensive review of the way we regulate dangerous pathogens, how researchers are trained in biosecurity practices, how the laboratories that work on these agents are secured, and how we engage the life sciences community who perform this work.

While the U.S. must give considerable attention to discovering and disrupting terrorist use of dangerous pathogens, we must si-

<sup>23</sup> *Id.* at 25.

<sup>24</sup> *National Strategy for Countering Biological Threats* at 2.

<sup>25</sup> See Department of Justice, *Amerithrax Investigative Summary* (February 19, 2010), available at <http://media.washingtonpost.com/wp-srv/politics/documents/documents/amx-investigative-summary.pdf?sid=ST2010021904257> (last accessed April 12, 2010).

<sup>26</sup> *National Strategy for Countering Biological Threats* at 2.

<sup>27</sup> *World at Risk* at 23. Emphasis on the role for policy makers added.



multaneously address our own potential vulnerabilities—the security of the pathogen stocks our scientists use for legitimate research, commercial, and public health purposes. As the commissioners put it: “Although dangerous pathogens such as the anthrax bacterium can be isolated from natural sources, it would generally be easier for terrorists to steal or divert well-characterized ‘hot’ strains from a research laboratory or culture collection.”<sup>28</sup> Indeed, all prominent examples of modern bioterrorism or crimes involving biological agents used material obtained from laboratory sources or pathogen repositories—not pathogens independently derived from natural sources by the perpetrators of the attack.<sup>29</sup>

Unfortunately, although the government has taken steps to secure U.S. laboratories working on the most dangerous pathogens, robust laboratory security has remained elusive. The government must do more to address these security deficiencies. In 2008, the Government Accountability Office (GAO) reported that two of the nation’s five highest level containment labs, which handle some of the most dangerous pathogens, had significant deficiencies in accepted practices for securing facility perimeters.<sup>30</sup> High-containment labs are designed to prevent the release of infectious agents that can spread through the air. The highest level of these labs, those labeled biosafety level 4, is often used for research on pathogens for which there are inadequate or no therapies to treat the disease they cause. In July of 2009, GAO observed in an updated report that deficient facilities made some improvements in perimeter security, but GAO continued to find fault with federal oversight of these facilities. GAO noted that the security improvements came as a result of public attention and not from any new requirements or directives by government auditors.<sup>31</sup>

A related GAO report identified additional risk factors beyond perimeter security that increase the likelihood of laboratory accidents or intentional misuse of dangerous pathogens at high-containment facilities.<sup>32</sup> GAO noted that the United States is currently undergoing a construction boom of new high-containment laboratories and warned of insufficient attention to identifying current high-containment laboratory capacity or to planning how the new capacity will be used and maintained. Many of the planned facilities have poorly defined mission needs or objectives, insufficient maintenance resources and incomplete biosafety and biosecurity systems.

The Obama Administration agrees that more needs to be done to improve lab biosecurity. The National Strategy for Countering Biological Threats calls for reducing the risk posed by deliberate use

<sup>28</sup>*Id.* at 24.

<sup>29</sup>The 1995 plague samples obtained by the neo-nazi extremist Larry Wayne Harris were ordered from the pathogen repository American Type Tissue Collection (ATCC); the 1984 salmonella strain used by the Rajneeshee religious cult to contaminate Oregon restaurant salad bars came from a commercial distributor and was a common strain found in pathogen repositories; the 1993 nonvirulent anthrax strain used by the Japanese Aum Shinrikyo religious cult was a common vaccine strain used in veterinary medicine; the 1996 intentional shigella infection of Dallas, Texas hospital staff by a co-worker was obtained from the hospital’s collection; and, the 2001 anthrax postal mailing attacks was traced back to a U.S. Army research institute.

<sup>30</sup>Biosafety Laboratories: Perimeter Security Assessment of the Nation’s Five BSL-4 Laboratories GAO-08-1092, September 17, 2008.

<sup>31</sup>Biosafety Laboratories: BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC GAO-09-851, July 7, 2009.

<sup>32</sup>High-Containment Laboratories: National Strategy for Oversight is Needed. GAO-09-574, September 2009.

of pathogens and toxins “by limiting ready access to known virulent strains of high-risk pathogens and toxins.”<sup>33</sup> It further recognizes that the government needs to optimize “our domestic laws, regulations, policies and practices for securing high risk pathogens and toxins and [provide] detailed guidance for improved compliance.”

#### *Biological Select Agent and Toxin Program*

The current regime regulating dangerous pathogens—the Biological Select Agent and Toxin (BSAT) Program—simply doesn’t offer the tools necessary to improve the situation. The BSAT program was established in The Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104–132) after a neo-Nazi extremist in 1995 obtained a strain of *Yersinia pestis*, the causative agent of plague, from a U.S. pathogen research repository. At the time there were no prohibitions against unapproved acquisition of dangerous disease agents, and the perpetrator eventually pleaded guilty only to wire fraud. The statute authorized the Centers for Disease Control and Prevention (CDC) to promulgate regulations establishing a list of dangerous pathogens and toxins and for controlling the transfer of those pathogens to appropriate research facilities. Select agents were to be made available only to people and laboratories that had registered with the CDC. The new law did not, however, impose penalties on individuals for inappropriately possessing select agents themselves, attainable via such means as by acquiring select agents overseas or isolating the pathogens from the environment.

Following the October 2001 anthrax attacks, Congress passed the USA PATRIOT Act (P.L. 107–56), which added criminal penalties for the illicit possession and use of biological threat agents by anyone who cannot prove reasonably that they are using a biological agent, toxin, or delivery system for purposes of “prophylactic, protective, bona fide research, or other peaceful purposes.”<sup>34</sup> In 2002, Congress amended the statute authorizing the BSAT program in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107–188) to require regulations for the possession and use of select agents regardless of the manner in which they were acquired.<sup>35</sup>

#### *Insufficient focus on bioterrorism potential*

The BSAT regulations are intended to keep dangerous pathogens that could be used as bioweapons out of the hands of terrorists. In practice, the regulations cast such a wide net that they produced a bloated BSAT list, one that impedes sufficient focus on securing the most dangerous agents, while imposing excessive security burdens on research where it is not warranted. Instead of defining the pathogens subject to its regulation with reference to the material’s ability to be weaponized, the authorizing statute mandated the use of a threat to public health as the main criteria for inclusion on the

<sup>33</sup> *National Strategy for Countering Biological Threats* at 13.

<sup>34</sup> USA PATRIOT Act of 2001, P.L. 107–56, 115 Stat. 0385–386, (amending 18 U.S.C. § 175), (2002).

<sup>35</sup> Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107–188, 116 Stat. 637–662 42 U.S.C. § 262a, 7 U.S.C. § 8401, 7 U.S.C. § 8411 (2002). The regulations are contained in CDC Select Agents Regulations (42 CFR Part 73) and APHIS Select Agents Regulations (7 CFR Part 331 and 9 CFR Part 121), available at <http://www.selectagents.gov/Regulations.html>.

list.<sup>36</sup> No criteria assess the agent's suitability to be weaponized or the effectiveness of the potential weapon to cause significant casualties or economic repercussions. The BSAT regulations are also "all or nothing"—imposing the same security requirements on all agents, regardless of whether the bioterrorism risk they pose is little, moderate, or significant. As a result, the BSAT list has ballooned to 82 listed pathogens and toxins, many of which are believed unsuitable for the development of effective biological weapons but all of which face the same regulations. Some of these unsuitable agents may be able to cause significant disease outbreaks in a natural setting but lack features necessary for an effective biological weapon, such as ease in producing significant weapons material, stability in delivery systems, and the ability to be broadly disseminated. In contrast, for purposes of developing medical countermeasures (MCMs) against potential WMD threats, DHS recognizes just 11 biological agents as material threats to the U.S. population sufficient to affect national security.<sup>37</sup>

The apparent over-reach of the current regulatory regime has had serious consequences. Not only has it diluted government security efforts, but it also has imposed resource constraints on the labs themselves and resulted in confusing and often inconsistent regulatory overlaps.

*Inconsistent and overlapping regulatory requirements for institutions*

The large size of the list has meant that the regulations sweep in a large number of institutions and personnel, affecting many laboratories that do not contain pathogens of significant bioweapon potential and people who do not work on the most dangerous pathogens, but all of whom require, under current law, a similar investment of limited governmental regulatory resources. Approximately 400 institutions and 15,000 personnel have had to register to conduct research on 82 select agents. Laboratories handling human pathogens are regulated by the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS), while laboratories working with animal or plant pathogens face regulation from the Department of Agriculture (USDA). Facilities working with pathogens that pose a threat to both human and animal health, termed "overlap agents", can choose to be regulated either by the CDC or USDA. Institutions, along with the officials who oversee the institution's BSAT program

<sup>36</sup> P.L. 107–188, 42 U.S.C. § 262a, 116 Stat. 637–638 (2002). In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall consider—

“(I) the effect on human health of exposure to the agent or toxin;

“(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

“(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

“(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate.

<sup>37</sup> The authority to make such declarations is given in the Project Bioshield Act of 2004, P.L. 108–276, 118 Stat. 844, 42 U.S.C. § 247d–6b (2004). Under the Act, the Secretary of Homeland Security issues Material Threat Determinations (MTDs) for chemical, biological, and radiological agents that could be used in a weapon endangering enough people to threaten national security. MTDs issued for biological agents include Botulinum Toxin (*Clostridium botulinum*), Plague (*Yersinia pestis*), anthrax (*Bacillus anthracis*), multi-drug resistant anthrax (*Bacillus anthracis*), smallpox (*Variola Major*), Tularemia (*Francisella tularensis*), Typhus (*Rickettsia prowazekii*), Glanders (*Burkholderia mallei*), Melioidosis (*Burkholderia pseudomallei*), Viral Hemorrhagic Fevers (Filovirus family such as *Marburg* or *Ebola*), and Viral Hemorrhagic Fevers (Arenavirus, Flavivirus, and Bunavirus families).

compliance, must re-apply for registration every three years and renewal is dependent on a site visit by federal inspectors.

Institutions performing select agent research often face a number of additional security requirements outside the BSAT program that can prove confusing or inconsistent. These requirements may come from their home agency or institution, local and state regulators, federal funding agencies, or overlapping regulatory agencies. Regulated entities frequently report that the requirements and inspections that result from this broad array of oversight entities are poorly coordinated, often inconsistent with one another, and expensive in both their financial cost and the lost research time required to prepare and undergo multiple inspections. The BSAT regulations also lack specificity in their implementation requirements for areas such as physical security or inventory accountability, which has led to variability among oversight agencies in interpreting regulatory compliance. As a result, registered entities often report confusing or contradictory security requirements imposed on them by inspecting agencies.<sup>38</sup>

#### *Inadequate scrutiny of individuals handling pathogens*

At the same time, the individuals handling select agents are not subject to sufficient scrutiny, given the risks posed by the materials they handle. The FBI conducts a Security Risk Assessment on these individuals every 5 years with little to no follow-up between applications. The Assessment involves checking a series of databases to determine whether the individual has any prohibited characteristics.<sup>39</sup> The law prohibits anyone with known associations with terrorists, a criminal record, a history of mental health problems, or is an unlawful alien from being granted clearance to work with select agents.<sup>40</sup> Significantly, while the security risk assessment examines domestic criminal records and reviews a few broad international criminal databases, it does not include a check of criminal records in the particular home nations of applicants originating from foreign countries. The FBI recently established a system under which the bureau is automatically notified if an approved select agent user is arrested and fingerprinted. Institutes hiring BSAT qualified personnel report that they cannot access information pertaining to any prior biosecurity concerns regarding the applicant at another institution because of the previous em-

<sup>38</sup> Personal communication with the Committee, and "Report of the Working Group on Strengthening the Biosecurity of the United States," January 8, 2010, <http://www.hhs.gov/aspr/omsp/biosecurity/biosecurity-report.pdf> (Last Accessed September 30, 2010), at 4.

<sup>39</sup> Presentation at the June 2010 Select Agent Workshop by FBI Criminal Justice Information Service and the Select Agent Programs of HHS and USDA entitled "Security Risk Assessments—Overview, FBI Updates, Visitor Movement," available at <http://www.selectagents.gov/resources/FULL%20WORKSHOP%20PRESENTATION%20START%20TO%20FINISH.pdf> (last accessed August 27, 2010). Slides 164–165. The databases checked during the Security Risk Assessment for Select agent program applicants are: Central Index System (CIS), Computer Linked Application Information Management System (CLAIMS), Deportable Alien Control System (DACS), National Automated Immigration Lookout System (NAIIS II), Nonimmigrant Information System (NIIS), Student and Exchange Visitor Information System (SEVIS), Redesignated Naturalization Application Casework System (RNACS), Refugee, Asylum, and Parole System (RAPS), Enforcement Case Tracking System (ENFORCE), Treasury Enforcement Communications System (TECS), Interstate Identification Index (State/Local criminal history), Automated Case Support (ACS; FBI case file database), National Crime Information Files including: Foreign Fugitive File, Deported Felon File, Protection Order File, Wanted Person File, U.S. Secret Service Protective File, SENTRY File (Bureau of Prisons), Convicted Person on Supervised Release File, Convicted Sexual Offender Registry.

<sup>40</sup> USA PATRIOT Act of 2001, P.L. 107–56, 115 Stat. 0386, (amending 18 U.S.C. § 175b), (2002).

ployer's liability concerns. Employers are not required to report to the regulating agency detrimental behavior of BSAT personnel resulting in their termination.

Federal agencies and some state and private institutions conducting select agent research have chosen to implement additional safeguards for personnel handling select agents that go beyond personnel examinations required under the BSAT program. Because these measures are undertaken on the initiative of the individual select agent research entities, there is inconsistent application of which measures are employed and how strenuously they are enacted. These more rigorous employee evaluation and monitoring policies are sometimes termed Personnel Reliability Programs (PRPs). PRPs are designed to account for the trustworthiness, competency and stability of users given access to select agents and toxins. PRPs can include a wide range of practices from background investigations, mental health screening and credit checks to continuous monitoring and reporting programs.<sup>41</sup>

#### *Recent reports on improving laboratory biosecurity*

Recognizing the need to improve laboratory biosecurity, particularly for BSAT research, the federal government has conducted a series of studies examining various aspects of the current regulatory scheme and how it might be improved. Some of the most pertinent to this legislation have recently been concluded and are discussed further below, including those that were released following the Committee's consideration of this legislation.

In January 2009, the outgoing administration issued an Executive Order (13486) that established the "Working Group on Strengthening the Biosecurity of the United States," co-chaired by the Departments of Health and Human Services and Defense. The Executive Order called for the working group to look at the existing security regime and recommend any necessary statutory or regulatory changes to ensure a uniform and effective regulatory system for all facilities and individuals handling dangerous pathogens.<sup>42</sup>

The working group established by the 2009 Executive Order tasked the National Academies to review the select agent program.<sup>43</sup> The panel appointed by the National Academies recommended dividing the select agent list into stratified groups based on risk tiers, establishing minimum physical security requirements that satisfy the requirements of all relevant federal agencies, giving standardized training to all agency inspectors, establishing an advisory committee of stakeholders to review policies,

<sup>41</sup> Some sectors such as sensitive nuclear research also include the use of polygraphs but, outside of the intelligence community, polygraphs do not appear to be applied to biological select agent research. For further discussion of PRP see: Report of the Defense Science Board Task on Biological Safety and Security Program. May 2009. <http://www.acq.osd.mil/dsb/reports/ADA499977.pdf>; (Last Accessed September 30, 2010) *Enhancing Personnel Reliability among Individuals with Access to Select Agents*. May 2009. [http://oba.od.nih.gov/biosecurity/biosecurity\\_documents.html](http://oba.od.nih.gov/biosecurity/biosecurity_documents.html) (Last Accessed September 30, 2010); and, Responsible Research with Biological Select Agents and Toxins. National Research Council of the National Academies. September 2009.

<sup>42</sup> Executive Order 13486 "Strengthening Laboratory Biosecurity in the United States." January 9, 2009. <http://edocket.access.gpo.gov/2009/pdf/E9-818.pdf> (Last Accessed September 30, 2010).

<sup>43</sup> Responsible Research with Biological Select Agents and Toxins. National Research Council of the National Academies. September 2009.

and making available a separate category of funding to support security measures at select agent laboratories.<sup>44</sup>

The working group released its final report in January 2010, offering a number of findings and recommendations. It concurred with the observations above (1) that the BSAT list contains pathogens posing differing levels of risk and as a result should be either reduced or divided into different regulatory tiers; (2) that the program suffers from numerous uncoordinated federal inspections and oversight mandates, each with its own performance expectations or regulatory requirements; and (3) that registered entities do not clearly understand what they must do to comply with select agent program requirements.<sup>45</sup>

The working group supplied a recommendation to address each of these key findings:

*(1) Perform a risk assessment for each select agent and toxin on the BSAT list and develop a stratification scheme that includes bio-defense and biosecurity criteria, as well as risk to public health, so that security measures may be implemented based upon risk.*

*(2) Enhance U.S. Government coordination of oversight and inspections as well as institutional implementation, compliance, oversight, and accountability.*

*(3) Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.*<sup>46</sup>

The working group also recommended improved vetting and continuous monitoring measures, consisting of some common PRP measures, of approved BSAT users and the development of minimum prescriptive physical security standards.

A number of other federally sponsored reports have examined these and other aspects of laboratory biosecurity. For example, HHS' National Science Advisory Board for Biosecurity, established by Congress in the Pandemic and All-Hazards Preparedness Act of 2006, released in May 2009 a report entitled "Enhancing Personnel Reliability among Individuals with Access to Select Agents."<sup>47</sup> The report recommended, among other things, strengthening the background check process for select agent applicants and reducing the list of select agents and toxins. While the report found no need for a national personnel reliability program at this time, it found that "personnel reliability programs can help to reduce but cannot eliminate the risk of an insider threat."<sup>48</sup> The report also recommended that "institutions that are engaged in select agent research should review their employment practices and other existing select agent personnel reliability-related policies to determine whether there is a need to implement additional personnel reliability measures."<sup>49</sup>

The Department of Defense (DOD) also initiated a security review of its own select agent research policies, which in many as-

<sup>44</sup>*Id.* at 2–5.

<sup>45</sup>"Report of the Working Group on Strengthening the Biosecurity of the United States" January 8, 2010. <http://www.hhs.gov/aspr/omsph/biosecurity/biosecurity-report.pdf> (Last Accessed September 30, 2010), at 4.

<sup>46</sup>*Id.* at 4.

<sup>47</sup>The National Science Advisory Board for Biosecurity was established in the Pandemic and All-Hazards Preparedness Act, P.L. 109–417, 120 Stat. 2851, 42 U.S.C. § 262a note. The report is entitled "Enhancing Personnel Reliability Among Individuals with Access to Select Agents." May 2009. [http://oba.od.nih.gov/biosecurity/biosecurity\\_documents.html](http://oba.od.nih.gov/biosecurity/biosecurity_documents.html) (Last Accessed September 30, 2010).

<sup>48</sup>*Id.* at 5.

<sup>49</sup>*Id.* at 11.

pects exceed CDC regulations.<sup>50</sup> Among the DOD panel's recommendations: increase cybersecurity efforts, maintain the biological personnel reliability program, and improve inspection procedures to reduce their burden on inspected facilities. DOD's report also pointed to the expense of complying with biosecurity programs and the need for additional financial support for regulated entities.

Another group—the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, chaired by officials from HHS and USDA with representatives from other federal agencies—focused primarily on the safe operation of high-containment laboratories rather than biosecurity practices. Still, the report offered a number of proposals relevant to both biosafety and biosecurity of high-containment laboratories.<sup>51</sup> The Task Force recommended establishing coordinated and improved oversight, requiring registration of high-containment laboratories, implementing improved training of laboratory personnel, and ensuring proper maintenance resources for facilities housing dangerous pathogens.

#### *B.2. Title I of the WMD Prevention and Preparedness Act of 2009—Enhanced Biosecurity*

The WMD Prevention and Preparedness Act responds to many of the collective findings and recommendations of these reports. Title I of the bill establishes a risk-based approach to improving security at U.S. biological laboratories by heightening security standards for labs handling the most dangerous pathogens while reducing the regulatory burden on laboratories handling agents that aren't suitable for use in an attack. In response to the general consensus that the BSAT lists many pathogens that pose little bioterrorism risk, this title divides the BSAT list into tiers and encourages the delisting or demotion of agents that are currently over-regulated. It enhances security on only those BSAT pathogens of greatest bioterrorism risk and provides for coordinated inspection policies and efforts to reduce the confusion over biosecurity requirements and the expense of complying with the inspections. Provisions in this title also establish a biosecurity grant program to assist institutions with meeting enhanced biosecurity requirements. And, to promote coordination among federal agencies and with local responders, the title provides for greater information sharing, with safeguards against inappropriate disclosure.

The bill would divide the BSAT list into three tiers. A new “Tier I” of select agents would be composed of a small subset of the current list, those that the Secretary of Health and Human Services or Secretary of Agriculture, as appropriate, determines to pose the greatest threat, as defined by having clear potential for weaponization and use in a biological attack causing significant casualties. Based on expert opinion and DHS Material Threat Determinations, the Committee expects that between roughly 5 and 11 of the 82 agents currently on the BSAT list would gain Tier I

<sup>50</sup> Report of the Defense Science Board Task on Biological Safety and Security Program. May 2009. <http://www.acq.osd.mil/dsb/reports/ADA499977.pdf> (Last Accessed September 30, 2010).

<sup>51</sup> Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. July 2009. <http://www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Documents/transfedbiocontainmentrpt092009.pdf> (last accessed September 30, 2010).

designation.<sup>52</sup> HHS and USDA would retain responsibility for the biosafety and scientific regulation of Tier I agents, while DHS—the department possessing the government’s infrastructure protection expertise—would ensure adequate physical and personnel security measures for Tier I agents.

This legislation gives DHS the principal role in securing Tier 1 agents because the department is specifically charged with increasing the security of the nation’s critical infrastructure across myriad sectors. An example of DHS working with the private sector to secure critical infrastructure is DHS’s work in the chemical security area. At Congress’s direction, DHS implemented and regulates the Chemical Facility Anti-Terrorism Standards, or CFATS—a program that requires science-based security standards development, vulnerability assessments, and site security plans while not impeding this critical infrastructure’s functioning.<sup>53</sup> DHS’s involvement in securing laboratories handling Tier 1 agents is expected to bring expertise to address security shortfalls in the current select agent regulatory regime, including in physical security, personnel screening, and information sharing with state and local law enforcement, first responders and emergency officials.

The current BSAT Program would in effect become the regulatory scheme for a second tier, encompassing agents that meet the preexisting BSAT program criteria plus a new criterion requiring consideration of their suitability to be weaponized. The new criterion would raise the bar, requiring an examination of not just the agent’s public health consequences but also whether it poses a bioterrorism risk. Combined with a mandated review of all agents on the BSAT list, this measure is intended to enable the removal of agents with little or no bioterrorism risk from the BSAT program. This second tier would exist as the BSAT program in its current form without the new enhanced biosecurity measures and would still be regulated for security, biosafety, and scientific purposes by HHS and USDA.

A new third category called “Registry Agents” would comprise the final and lowest risk tier. Registry agents would be those that have some potential to pose a severe threat to public, animal or plant health, but whose potential for use in a biological attack has not been established, whether because ease in producing significant weapons material, stability in delivery systems, or the ability to be broadly disseminated is questionable. This tier would likely include agents previously included in the Select Agent Program, but not meeting the criteria for inclusion in the top two regulatory tiers as defined in this legislation. Laboratories that handle Registry Agents would have to register with HHS, but would not face further regulation.

This measure would facilitate the removal from the BSAT program of agents that currently pose little bioterrorism risk while at the same time ensuring continued visibility of the agents if intel-

<sup>52</sup>This range is derived from analysis of biological agents that possess both the capability of being used to make a stable biological weapon as well as to cause significant casualties if deployed. DHS has issued Material Threat Determinations for 11 biological agents for purposes of identifying which pathogens to develop medical countermeasures for under Project Bioshield. Some or all of these agents may also possess the characteristics justifying a Tier 1 designation in this legislation.

<sup>53</sup>Department of Homeland Security Appropriations Act, 2007, P.L. 109–295, section 550, (2006).



ligence or threat analysis indicates an increased risk of their use in a bioterrorist event. The registry agent category would also facilitate the solicitation of information on the characteristics of emerging threat agents and how they are used in research. This would allow full consideration of these agents for possible inclusion in the BSAT program, if warranted, without subjecting them to the regulatory burden before the threat is clearly established. Currently, the federal government has little visibility into the research being conducted on emerging pathogens with bioweapon potential and can gain more insight into it only if and when it subjects the research to the entire scope of select agent regulation oversight.

Title I also directs new, enhanced biosecurity measures at agents on the Tier I BSAT list, but leaves the remaining BSAT agents at their current level of regulation, or brings them to an even lower one if they are delisted to the new Registry Agent category. The title directs DHS to promulgate new biosecurity regulations that include standards for (1) personnel reliability programs, (2) biosecurity training of responsible officials and laboratory personnel, (3) laboratory risk assessments, and (4) risk-based laboratory security performance expectations. While not appropriate for every level of biological research, these elements are vital to securing research with Tier I BSAT agents.

Personnel reliability programs, sometimes alternatively described as personnel assurance or continuous monitoring programs, play a role in ensuring that people with access to the most dangerous pathogens are not just run through a name check in databases once every five years, but are part of a program that continuously evaluates whether the person develops new restricting characteristics or extreme changes in behavior. Laboratory risk assessments identifying a particular laboratory's vulnerabilities and requirements for conducting specific research in a safe and secure manner are the cornerstone for implementing a robust security plan. Unfortunately, current practice is often variable in what is examined, the detail to which risks are identified, and who conducts the assessment. This title will help bring uniform expectations to the laboratory risk assessments that institutions conduct. Finally, based on these risk assessments, the regulations mandated by the bill would better define physical security requirements for Tier I labs eliminating much of the confusion among regulated entities due to conflicting expectations from different federal agencies.

While this legislation creates a framework for the stratification of select agents and for the development of enhanced security measures for Tier I agents, it is not prescriptive in what those measures will entail. As mentioned previously, there is a large body of work that makes numerous recommendations as to how to improve laboratory biosecurity. This legislation provides the vehicle by which those recommendations can be considered and implemented during a rulemaking process that brings the relevant stakeholders fully to the table.

Specifically, Title I directs the Secretary of Homeland Security, in consultation with the Secretaries of Health and Human Services and Agriculture, to establish Tier I biosecurity standards through a negotiated rule-making. In the negotiated rule-making, a committee of relevant parties would be assembled to seek to produce a consensus recommendation to the Secretary of Homeland Secu-

rity.<sup>54</sup> This committee would include federal agencies, academic and private research institutions, and other key stakeholders. The committee would make recommendations to the Secretary within six months of the bill's enactment, and the Secretary would promulgate a final rule within a year. The bill requires the negotiated rulemaking committee and the Secretary to consider the full spectrum of views, reports and recommendations of recent scientific and interagency working groups and how to minimize disincentives posed by security standards to biological research.

The Secretary of Homeland Security, in consultation with the Secretaries of Health and Human Services and Agriculture, would enforce the regulations promulgated for laboratories handling Tier 1 agents through issuance of regulations, guidance, and by performing inspections. These compliance efforts would include participation of HHS and USDA personnel as appropriate. While DHS is responsible for inspecting whether staff handling Tier 1 agents are in compliance with the training standards, HHS is responsible for developing or approving the training programs such staff will take, as the programs likely will apply across both biosecurity and biosafety competencies. In addition to inspections, DHS is given authority to impose civil penalties for violations of the regulations, as well as intermediate sanctions aimed at correcting deficiencies in lieu of civil penalties.

In addition to stratifying the BSAT list and putting in place security measures that are commensurate with the risk, this title includes additional measures to bring efficiency to the oversight of BSAT research and to help support institutions conducting BSAT research. The title directs agencies reviewing a BSAT research institution for regulatory or contractual compliance with the BSAT regulations to carry out those reviews jointly to the extent practicable. In order to reduce divergent or conflicting expectations among federal agencies on how to comply with the BSAT regulations, the bill directs agencies to coordinate and agree upon inspection procedures. Finally, to reduce the need for agencies to conduct redundant inspections simply due to lack of access to inspection results from another agency, this title requires that agencies inspecting for regulatory or contractual compliance share their reports with other agencies that have a vested interest in the inspected facility.

Institutions with BSAT programs often face significant costs to physically secure, monitor, and conduct the research. These costs can exceed the allowable overhead of the research grants that fund much of this research. This title establishes a DHS administered grant program to help offset additional costs that may be associated with the enhanced biosecurity measures associated with the new Tier I BSAT regulations. It also encourages the use of the DHS voluntary vulnerability assessment program that can help BSAT research institutions access the Department's expertise in evaluating site vulnerability at no cost to the institution and in a manner that preserves confidentiality.<sup>55</sup>

<sup>54</sup>The procedures for negotiated rulemakings are prescribed in the Negotiated Rulemaking Act of 1990, P.L. 101-648, 5 U.S.C. 561 et seq. (1990).

<sup>55</sup>Since the Committee consideration of this legislation, the Administration issued Executive Order 13546, Optimizing the Security of Biological Select Agents and Toxins in the United States, on July 2, 2010. Several of the measures laid out in the Executive Order are consistent with those in this legislation, including risk-based tiering of the select agent list and designation

## C. ENSURING A ROBUST RESPONSE TO A WMD ATTACK

*C.1. Background*

The government must work not only to prevent a bioterrorist or other WMD attack; it also must prepare to care for its people in the event terrorists succeed in launching such an assault. We must stand ready to quickly and comprehensively deliver so-called MCMs—medical countermeasures like antibiotics, toxin antidotes, or radiation treatments—to those in need. We must be prepared to effectively communicate what is going on and what needs to be done, both with first responders and with affected populations. And we must know how to scientifically limit the impact of any attack that occurs by having the knowledge and ability necessary to analyze, track and contain dangerous pathogens once they are released. Unfortunately, this all is something the government is not yet prepared to do.

In January 2010, the Prevent WMD Commission issued a report card grading the government's progress in implementing the Commission's December 2008 recommendations.<sup>56</sup> The Commission found improvements in a few areas, but it gave the government a highly troubling 'F' for its inability to respond quickly to and prevent mass casualties from a biological attack.<sup>57</sup> Unfortunately, the government does not dispute the basis for this grade. The government has recognized it must do more to strengthen our preparedness efforts for all WMD threats and more fully inform and engage the public in its activities as stated by Secretary of Homeland Security, Janet Napolitano, in a recent speech, "We may be better prepared as a nation than we were on 9/11, but we are nowhere near as prepared as we need to be."<sup>58</sup>

*Dispensing medical countermeasures*

Quick dispensing of the correct medicines could tremendously diminish the numbers of those injured or killed if a weapon of mass destruction hits our homeland. To the government's credit, it has long maintained a store of medicine and medical supplies, managed by the CDC and called the Strategic National Stockpile (SNS). The SNS contains rapid deployment packages that the federal government can deliver to any designated state receiving area within 12 hours with additional supplies available within 24 hours. In the

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of the most dangerous pathogens as "Tier 1" select agents; enhancing security on Tier 1 pathogens by developing standards for personnel reliability and laboratory physical security; evaluating whether biological agents that pose little or no bioterrorism risk can be removed from the select agent list; and coordinating the oversight of BSAT laboratories conducted by different Federal agencies for regulatory and contractual purposes. The Executive Order diverges significantly from this legislation, however, by giving DHS only a peripheral role in the rule making process and no clearly identified role in its implementation. The DHS role under the Executive Order is limited to participation on an interagency advisory panel chaired by HHS and USDA and leading the panel's working group on physical and cybersecurity. The interagency advisory panel was given four months to organize itself and its working groups, analyze its options, and develop consensus standards. HHS and USDA have an additional eleven months after the recommendations are submitted to develop draft regulations. Final rules are to be noticed by twenty-seven months after issuance of the Executive Order.

<sup>56</sup> Prevention of WMD Proliferation and Terrorism Report Card. Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. January 2010. Available at <http://www.preventwmd.gov/static/docs/report-card.pdf> (Last Accessed September 30, 2010).

<sup>57</sup> *Id.* at 6.

<sup>58</sup> From Homeland Security Secretary Janet Napolitano's July 29, 2009 speech before the Council on Foreign Relations entitled "Common Threat, Collective Response: Protecting Against Terrorist Attacks in a Networked World."

federal government's view, it is then up to state and local authorities to dispense the medicines to the people who need them.

Unfortunately, getting materials the last mile to those people has turned out to be the system's greatest weakness. As a 2008 Institute of Medicine-sponsored workshop found: "if we do not have the mechanisms to get these lifesaving medicines in the hands of Americans after such an attack or multiple attacks within a very short timeframe, we have squandered an opportunity to save lives."<sup>59</sup> The consensus from the workshop was that "the nation is not comprehensively prepared to mount the greatest possible defense."<sup>60</sup> The Centers for Disease Control and Prevention (CDC) has established a program called the Cities Readiness Initiative. That program has increased the dispensing capability of some cities, but covers only 72 metropolitan regions representing an estimated 57% of the U.S. population. What's more, not one of the covered metropolitan regions can yet meet the program's goal of delivering antibiotics to its entire population within 48 hours; it remains unclear how long after the attack it would take for those jurisdictions to provide treatment to their populations or if the help would come too late.<sup>61</sup> A complimentary approach involves using the U.S. Postal Service to rapidly deliver a short course of antibiotics following a biological attack to gain time for more substantial resources to be deployed. The approach has been exercised and is currently being piloted in one city but is still not deployed widely.<sup>62</sup>

#### *Establishing an effective communications system*

Just as important as getting medicines to people is informing people of how to protect themselves from a biological, chemical or radiological event. As one expert has observed, "in disaster and emergency situations, effective communication is . . . critical. The timely and effective flow of information between agencies and the public is vital for facilitating and encouraging appropriate protective actions, reducing rumors and fear, maintaining public trust and confidence, and reducing morbidity and mortality."<sup>63</sup>

To be effective and save lives, the government would need to send these messages almost immediately after the attack and that means the guidance should be pre-scripted to the greatest extent possible and distribution channels should be well established in advance. There will be no time after the weapon's release or detonation to start drafting from scratch, or to think for the first time about how to—or who will—distribute the information. Unfortunately, what efforts are underway to develop pre-scripted messages

<sup>59</sup>*Dispensing Medical Countermeasures for Public Health Emergencies: Workshop Summary*. Miriam Davis, Marnina S. Kammersall, and Bruce M. Altevogt. Forum on Medical and Public Health Preparedness for Catastrophic Events. The National Academies Press. p.31. March 3, 2008.

<sup>60</sup>*Id.* at 32.

<sup>61</sup>For a review of the program see "Initial Evaluation of the Cities Readiness Initiative" Henry H. Willis et al. Rand Corporation. 2009.

<sup>62</sup>The U.S. Postal Service (USPS) Plan has been exercised in 2006 and 2007 in Seattle, Boston, and Philadelphia with mock antibiotics being dispensed to tens of thousands of homes and took only 6–9 hours. Since 2007 HHS and USPS have run a pilot program in the Minneapolis-St. Paul area of Minnesota. The pilot is assessing the ability of the program to solicit and train postal service employees, collaborate with local law enforcement, and deploy personal medkits to USPS volunteers so they are prepared to deploy in the event of an attack.

<sup>63</sup>*Emergency Communication and Information Issues in Terrorist Events Involving Radioactive Materials*. Steven M. Becker. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science, Volume 2, Number 3, 2004.

and templates in different federal agencies are too often uncoordinated and lack the clarity that would be needed to respond to the confusion and panic that would follow a WMD attack.

Providing notice in advance of a spreading airborne (or aerosol) plume of radioactive, chemical or biological materials may provide a particularly significant opportunity to save lives. Modeling of the spread of a nuclear plume based on real-time wind patterns can be used to focus response and communications efforts not only in areas that have already been contaminated but also in those areas that will be affected in the near future. Credible and effective communications during an aerosol WMD attack will depend on identifying which areas have been affected or are at risk during an attack and making that information clearly understandable and readily distributable to the public. The federal government generates just such area predictions and analysis of health threats from dangerous spreading plumes, but it currently communicates that information in a technical manner to a limited number of recipients.<sup>64</sup> While this approach is adequate for small-scale incidents, it would likely prove too slow during a widespread terrorist incident affecting multiple localities or states. During a large-scale incident, with millions of people at risk, credible and informative products releasable by incident commanders directly to the public will be necessary. Currently those leading the response have to convert the federal government's technical maps and descriptive information into a publicly releasable form if they have the need to do so, steps which take valuable time. As a result, getting the message out about where the risk is and what protective steps the public should take could be too slow to prevent significant casualties during a large scale, fast unfolding WMD incident.

#### *Tracking down the material used in a biological attack*

In contrast to the production of conventional or nuclear weapons, it is relatively easy to generate multiple biological weapons after mastering the first due to the ability of microorganisms to rapidly reproduce. This trait means that it is perhaps more likely that we would face a campaign of bioterrorist attacks, not just a single incident. As a result, as the government grapples with the massive public health response to a biological attack, it must simultaneously examine the attack and weapons material in an effort to identify the perpetrators before more attacks follow.

Bioforensics, also referred to as microbial forensics, is defined as the scientific discipline dedicated to analyzing evidence from a bioterrorism act, biocrime, or inadvertent microorganism/toxin release to support "attribution" (*i.e.*, to identify the perpetrators). Alongside traditional forensic and investigative techniques, bioforensics can provide information needed by law enforcement to catch a bioterrorist group by shedding light on what pathogen is being used in the attack, its defining characteristics, and its origin. Unfortu-

<sup>64</sup> Incident commanders and other officials responding to an aerosol event can request plume models from the DHS Interagency Modeling and Atmospheric Assessment Center (IMAAC) located at Lawrence Livermore National Laboratory in Livermore, California, which has been designated as the single point for the coordination and dissemination of Federal modeling products. The IMAAC is able to provide maps, reports, and interpretation guides that include detailed information such as where hospitals are located in relation to hazardous areas. They can also generate models that delineate areas of life threatening effects, long term effects, and areas of notable discomfort based on criteria defined by national standards. The IMAAC also has quick access to subject matter experts at the national labs and federal agencies.

nately, much of the science behind the forensic analysis of biological attacks is relatively new, having largely been developed during the investigation of the 2001 anthrax attacks.<sup>65</sup> The Prevent WMD Commission recommended strengthening the nation's bioforensic capability by developing a national strategy to further the scientific field of bioforensics, establishing a comprehensive library of pathogen reference strains, and clearly identifying the roles and responsibilities of federal agencies.<sup>66</sup>

*C.2. Title II of the WMD Prevention and Preparedness Act of 2009—Response to a WMD Attack*

Title II enhances the nation's ability to minimize mass casualties from WMD attacks by ensuring that we will have systems in place to get life-saving medications into victims' hands and provide critical protective information to people in the vicinity of an attack. This title also advances the government's bioforensic capabilities to support attribution and prevention of follow-on attacks.

Title II directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and the Postmaster General, to develop a national strategy for improving our ability to dispense medical countermeasures (such as antibiotics needed to respond to an anthrax attack) to individual citizens. This strategy will describe federal agencies' roles generally and the assistance the federal government will provide to State, local, and tribal governments for MCM dispensing. The strategy will include a variety of elements, such as a staffing plan, requirements for timeliness of MCM dispensing, security, transportation, and communications to the public regarding how to obtain MCMs. To ensure as rapid a response as possible, the strategy is to be tailored to local communities participating in the Cities Readiness Initiative and representative localities of varying geographic sizes, population densities, and demographics to account for features unique to those communities *before* they are faced with a WMD attack.<sup>67</sup>

Title II requires a multi-pronged approach to building MCM dispensing capability in local towns and cities. In the first such approach, the legislation implements or expands federal programs for disseminating MCMs after an attack and requires the government to develop and implement a national strategy. Title II expands an existing pilot program for using the Postal Service to deliver MCMs to five additional cities within one year and fifteen additional cities within two years. It is expected that such a program could eventually be expanded to cover the entire nation. To help reduce the burden on public dispensing sites in the communities that host those federal agencies and to ensure that the federal government is able to continue critical operations in a WMD attack, Title II also di-

<sup>65</sup> Bioforensics, also referred to as microbial forensics, has been defined as the scientific discipline dedicated to analyzing evidence from a bioterrorism act, biocrime, or inadvertent micro-organism/toxin release for attribution purposes. For a discussion of establishing the definition and capability see Budowle et. al., "Building Microbial Forensics as a Response to Bioterrorism," *Science* 301, at 1852, September 2003.

<sup>66</sup> *World at Risk* at 29.

<sup>67</sup> While elements of MCM dispensing strategy have been captured in the Cities Readiness Initiative, there has yet to be formulated a comprehensive strategy that accounts for all of the critical elements necessary to ensure an effective response, such as redundant methods of delivery, protecting communities of differing composition, health and liability protection of MCM dispensing providers, communications with the public, or security of material and personnel among other key issues.

rects executive agencies to develop plans to dispense MCMs to their employees.<sup>68</sup>

Because there is no faster response available than to have MCMs pre-positioned where they will be needed, Title II expands the use of “medkits,” small packages of antibiotics—and conceivably other medical countermeasures—that can be stored in the home or workplace to be used in case of a WMD incident. Use of such medkits could allow first responders to immediately respond to an incident without additional fear of personal harm and they also could serve to buy time for more robust, but slower, dispensing centers to be established to handle greater numbers of people. This legislation will place medkits in the workplaces and homes of emergency response providers, allowing them to react quickly to a bioterrorist event by protecting themselves and their families from undue risk. This program, similar to that for postal employees in the U.S. Postal Service MCM dispensing program, would provide for the education and health screening of first responders participating in the program and track the proper usage of the medkits. Title II would also authorize a large pilot study of the feasibility of making such a program available to the general population, something that could save valuable response time in the aftermath of a WMD attack. The study would be larger and more comprehensive than studies conducted previously and would assess whether participants are properly trained on the maintenance and use of medkits in the home.<sup>69</sup>

Finally, Title II tasks the federal government with helping the private sector develop its own MCM dispensing plans through the distribution of best practices guidance. Large companies with many employees could help reduce the burden on surrounding communities by ensuring that their employees can access company-based dispensing systems. Large employers often have on-site medical personnel that would expand the number of specialists in any given community to dispense medical countermeasures. Moreover, with most of the nation’s critical infrastructure owned and operated by the private sector, having an on-site dispensing capability would aid the overall response as these facilities would continue to operate and provide critical services.

To ensure that the population is rapidly informed of life saving information in an effective manner, Title II also directs the FEMA Administrator, in consultation with other Federal, State, local, and tribal officials, to develop pre-scripted messages and message templates that provide information quickly to affected populations

<sup>68</sup> Since the Committee consideration of this legislation, the Administration issued an Executive Order 13527, mandating steps comparable to these two requirements (but not addressing the other components of the legislation’s multi-pronged strategy). *Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack* (December 30, 2009). The Executive Order directs the Department of Health and Human Services (HHS) and the U.S. Postal Service (USPS) to set up a national system using postal service employees to dispense MCMs to homes at risk from a large-scale biological attack. The Executive Order instructs the Secretaries of Homeland Security and Defense, and the Attorney General to support this effort by developing an accompanying plan to supplement local law enforcement personnel to escort the USPS workers delivering medical countermeasures. Additionally, the Executive Order calls for all federal agencies to develop plans to provide MCMs to their own employees. The Executive Order is available at <http://edocket.access.gpo.gov/2010/pdf/2010-38.pdf> (Last Accessed September 30, 2010).

<sup>69</sup> In 2006 the Centers for Disease Control and Prevention ran a pilot program in St. Louis Missouri to assess whether participants would correctly store and use a home medkit. The overwhelming majority of study participants appropriately followed instructions and only used the kit as directed by public health officials.

after natural disasters, acts of terrorism, and other man-made disasters. The bill requires the messages to be developed in multiple formats to ensure delivery when usual communications infrastructure is unavailable. It would also require the drafters to ensure effective communication with individuals with disabilities or other special needs.

Title II also ensures that in the event of a spreading aerosol plume of radioactive, chemical or biological materials, the federal government's modeling efforts are integrated with guidance instructing the public about how to protect itself. Importantly, these products are to be made available in a publicly releasable form that the incident manager leading the response effort can disseminate directly if the need arises. This step ensures that the best guidance available from the government's labs and health experts is quickly communicated to the public, without timely conversion, while not circumventing the centralized command structure needed to maintain an orderly response.

As was observed during the anthrax attacks of 2001, we need to prepare for a series of related bioterrorist attacks not just one or two. This title authorizes a National Bioforensics Analysis Center at DHS to serve as the lead federal facility for technical forensic analysis following a bioattack. It establishes a repository collection to provide samples that will enable the advancement of bioforensic science and the development of sample testing materials. This section also directs the Secretary of Homeland Security to develop a National Bioforensics Strategy laying out federal agencies' roles in analyzing bioforensic evidence, coordination with State, local, and tribal governments, and development of collection standards.<sup>70</sup>

#### D. CONFRONTING THE INTERNATIONAL BIOLOGICAL WMD THREAT

##### *D.1. Background*

Advances in biotechnology are taking place worldwide, bringing with them great promise for advancing public health, alternative energy production, and material manufacturing sciences. These advances also mean that the equipment and knowledge needed to employ biotechnology for both peaceful and malicious intents alike are also widespread. As a result, any efforts we take to safeguard the nation domestically must address vulnerabilities internationally and include efforts to secure dangerous pathogen stocks overseas, enhance foreign disease outbreak response and preparedness capabilities, and support international exchanges of public health and biodefense information and experts.

The attempts by al-Qaeda and Aum Shinrikyo to develop and deploy anthrax bioweapons underscore that the intention to carry out bioterrorist acts exists in both well known adversaries and in previously unrecognized threat groups. With international travel now

<sup>70</sup> Since the Committee's consideration of this legislation the Administration has developed the U.S. National Research and Development Strategy for Microbial Forensics (November 2009). The strategy appears to largely meet the objectives of this legislation and includes common elements including: coordination of Federal microbial forensics research and practices, development of new diagnostic capabilities, and creation of a reference national bioforensics repository collection. It lacks an important detail, however, in that it does not clearly specify the roles and responsibilities of the different Federal agencies, which could lead to bureaucratic battles over leadership or to capability gaps for which no agency claims responsibility. <http://www.whitehouse.gov/files/documents/ostp/NSTC%20Reports/National%20MicroForensics%20R&DStrategy%202009%20UNLIMITED%20DISTRIBUTION.pdf> (last accessed September 30, 2010).



so widespread, an attack with an infectious pathogen would rapidly spread across borders. As the National Security Council has stated, “A biological incident that results in mass casualties anywhere in the world increases the risk to all nations from biological threats”<sup>71</sup>

The more developed public health systems of the U.S. and many other developed nations give them an advantage when mitigating the threat of both bioterrorism and infectious disease. Effective disease surveillance systems help public health officials respond to an outbreak of disease initiated by terrorists the same way as they would for a pandemic influenza outbreak. Experienced epidemiologists with access to modern diagnostic equipment allow the ability to identify and generate samples of the causative agent from either type of outbreak.

Unfortunately, the public health systems in developing countries do not possess the same attributes. As a result, there is a larger global risk, including to the U.S., regardless of whether the threat is natural or man-made. This point was brought home during the 2009 H1N1 outbreak, when the CDC had to scramble to help establish public health laboratories, diagnostic capacity, and provide antiviral medications in Mexico to help stem the onslaught of new cases occurring in the U.S. as the disease spread alongside widespread commerce and travel between the two countries. The World Health Organization (WHO) concluded that over 60 percent of laboratory equipment in developing countries was either outdated or non-functioning. Further, the vast majority of foreign national personnel were not familiar with principles of quality assurance for handling and analyzing biological samples. Deficiencies in training and equipment meant that many public health units in Africa and Asia were unable to perform accurate and timely disease surveillance.<sup>72</sup>

The Prevent WMD Commission noted that international public health measures, such as disease surveillance, are critical to defending against the development and use of biological weapons worldwide. It made numerous recommendations to facilitate broad international involvement in support of measures for public health and biosecurity.<sup>73</sup>

#### *A global approach to biosecurity*

There are several key international agreements and documents that shape international efforts to contain and counter the threat of bioterrorism. The Prevent WMD Commission recommended renewing and strengthening these international agreements.<sup>74</sup>

The 1972 Biological and Toxin Weapons Convention (BWC) is the foundation of international efforts to prevent the weaponization of biological agents and to keep them out of the hands of terrorists.<sup>75</sup> The treaty bans the development, production and acquisition of these weapons as well as the delivery systems to disperse such tox-

<sup>71</sup>*National Strategy for Countering Biological Threats*. National Security Council. November 2009, at 3.

<sup>72</sup>*Global Health: Challenges in Improving Infectious Disease Surveillance Systems*. United States General Accounting Office. GAO-01-722 (August 2001), at 3.

<sup>73</sup>*World at Risk* at 34-42.

<sup>74</sup>*Id.* at 34.

<sup>75</sup>Text of the BWC and proceedings of the BWC review conferences can be found at <http://www.opbw.org/> (last accessed December 2, 2010).

ins. However, the BWC's lack of a formal verification mechanism has rendered the treaty ineffective at identifying and holding violating nations accountable. Both the Prevent WMD Commission and the National Strategy for Countering Biological Threats call for revitalization of the BWC as a critical part of international efforts to stop the proliferation of biological weapons and an important link between global security and public health systems.<sup>76</sup>

The World Health Organization (WHO) coordinates disease surveillance and information sharing efforts for participating countries so that disease outbreaks can be identified and public health responses can be launched to contain their spread. The International Health Regulations (IHR), issued by the WHO, legally bind the 194 signatory countries, including all the Member States of the WHO.<sup>77</sup> The IHR require countries to report certain disease outbreaks and public health events to the WHO. The IHR define the rights and obligations of countries that report public health events and require countries to strengthen their existing public health surveillance and response capabilities. However, timeliness of reporting varies, decreasing the effectiveness of the surveillance program.<sup>78</sup>

Controls on the export of technologies or materials that could be misused for bioterrorism are managed through an informal assemblage of 40 countries called the Australia Group. The Australia Group, of which the United States is a member, maintains lists of controlled technologies and biological pathogens that require licensing for shipping outside of the Australia Group countries.<sup>79</sup>

Most recently, the Administration's 2009 "National Strategy for Countering Biological Threats" placed a primary focus on strengthening international public health and notes that efforts to reduce the risk of biological threats have a global benefit. The strategy is intended to reduce biological threats by improving global access to tools to combat infectious diseases; establish and reinforce standards to discourage the misuse of the life sciences; and institute a series of activities to help influence, identify, inhibit and interdict those who seek to harm others through the misuse of life sciences.<sup>80</sup>

#### *D.2. Title III of the WMD Prevention and Preparedness Act of 2009—International Measures to Prevent Biological Terrorism*

Title III of the WMD Prevention and Preparedness Act strengthens efforts to prevent the international proliferation of biological weapons. It encourages the United States to collaborate with other countries to improve cross-border and internal biosecurity efforts and includes provisions to improve global surveillance of dangerous agents. It fosters critical partnerships with foreign public health systems that would be necessary to share samples, provide surge response forces, and assist in identifying the origin of an attack or pandemic.

<sup>76</sup> *World at Risk* at 41. National Strategy for Countering Biological Threats. National Security Council. November 2009, at 19.

<sup>77</sup> Text of the IHRs are available at [http://whqlibdoc.who.int/publications/2008/9789241580410\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf) (last accessed December 2, 2010).

<sup>78</sup> *World at Risk* at 37.

<sup>79</sup> Report of the Working Group on Strengthening the Biosecurity of the United States, at 10.

<sup>80</sup> National Strategy for Countering Biological Threats. National Security Council. November 2009, at 3.

Subtitle A provides for the prevention and protection against international biological threats. It requires the Director of National Intelligence to assess the international threats, and directs the Secretary of State to work with countries to raise awareness of biological threats internationally and assist those countries deemed a high priority with mitigating threats. The Secretary will also develop a strategy to ensure that international agreements regarding WMDs are widely adhered to and to create safeguards to prevent the misuse of biotechnology.

Subtitle B, the “Global Pathogen Surveillance Act of 2009”, seeks to enhance the international community’s ability to detect, identify, and contain infectious disease outbreaks, whether the cause of those outbreaks is intentional or natural in origin.<sup>81</sup> Its objective is to expand U.S. assistance to developing nations in the following areas: the training of public health personnel in epidemiology, particularly the diagnosis and containment of likely bioterrorism agents; the acquisition of laboratory and diagnostic equipment; the acquisition of communications technology allowing for the rapid dissemination of data regarding disease patterns and pathogen diagnoses to public health authorities and international entities; the expansion of facilities overseas by the CDC and the Department of Defense to conduct research and disease surveillance, with the approval of the host country; and, expanded assistance to the WHO and other regional disease surveillance efforts.

Subtitle C of Title III strengthens the ability of the United States to confront the threats of nuclear nonproliferation. This subtitle requires the President’s Coordinator for the Prevention of WMD Proliferation and Terrorism, established in the Implementing Recommendations of the 9/11 Commission Act, to make an annual report on U.S. nonproliferation efforts and the U.S. nonproliferation efforts in working with the International Atomic Energy Agency (IAEA).<sup>82</sup> It specifically addresses a series of findings and recommendations from the Prevent WMD Commission regarding the revitalization of the Nuclear Nonproliferation Treaty (NPT). Over time, the nonproliferation regime in the NPT has eroded and the International Atomic Energy Agency’s financial resources have fallen far short of what is required to fulfill its expanding mandate.<sup>83</sup>

Subtitle D of Title III would implement Title V of the Nuclear Non-Proliferation Act of 1978 (Public Law 95–242), which requires greater U.S. assistance in establishing non-nuclear, alternative energy sources in developing countries. This would implement a key recommendation of the Prevent WMD Commission’s *World at Risk* report.<sup>84</sup> The Secretary of Energy, in cooperation with the Secretary of State and the Administrator of the United States Agency for International Development, would be required to establish strategic and implementation plans for the energy development program established under Title V of the Nuclear Non-Proliferation Act. The Secretary of Energy would be required to report annually

<sup>81</sup> The Global Pathogen Surveillance Act of 2009 is derived from similarly titled bills drafted by the Senate Foreign Relations Committee and passed by that Committee in 2008, 2007, 2005, 2004, 2003, and 2002 and by the full Senate in 2005 and 2002.

<sup>82</sup> The President’s Coordinator for the Prevention of WMD Proliferation and Terrorism was established under section 1841 of the Implementing Recommendations of the 9/11 Commission Act, P.L. 110–53, 121 Stat. 498, 50 U.S.C. § 2931 (2007).

<sup>83</sup> *World at Risk* at 46.

<sup>84</sup> *Id.* at 51.

on the efforts and commitments under this program and consider the feasibility of expanding cooperative activities to include a volunteer Alternative Energy Corps.

#### E. ORGANIZING GOVERNMENT TO RESPOND EFFECTIVELY

##### *E.1. Background*

The Prevent WMD Commission identified three key areas in which government organization should be improved in order to strengthen the U.S. Government's capacity to prevent and prepare for a WMD attack. The first two areas pertain to U.S. intelligence capabilities, while the third relates to advice provided to Congress concerning counterterrorism technology.

With respect to intelligence, the WMD Commission stated that "praise is warranted to Congress for its efforts to push intelligence community reforms" beginning with the Intelligence Reform and Terrorism Prevention Act of 2004 and to agencies for their subsequent work including initiatives at the National Counterterrorism Center, the DNI's 500 Day Plan for Intelligence Community reform, and the revision to the cornerstone of the Intelligence Community's regulatory structure, Executive Order 12333. However, the Commission found that the number and diversity of WMD-related targets are increasing and that (1) such targets are especially challenging for traditional collection techniques and (2) intelligence analysts lack the requisite scientific and technical expertise. The Commission also noted that engagement with outside experts is particularly important in the biological area because of the speed of advancements. Finally, the Commission noted that the increase in the number of codeword compartments—an additional restriction placed on top secret information to further limit the number of people with access to it—in the Intelligence Community for WMD-related intelligence hinders information-sharing. Accordingly, the Commission recommended that the Intelligence Community prioritize efforts to collect and analyze intelligence related to the nexus of WMD and terrorism, with an emphasis on recruiting employees with scientific and technical expertise and ensuring information-sharing.<sup>85</sup>

Also with respect to intelligence, the WMD Commission found that human intelligence collection requires that intelligence personnel have the necessary language skills and ethnic and cultural backgrounds to gain access to communities in which terrorists operate. The Commission noted that significant strides have been made to recruit individuals with such skills, including adoption of the Intelligence Community's Foreign Language Strategic Program in 2003 and gains in language capabilities made by the Central Intelligence Agency. However, the Commission found that the Intelligence Community is still deficient in this area and recommended that the Intelligence Community accelerate its recruitment and retention efforts, with a focus on clearing any security clearances barriers.<sup>86</sup>

In addition, the Commission found that the interdisciplinary nature of WMD and counterterrorism issues cuts across relevant Congressional committees' jurisdiction. Moreover, the Commission rec-

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<sup>85</sup>*Id.* at 99.

<sup>86</sup>*Id.* at 99.

ommended that Congress strengthen its oversight and legislative functions by consulting closely with experts versed in relevant scientific and technical disciplines. Accordingly, the Commission recommended that Congress create an office in the Legislative Branch to serve as the repository of counterterrorism scientific and technical knowledge in order to advise Members and Committees.

*E.2. Title IV of the WMD Prevention and Preparedness Act of 2009—Government Organization*

Title IV implements the Commission's recommendations to improve Intelligence Community capabilities concerning WMD and terrorism. Title IV requires the DNI to adopt a strategy to improve the Intelligence Community's performance regarding WMD intelligence. Specifically, this strategy should include hiring scientists, collaborating with nongovernmental experts, developing innovative collection techniques against countries and transnational actors such as criminal enterprises, and improving information-sharing. Title IV also requires the DNI to develop a strategy for recruiting employees with critical language skills and cultural backgrounds relevant to counterterrorism based on predicted needs over a ten-year time frame. Among other things, that strategy should remedy security clearance barriers to recruitment of such individuals.

Title IV ensures that each of these two strategies will be systematic and articulate a measurable course of action. Title IV mandates that each strategy contain five process elements, including prioritized objectives and a schedule for meeting them; assignment of roles and responsibilities in the Intelligence Community; a description of the personnel and financial resources necessary to implement the strategy; metrics to measure efficiency and effectiveness; and a schedule for assessing the strategy.

Finally, Title IV implements the Commission's recommendation to strengthen the science and technical advisory capabilities available to Congress. Title IV uses a three-tiered approach—utilizing existing organizations rather than creating an expensive new Legislative Branch office—to provide Congress with assessments of technology and technological applications relevant to counterterrorism. First, Title IV requires the Congressional Research Service (CRS) to establish an interdisciplinary capability in order to be able to supplement the advice that CRS normally provides to Congress with advice concerning counterterrorism technology and technological applications. Second, Title IV requires the Government Accountability Office (GAO) to form its own interdisciplinary capability to conduct assessments of counterterrorism technology or technological applications to include their actual or anticipated impact, effectiveness, or efficiency as well as any test results, technological alternatives, actual and anticipated costs and benefits, and actual or anticipated countermeasures. Third, Title IV authorizes GAO to contract with the National Academy of Sciences to provide long-range assessments of counterterrorism technological trends and gaps as well as advice concerning needed investments. Title IV authorizes \$2 million per year for each fiscal year 2011–2013 for each of CRS, GAO, and GAO's funding of related studies by the National Academy of Sciences.

## F. EMPOWERING CITIZENS AND COMMUNITIES IN THE RESPONSE

*F.1. Background*

The first person on the scene of an incident to help those in need is not likely to be a federal strike team member or even a local emergency response provider, but rather a neighbor or co-worker who will provide assistance in those critical first few moments. Local first responders will next be responsible for shouldering most of the burden of the response alone from the first hours through the beginning days of the response and likely will provide the bulk of the response during the entire incident. While some federal response providers likely will arrive on scene in the first day of a catastrophic incident, several days will likely pass before significant federal capabilities arrive. In short, logistical realities suggest that individual citizens and communities will form the cornerstone of any response effort.

The Prevent WMD Commission appropriately stressed the criticality of citizens' roles in preventing and responding to terrorism involving WMD. As the Commission noted, "A well-informed and mobilized citizenry has long been one of the United States' greatest resources."<sup>87</sup> To that end, the Commission recommended increasing public education concerning the nature of WMD and terrorism threats, what they should expect from the government in the event of a crisis, and what advance preparations and actions they should take.

*F.2. Title V of the WMD Prevention and Preparedness Act of 2009—Emergency Management and Citizen Engagement*

Title V seeks to strengthen citizen involvement and preparedness by requiring that the government practice greater openness of public information. Title V requires the Secretary of Homeland Security, in coordination with the Attorney General, to provide unclassified terrorism-related threat and risk assessments to the public on a timely basis. These assessments should include guidelines for the public to prevent and respond to terrorism. The title also requires the Secretary of Homeland Security to provide guidelines to State, local, and tribal governments on disseminating information concerning terrorism threats and risks to the public.

In this vein, Title V amends section 201 of the Homeland Security Act of 2002, as amended, which institutes the Homeland Security Advisory System, to ensure that the Secretary provides information to the public for deterring and responding to terrorism. The Committee has had long-standing concerns regarding DHS's implementation of the Homeland Security Advisory System. Due to these concerns, Title V requires that DHS submit a report to the Senate Homeland Security and Governmental Affairs Committee and the House Homeland Security Committee within 180 days of the enactment of this bill on implementation of the Homeland Security Advisory System.

Title V provides emergency response providers with the guidance they need to protect themselves and the citizens of their community during a WMD incident. An explosion or release of nuclear, biological, radiological, or chemical material will pose unique chal-

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<sup>87</sup> *World at Risk* at 108.

allenges to first responders if the expertise to deal with the incident safely and effectively lies outside of the affected local community. Title V ensures that the expertise that exists in emergency response organizations, in different communities across the nation, and in our national labs and federal agencies is put to use to develop best practices and guidelines for use in any community during an incident before we are faced with such an attack. The guidelines compiled or developed pursuant to Title V will provide descriptive information on the effects of different WMD threats and recommendations for protective actions to ensure the health and safety of emergency response providers. They will also address how emergency response providers and mass care facilities can care for citizens affected by the incident who may have needs unique to the threat, such as radioactive or biological contamination. The title requires the Secretary of Homeland Security to evaluate current guidance documents generated by nongovernmental organizations or government agencies for their applicability to this purpose and to identify gaps where new guidance needs to be developed. This guidance is to be updated regularly to capture the best practices in the field as it evolves.

Of course, a rapid response relies on strong communities and the preparedness organizations that provide the first responders on the scene. Title V assists communities in identifying their preparedness capabilities and gaps through the development of guidance documents and checklists. It fosters outreach efforts to communities and individuals to provide information and training to all hazard threats. It also provides for support of voluntary community preparedness programs, such as the Community Emergency Response Teams, Fire Corps, Medical Reserve Corps, Volunteers in Police Service, USAonWatch-Neighborhood Watch, and other voluntary programs. It authorizes the FEMA Administrator to provide \$15 million in such grants in FY2011 and \$20 million in each of FY2012 and FY2013.

### III. LEGISLATIVE HISTORY

Chairman Lieberman and Ranking Member Collins introduced S. 1649 on September 8, 2009. The bill was read twice and referred to the Committee on Homeland Security and Governmental Affairs. Senators McCaskill, Robert Bennett (UT), and Michael Bennet (CO) subsequently joined as cosponsors.

The Committee held a hearing to discuss the bill on September 22, 2009, entitled “*World At Risk: The Weapons of Mass Destruction Prevention and Preparedness Act of 2009*.”<sup>88</sup> Witnesses included: The Honorable Bob Graham, Chairman, and The Honorable Jim Talent, Vice Chairman, of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, and Gregory D. Kutz, Managing Director of Forensic Audits and Special Investigations, U.S. Government Accountability Office. At the hearing, former Senators Graham and Talent called for passage of S. 1649 to fulfill many of the recommendations contained in their re-

<sup>88</sup>The Committee had previously heard from the Commission’s Chair and Vice-Chair, as well as other Commission members during a hearing on December 11, 2008, entitled “*World at Risk: A Report from the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*.” The Commission members’ testimony regarding their findings and recommendations significantly informed the drafting of S. 1649.

port. Gregory Kutz testified on the limited improvement that laboratories designed to handle the most dangerous pathogens had made in improving their external physical security since the GAO's initial report (GAO-08-1092, GAO-09-851).<sup>89</sup>

The Committee considered S. 1649 on October 28, 2009 and November 4, 2009, and adopted several amendments by voice vote:

- Lieberman-Collins substitute amendment that clarified the stratification of the Select Agent Program into three tiers, contained provisions to clarify the roles for agencies, and required increased interagency coordination—including references to the Secretary of Defense and other Cabinet secretaries, clarified numerous definitions, lowered authorization amounts in several sections, and made numerous technical changes. Senators present were Lieberman, Levin, Akaka, Pryor, McCaskill, Collins, Voinovich, and Graham.

- An Akaka amendment requiring the Secretary of Energy to provide implementation plans for an Energy Development Program to support the development of non-nuclear, alternative energy sources in developing nations and strengthen international efforts to prevent nuclear proliferation consistent with Title V of the Nuclear Non-Proliferation Act of 1978. Senators present were Lieberman, Levin, Akaka, Pryor, Collins, and Graham.

- An Akaka amendment, as modified, requiring reports on U.S. nuclear nonproliferation efforts and on U.S. involvement with the International Atomic Energy Agency. Senators present were Lieberman, Levin, Akaka, Pryor, Collins, and Graham.

- A McCaskill amendment authorizing the Secretary of Homeland Security to suspend research at any lab found to have violated the department's biosecurity regulations governing the most lethal (Tier I) agents, if the violations endangered security, until the vio-

<sup>89</sup> This legislation also responds to this Committee's own analysis of the threat of bioterrorism. Committee staff conducted extensive outreach to numerous scientific organizations and all relevant federal agencies prior to drafting this legislation in order to examine the issue of biosecurity and WMD preparedness—and subsequently to review and refine drafts of the legislation. Committee staff met or consulted with, for example, representatives of the American Association for the Advancement of Science, the American Society for Microbiology, the Federation of American Societies for Experimental Biology, the Biotechnology Industry Organization, the American Biological Safety Association, Galveston National Laboratory, the Center for Biosecurity, the International Association of Fire Chiefs, and numerous private companies among others.

The Committee has also conducted extensive oversight and investigative work—under the leadership of chairmen from both parties—concerning U.S. counterterrorism performance and the WMD threat since September 11, 2001. Among its numerous hearings concerning the threat of global terrorism to the homeland, the Committee has held a series of hearings on the danger of nuclear terrorism and our preparedness for a possible nuclear terrorist attack. These hearings were the result of an investigation into U.S. preparedness for and defenses against nuclear terrorism, involving numerous briefings from and interviews with key Executive Branch personnel across the Departments of Homeland Security, Energy, and Defense. See hearings before the Senate Committee on Homeland Security and Governmental Affairs, e.g., *Nuclear Terrorism: Assessing the Threat to the Homeland*, April 2, 2008; *Nuclear Terrorism: Confronting the Challenges of the Day After*, April 15, 2008; *Nuclear Terrorism: Providing Medical Care and Meeting Basic Needs in the Aftermath*, May 15, 2008; *Nuclear Terrorism: Providing Medical Care and Meeting Basic Needs in the Aftermath—The Federal Response*, June 26, 2008; *The Global Nuclear Detection Architecture: Are We Building Domestic Defenses That Will Make the Nation Safer?*, July 16, 2008; *Preventing Nuclear Terrorism: Hard Lessons Learned From Troubled Investments*, September 25, 2008; *Nuclear Terrorism: Strengthening Our Domestic Defenses, Part I*, June 30, 2010; and *Nuclear Terrorism: Strengthening Our Domestic Defenses, Part II*, September 15, 2010. The Committee has also conducted oversight and hearings concerning our preparedness for a pandemic, whether naturally occurring or the result of a biological attack. See hearings before the Senate Committee on Homeland Security and Governmental Affairs, e.g., *Six Years After Anthrax: Are We Better Prepared to Respond to Bioterrorism?*, October 23, 2007; *Swine Flu: Coordinating the Federal Response*, April 29, 2009; *H1N1 Flu: Protecting Our Community*, September 21, 2009; *H1N1 Flu: Monitoring the Nation's Response*, October 21, 2009; and *H1N1 Flu: Getting the Vaccine to Where It Is Most Needed*, November 21, 2009.



lation has been remedied. Senators present were Lieberman, Levin, Akaka, Pryor, McCaskill, Collins, and Graham.

- A Graham amendment, as modified, directing HHS, in coordination with DHS, to promulgate regulations on handling portions of smallpox DNA (known scientifically as Variola virus). Senators present were Lieberman, Levin, Akaka, Pryor, Collins, and Graham.

- A Graham amendment requiring the National Academies' Institute of Medicine to conduct a study of the feasibility of supplying medical countermeasures from the Strategic National Stockpile that are about to expire to first responders. Senators present were Lieberman, Levin, Akaka, Pryor, Collins, and Graham.

The Committee ordered the bill, as amended, reported favorably on November 4, 2009 by a roll call vote of 8–1. Senators Lieberman, Akaka, Carper, Pryor, Landrieu, Burris, Collins, and Bennett (UT) voted in favor of the bill, while Senator Levin voted against it. Senators McCaskill, Tester, Kirk, and Graham asked to be recorded in favor of the bill by proxy, while Senators Coburn and Voinovich asked to be recorded against the bill by proxy.

#### IV. SECTION-BY-SECTION ANALYSIS

##### *Section 1. Short title; and table of contents*

This section gives the bill the short title of the “Weapons of Mass Destruction Prevention and Preparedness Act of 2009” or the “WMD Prevention and Preparedness Act of 2009” and provides its table of contents.

#### Title I—Enhanced Biosecurity

##### *Section 101. Designation of Tier 1 agents*

This section amends the sections of the Public Health Service Act and the Agriculture Bioterrorism Protection Act of 2002 that established the Select Agent Program. The Secretaries of Health and Human Services and Agriculture are directed to establish a Tier I designation for the small number of select agents with clear potential to be used effectively in a biological attack and that could cause significant human casualties or catastrophic agricultural consequences. The creation of a Tier I category allows for the directed application of enhanced security measures promulgated pursuant to the section 102.

Subsection 101(a) amends section 351A of the Public Health Service Act (42 U.S.C. § 262a) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to designate by rule “Tier 1 agents.” The provision directs the secretaries to consider several criteria in designating biological agents and toxins as Tier 1 agents, including whether the Secretary of Homeland Security has issued a Material Threat Determination regarding the agent or toxin, relevant biological risk assessments conducted by DHS or other agencies and whether the agent or toxin has the clear potential to be used effectively in a biological attack that causes significant casualties. The list of Tier 1 agents is to be reviewed at least biennially.

Subsection 101(b) amends section 212(a) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(a)) regarding the

designation of agricultural “Tier 1 agents” in an analogous manner to that done for human health “Tier 1 agents” in section 101(a). The Secretary of Agriculture, in coordination with the Secretary of Homeland Security is to designate by rule “Tier 1 agents”. Several criteria will be considered in designating biological agents and toxins as Tier 1 agents including issuance of a Material Threat Determination regarding the agent or toxin by the Secretary of Homeland Security, relevant biological risk assessments conducted by DHS or other agencies, and whether the agent or toxin has the clear potential to be used effectively in a biological attack that causes catastrophic consequences. The list of Tier 1 agents is to be reviewed at least biennially.

*Section 102. Enhanced biosecurity measures*

This section enhances the biosecurity standards for laboratories handling Tier I agents while leaving the other aspects of the current Select Agent Program, such as biosafety, in effect as they exist today. The provision sets forth categories of security protections that should be considered—including staff training, personnel reliability, laboratory risk assessments, risk based laboratory security performance standards—but does not prescribe what those security standards should be. Instead, this section creates the framework for the development of such standards by DHS through a process with maximum participation of government and nongovernmental stakeholders.

Specifically, this section directs the Secretary of Homeland Security, in consultation with the Secretaries of Health and Human Services and Agriculture, to establish Tier I biosecurity standards through a negotiated rule-making. In a negotiated rule-making, a committee of relevant parties is assembled to seek to produce a consensus recommendation to the Secretary of Homeland Security. This committee will include Federal agencies, academic and private research institutions, and other key stakeholders. The committee would make recommendations to the Secretary within six months of the bill’s enactment, and the Secretary would promulgate a final rule within a year. The provision directs the negotiated rulemaking committee and the Secretary to consider the full spectrum of views, reports and recommendations of recent scientific and interagency working groups, and how to minimize disincentives posed by security standards to biological research.

The Secretary of Homeland Security, in consultation with the Secretaries of Health and Human Services and Agriculture, would enforce the regulations promulgated under this section. Training programs, which will be broadly applicable across both biosecurity and biosafety concerns, are to be developed or approved by the Secretary of Health and Human Services. This section provides for civil penalties for violations of the regulations, as well as for intermediate sanctions for correcting lesser deficiencies in lieu of civil penalties.

To minimize the financial and administrative burden on laboratories subject to often redundant inspections by multiple agencies, this section requires that all inspections related to Tier I or select agent regulations by a regulatory agency or an agency evaluating biosecurity measures pursuant to a contractual obligation shall, to the extent practicable, be conducted simultaneously and with har-

monized procedures. This section also directs that agencies inspecting for regulatory or contractual purposes share their reports with other agencies with a regulatory or contractual interest in order to reduce redundant inspections that arise for lack of access to inspection results from another Federal agency. These measures intend to foster a unified Federal inspection team and keep agencies from imposing conflicting demands on an evaluated laboratory.

Subsection 102(a) provides definitions for this section. “Listed agents” are those biological agents or toxins that populate the current select agent list and are defined by inclusion on the list established and maintained by the Secretary of Health and Human Services under section 351A(a)(1) of the Public Health Service Act (42 U.S.C. § 262a(a)(1)); or the list established and maintained by the Secretary of Agriculture under section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(a)(1)). The term “person” has the meaning given that term in section 351A(l)(6) of the Public Health Service Act (42 U.S.C. § 262a(l)(6)) and includes individuals or entities seeking to access select agents, including Federal, State, and local governmental and private entities. The term “Tier 1 agent” has the meaning given to it in section 101 of this Act.

Subsection 102(b) mandates a negotiated rulemaking through which the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, establishes enhanced biosecurity measures for persons that possess, use, or transfer Tier 1 agents. It requires rules addressing standards for (1) personnel reliability programs, (2) biosecurity training of people involved in the use of Tier 1 agents, (3) performing laboratory risk assessments, (4) risk based performance measures for laboratory security, and (5) any other security standards determined necessary jointly by the Secretaries of Homeland Security and Health and Human Services.

Subsection 102(c) lists those to be included in the negotiated rulemaking committee and includes representatives from several federal agencies and from the regulated community.

Subsection 102(d) provides a deadline of 6 months from the date of this legislation’s enactment for the negotiated rulemaking committee to provide its recommendations and 1 year from enactment for the promulgation of a final rule.

Subsection 102(e) directs the Secretary and the negotiated rulemaking committee to consider reports from several identified federally mandated commissions and advisory boards and how any disincentives to biological research arising from the enhanced biosecurity measures can be minimized.

Subsection 102(f) describes how the enhanced biosecurity measures should be implemented. It directs the Secretary of Homeland Security, in consultation with the Secretaries of Health and Human Services and Agriculture, to enforce the enhanced biosecurity standards promulgated under this section. The Secretary of Health and Human Services, in consultation with the Secretary of Homeland Security, is to develop or approve training programs that meet the standards promulgated under this section. This subsection directs that regulations under the current select agent security regime promulgated under section 351A(b)(1) of the Public Health Service Act (42 U.S.C. § 262a(b)(1)) or under section 212(b)(1) of the

Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(b)(1)) shall be amended when they conflict with the regulations promulgated under this section. This subsection provides for penalties for non-compliance with the enhanced biosecurity measures, including civil monetary penalties, suspension of research, or intermediate sanctions such as issuance of corrective action plans and onsite monitoring.

To bring efficiency to the oversight of biological select agent and toxin research, subsection 102(f) directs agencies reviewing a BSAT research institution for regulatory or contractual compliance with the BSAT regulations to carry out those reviews jointly to the extent practicable. In order to reduce divergent or conflicting expectations amongst federal agencies on how to comply with the BSAT regulations, agencies are expected to ensure that inspection procedures are coordinated and mutually agreed to beforehand. Finally, to reduce the need for agencies to conduct redundant inspections simply for lack of access to inspection results from another agency, this title requires that agencies inspecting for regulatory or contractual compliance share their reports with other agencies that have a vested interest in the inspected facility. This subsection also authorizes to be appropriated such sums as may be necessary to carry out this section and provides for technical and conforming amendments to the Homeland Security Act of 2002 (6 U.S.C. § 101 et seq.).

### *Section 103. Laboratory and facility registration and database*

This section requires the Secretary of Health and Human Services, in coordination with the Secretaries of Homeland Security and Agriculture, to mandate the registration of laboratories that (1) have characteristics that could facilitate the misuse of a laboratory for the purposes of developing a biological weapon, or (2) that work on agents posing a severe threat to public health. The registration of laboratories is intended to provide the government with awareness as to their location and facilitate the distribution of biosafety and biosecurity best practices.

The current lists of select agents include many agents that could not be used effectively in developing a biological weapon. This situation arises in part because the statutory provisions governing the designation of select agents do not require the Secretaries of Health and Human Services or Agriculture to consider the suitability of the agent for use in a biological weapon or any other biosecurity factor when designating agents as select agents. The section encourages the removal from the select agent list of those agents that would not be suitable for use as a biological weapon, thus furthering the stratification of agents, ensuring that security regulations are commensurate with the risk posed by the agent, and reducing the overall burden of the security regulatory regime on laboratories. It is expected that the list of Registry Agents would likely consist primarily of agents removed from the select agent list but also include emerging threats for which the severity of the threat is still being evaluated. Laboratories and persons possessing Registry Agents would be required to register with the Secretary of Health and Human Services but would not otherwise be subject to biosecurity regulations.

Subsection 103(a) amends section 351A of the Public Health Service Act (42 U.S.C. § 262a) by inserting a new subsection “(f) Laboratory and Facility Registration and Database.” Subsection “351A(f)(1)” directs the Secretary of Health and Human Services to issue a regulation establishing criteria for defining which laboratories would be subject to registration requirements, with a focus on laboratories with features that could be useful in developing a biological weapon, such as the synthesis of Tier 1 agents, or which would enable an individual to develop a biological weapon while escaping detection. Subsection “351A(f)(2)” directs the Secretary of Health and Human Services to establish by regulation a designation of “Registry Agents” which are to encompass those biological agents and toxins which have the potential to pose a severe threat to public, animal, or plant health but for which the potential to be used in a biological attack has not been established. These agents do not pose as significant or as clear of a threat as do select agents or Tier 1 select agents. Subsection “351A(f)(3)” requires the Secretary of Health and Human Services to register persons or facilities regulated pursuant to Subsections “351A(f)(1)” and “351A(f)(2)” and to establish a database of those persons or facilities. Subsection “351A(f)(4)” provides for civil monetary penalties for persons violating any rules promulgated pursuant to this section. Subsection “351A(f)(5)” describes which federal entities shall have access to the database established under subsection “351A(f)(3).” Subsection “351A(f)(6)” directs the Secretary of Health and Human Services to promote biosecurity and biosafety best practices to persons registered under this section. Subsection “351A(f)(7)” protects against inappropriate disclosure of sensitive information.

Subsection 103(b) directs the Secretaries of Health and Human Services and Agriculture to conduct a comprehensive review of the list of biological agents and toxins on the select agent list to determine which would more appropriately meet the criteria of the “registry agent” category. It also amends section 351A of the Public Health Service Act (42 U.S.C. § 262a) and section 212(a) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(a)) to include consideration of the suitability of the agent to be used in a biological attack in the criterion for designating select agents. This subsection also exempts clinical or diagnostic laboratories that may come into transitory possession of registry agents from having to register with the Secretary of Health and Human Services and is consistent with the exemptions for these entities currently in place for the Select Agent Program.

Subsection 103(c) authorizes such sums as may be necessary to carry out this section. Subsection 103(d) makes conforming amendments.

#### *Section 104. Background checks*

This section directs the Attorney General, when conducting a background check on individuals seeking access to select agents, to consult with the Secretary of Homeland Security to determine whether there is reason to believe that those individuals have knowing involvement with a terrorist organization. Current DOJ background checks do not generally include a review of all relevant intelligence in the hands of other government agencies. Consultation with the Department of Homeland Security could provide im-

portant information to the Department of Justice concerning an applying individual's possible terrorist ties, particularly as it relates to any contacts of concern in foreign settings.

*Section 105. Biological laboratory protection*

This section provides resources that are intended to reduce the burden that laboratories conducting Tier 1 select agent research carry by providing financial assistance to meet the enhanced security measures promulgated pursuant to section 102. This section also provides all select agent laboratories greater access to the expertise of the Department of Homeland Security through participation in the department's confidential and voluntary vulnerability assessment program, the costs of which are carried by the department.

Subsection 105(a) authorizes the Secretary of Homeland Security to award \$50 million in grants for each of fiscal years 2011–2014 to academic and nonprofit organizations and State, local, and tribal governments to improve security at laboratories that handle Tier I agents.

Subsection 105(b) directs the Secretary of Homeland Security to encourage laboratories currently handling agents listed under the Select Agent Program to undergo voluntary DHS vulnerability assessments.

*Section 106. Biosecurity information sharing*

This section directs the Secretary of Homeland Security to ensure that State, local, and tribal governments have access to relevant safety and security information concerning biological laboratories in or near their jurisdictions, consistent with classified or sensitive information provisions and privacy laws. In doing so, the Secretary of Homeland Security may utilize information from the national databases maintained by HHS and USDA pursuant to the Select Agent Program.

Subsection 106(a) amends section 351A(d) of the Public Health Service Act (42 U.S.C. § 262a(d)) to provide access to the database of persons with access to select agents to the Attorney General, the Secretaries of Agriculture, Homeland Security, Energy, Defense, and other federal secretaries as the Secretary of Health and Human Services determines appropriate.

Subsection 106(b) amends section 212(d) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(d)) to provide access to the database of persons with access to select agents to the Attorney General, the Secretaries of Health and Human Services, Homeland Security, Energy, Defense, and other federal secretaries as the Secretary of Agriculture determines appropriate.

Subsection 106(c) directs the Secretary of Homeland Security to ensure that State, local, and tribal governments have access to relevant safety and security information relating to biological laboratories and facilities in their jurisdictions, as the Secretary determines appropriate. In carrying out this directive the Secretary is authorized to use data from databases to which the Secretary is provided access in subsections 106(a) and 106(b). The Secretary is to ensure that classified and sensitive safety and security information, or information that is subject to privacy regulations, is appropriately protected.

Subsection 106(d) makes technical and conforming amendments.

*Section 107. Research with the Variola virus genome*

This section directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to promulgate regulations on handling portions of the DNA of the Variola virus, the causative agent of smallpox. Possession of the entire smallpox virus genome is currently regulated under the Select Agent Program, but those regulations do not restrict possession of portions of its DNA, which can be very useful in research. These fragments of the virus genome do not pose a biological weapons or public health threat because the existing state of biotechnology does not enable those portions to be reassembled into a fully functioning infectious smallpox virus. The rapid advancement of biological sciences, however, means that scientists may well soon be able to accomplish just such a feat. The World Health Organization has issued non-binding recommendations on how nations should handle this research. This section directs the Secretary of Health and Human Services to develop binding regulations and to consider the World Health Organization recommendations when doing so.

Subsection 107(a) directs the Secretary of Health and Human Services to promulgate regulations governing the distribution, synthesis, and handling of Variola virus DNA.

Subsection 107(b) provides certain considerations that should be taken into account, including the World Health Organization recommendations of May 2008 on the distribution, synthesis, and handling of Variola virus DNA, as well as the continuing importance of legitimate research on components of Variola virus DNA for public health purposes.

Subsection 107(c) directs the promulgated rules to address which entities are qualified to handle research with Variola virus DNA, limits on the distribution and synthesis of Variola virus DNA, and the total size of the Variola virus genome that can be possessed.

Title II—Response to a Weapon of Mass Destruction Attack

Subtitle A—Ensuring Access to Medical Countermeasures During Emergencies

*Section 201. National Medical Countermeasures Dispensing Strategy*

This section requires the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and the Postmaster General, to develop a National Medical Countermeasure Dispensing Strategy. This strategy is focused on improving our ability to dispense medical countermeasures—such as antibiotics needed to respond to an anthrax attack—to individual citizens from staging and storage areas. Plans are currently in place for sending medical countermeasures to staging and storage areas from national stockpiles but there has been insufficient planning for distributing countermeasures the “last mile.” This strategy will describe federal agencies’ roles generally and outline the assistance federal agencies will make available to State, local, and tribal governments for medical countermeasure dispensing. The strategy will reflect that no single dispensing method is likely to be sufficient for

every community or for the duration of an incident. As such, the strategy will include measures to support a variety of approaches that will be layered to address the response needs of a community as the incident unfolds.

This section amends Title III of the Public Health Service Act (42 U.S.C. §§ 241 et seq.) to insert a new section “319N. National Medical Countermeasure Dispensing Strategy.”

Subsection “319N(a)” provides for definitions used in this section.

Subsection “319(b)” directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and Postmaster General, to develop, coordinate, and maintain a National Medical Countermeasure Strategy.

Subsection “319(c)” describes the content of the strategy and directs the strategy to include: descriptions of the federal role in dispensing medical countermeasures, how diverse population centers will be covered, how a multilayered approach can be used to overcome gaps or failures in any particular approach, how liability issues of different professional and volunteer emergency response providers should be addressed, how appropriate security will be incorporated, how information regarding obtaining medical countermeasures should be communicated to the public, and other items identified in this subsection or that the Secretary of Health and Human Services determines appropriate.

Subsection “319(d)” directs the responsible federal agencies to coordinate with State, local, and tribal government officials, private sector, and nongovernmental organizations when developing the strategy.

Subsection “319(e)” requires the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and the Postmaster General, to give Congress the strategy within 180 days of enactment and to provide an implementation plan 180 days after submission of the strategy. A status report on the implementation of the strategy is due one year after the submission of the implementation plan.

#### *Section 202. Tailoring of the National Medical Countermeasure Dispensing Strategy*

This section requires that the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security and, where appropriate, the Postmaster General, tailor implementation of the National Medical Countermeasure Dispensing Strategy by developing specific plans for each jurisdiction participating in the Cities Readiness Initiative and for representative localities of varying size and population makeup. The plans are to be developed in close discussion with the representative State, local, and tribal officials in those locations. The Secretary of Homeland Security is to review elements of the tailored plan developed by the Secretary of Health and Human Services for capabilities for which the Department of Homeland Security has particular expertise, including: security plans for infrastructure and personnel, coordination among law enforcement personnel in support of dispensing activities, logistical support during disasters, and other items identified in this subsection or that the Secretary of Homeland Security determines appropriate.



*Section 203. Expansion in the use of the U.S. Postal Service to deliver medical countermeasures*

This section expands the existing program for using the Postal Service to deliver medical countermeasures to five additional cities within one year and fifteen additional cities within two years.

Subsection 203(a) directs the Secretary of Health and Human Services, in coordination with the Postmaster General and the Secretary of Homeland Security, to expand the existing pilot programs utilizing the United States Postal Service to deliver medical countermeasures in an emergency.

Subsection 203(b) provides the timeline for the expansion, contingent on the voluntary participation of additional jurisdictions, to include five additional cities one year after the date of enactment, and to include fifteen cities within two years.

Subsection 203(c) establishes that the contents of the medkits used in this program shall be reevaluated biennially.

Subsection 203(d) provides the criteria to be considered in determining the contents of the medkits used in the program, including available threat assessments and the public health effects should such threats come to fruition.

Subsection 203(e) directs the Secretary of Health and Human Services, the Postmaster General, and the Secretary of Homeland Security to report on the implementation of this section.

Subsection 203(f) provides for definitions used in this section.

Subsection 203(g) authorizes appropriation of funds necessary to carry out this section.

*Section 204. Dispensing medical countermeasures through employers*

This section directs federal agencies to develop plans to dispense medical countermeasures to their employees in the event of a naturally occurring or man-made biological incident and to create best practices for medical countermeasure dispensing among private-sector entities. This section also requires federal agencies to exercise those plans biennially.

Subsection 204(a) provides for definitions used in this section.

Subsection 204(b) directs the head of each federal agency, in consultation with the Secretary of Health and Human Services and Secretary of Homeland Security, to develop a plan to receive and dispense medical countermeasures to their employees. This subsection describes the contents of the plans, the review of those plans by the Secretaries of Health and Human Services and Homeland Security, and directs that they shall be exercised at least biennially.

Subsection 204(c) directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to establish a set of best practices for dispensing medical countermeasures to employees for private sector entities.

Subsection 204(d) directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to report on the implementation of this section.

*Section 205. Personal “Medkits” for emergency response providers and members of preparedness organizations*

This section creates a program to provide personal medical kits to emergency response providers, members of preparedness organizations, and their immediate family members. Personal medical kits, which could contain antibiotics or other medical countermeasures that would be needed in the event of a WMD attack, are currently provided to Postal Service employees participating in the pilot program for delivering medical countermeasures. Individuals receiving medical kits are required to register with the Secretary of Homeland Security, receive training on storage and use of the medical kits, and report any use of a medical kit to the Secretary of Homeland Security. Immediate family members are included so that emergency response providers can focus on serving their community without worrying that their possible exposure to the WMD agent and cross contamination will put their families at greater risk than the general public. This section authorizes \$20 million per year for fiscal years 2011–2013 for this program.

Subsection 205(a) amends Title III of the Homeland Security Act of 2002 (6 U.S.C. §§ 181 et seq.) by adding “Section 320. Personal Medkits for Emergency Response Providers and Members of Preparedness Organizations.”

Subsection “320(a)” provides for definitions used in this section.

Subsection “320(b)” directs the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, to establish a medkit program for emergency response providers, members of preparedness organizations, and their immediate family members.

Subsection “320(c)” lays out elements of the emergency response provider medkit program including that participants be registered in the program, receive proper training, and undergo appropriate medical screenings.

Subsection “320(d)” directs that the program be coordinated with the Secretary of Health and Human Services and the Commissioner of Food and Drugs to establish the contents of the medkits and to attain an emergency use authorization for the medkits to be used in this program, in a manner consistent with applicable food and drug statutes.

Subsection “320(e)” directs the Secretary of Homeland Security to report to Congress on the implementation of this section.

Subsection “320(f)” authorizes \$20 million for fiscal years 2011 through 2013 for implementation of this section.

Subsection 205(b) provides for technical and conforming amendments.

*Section 206. General public “Medkit” pilot program*

This section requires the Secretary of Health and Human Services to conduct a pilot program to study the feasibility of providing personal medkits to the public. The program will evaluate the ability of households to maintain medical kits in their homes as directed and reserved for emergency use. Enrollment in the pilot program would encompass a diverse range of municipalities, geographic locations, and socio-economic statuses.

Subsection 206(a) provides for definitions used in this section, including for the term “medkit,” which the subsection defines as a

cache of antibiotics and other medical countermeasures to be used during a public health emergency.

Subsection 206(b) directs the Secretary of Health and Human Services, in coordination with the Secretary of Homeland Security, to conduct a pilot program to study the feasibility of providing personal medkits to the public.

Subsection 206(c) describes the requirements for the medkit pilot program, which is intended to enroll significantly more participants than previous studies on the feasibility of home medkits.

Subsection 206(d) directs that the pilot be coordinated with the Commissioner of Food and Drugs to establish the contents of the medkits and to attain an emergency use authorization for the medkits to be used in this manner.

Subsection 206(e) directs that a report evaluating the pilot program and providing recommendations for a national program be delivered to Congress.

Subsection 206(f) authorizes appropriations necessary to carry out this section.

#### *Section 207. Report on the use of expiring countermeasures*

This section directs the Secretary of Health and Human Services to contract with the Institute of Medicine to study the feasibility and effectiveness of using those medical countermeasures in the Strategic National Stockpile that are approaching expiration for pre-event or post-event vaccination or treatment of emergency responders.

### Subtitle B—Bioforensics Capabilities and Strategy

#### *Section 211. Bioforensics capabilities and strategy*

This section authorizes a National Bioforensics Analysis Center and a repository collection at DHS as the lead federal facility to conduct technical forensic analysis following a bioattack in order to support identification of the perpetrators. It directs federal agencies to provide samples of relevant agents to the repository and instructs the Secretary of Homeland Security to encourage participation by public and private agent collections. This section also directs the Secretary of Homeland Security to develop a National Bioforensics Strategy laying out federal agencies' roles in analyzing bioforensic evidence, coordination with State, local, and tribal governments, and development of collection standards.

Subsection 211(a) amends Title III of the Homeland Security Act of 2002 (6 U.S.C. §§ 181 et seq.), as amended, by adding "Section 321. Bioforensics Capabilities and Strategy." Subsection "321(a)" provides for definitions used in this section.

Subsection "321(b)" authorizes the National Bioforensics Analysis Center at the Department of Homeland Security. The Center is to serve as the lead federal facility to conduct technical forensic analysis following a bioattack in order to support efforts to identify the perpetrators, to maintain a national bioforensics repository collection, and to support research on advancing threat agent characterization capabilities and assay development.

Subsection "321(c)" establishes a National Bioforensics Repository Collection at the National Bioforensics Analysis Center. The repository is intended to receive, store, and distribute the pathogen

type strains it needs to support bioforensic analysis, studies characterizing threat agents, and the development of bioforensic assays. Other agencies that possess strains needed to fulfill this purpose are directed to make those strains and toxins available to the repository. The Secretary of Homeland Security is also to work with public and private biological agent and toxin collections whose samples were funded by federal investments to contribute needed samples to the repository. The Secretary is to establish mechanisms by which other federal agencies as well as public or private entities can access, as appropriate, the repository in order to support bioforensics activities and research. The Secretary is also directed to provide a report to Congress outlining how concerns relating to intellectual property or rights to access the repository among other issues are addressed.

Subsection “321(d)” directs the Secretary of Homeland Security, in coordination with heads of relevant agencies, to develop a National Bioforensics Strategy that provides for a coordinated approach across all executive agencies for bioforensic analysis and research and that describes the roles and responsibilities of those agencies.

Subsection 211(b) provides for technical and conforming amendments.

### Subtitle C—Communications Planning

#### *Section 221. Communications planning*

This section directs the Secretary of Homeland Security, acting through the FEMA Administrator, in consultation with State, local, and tribal officials, to develop pre-scripted messages and message templates to provide information quickly to affected populations after natural disasters, acts of terrorism, and other man-made disasters. The messages would be developed in multiple formats to ensure delivery when the usual communications infrastructure is rendered unusable and to provide direction to individuals with disabilities or other special needs. The FEMA Administrator will incorporate such messages into exercises conducted under the National Exercise Program.

Subsection 221(a) adds “Section 525. Communications Planning” to Title V of the Homeland Security Act of 2002 (6 U.S.C. §§ 311 et seq.).

Subsection “525(a)” directs the Secretary of Homeland Security, through the Administrator of the Federal Emergency Management Agency, to develop a public communications plan to provide information relating to preventing, preparing for, protecting against, and responding to imminent natural disasters, acts of terrorism and other man-made disasters.

Subsection “525(b)” directs the Administrator, in consultation with State, local, and tribal governments and in coordination with other responsible federal agencies, to develop pre-scripted messages or message templates that can be used by the responding State, local, and tribal officials, if they deem them to be necessary, to rapidly disseminate critical information to the public or to emergency responders in anticipation of the immediate aftermath of a disaster or incident. The messages should address concepts such as evacu-

ation, sheltering in place and issues of immediate health and safety.

Subsection “525(c)” directs that the pre-scripted messages or templates should be designed for multiple communications formats in order to ensure delivery even when particular communications infrastructure is damaged by the incident and to reach individuals with disabilities, special needs, or limited English proficiency.

Subsection “525(d)” directs that the pre-scripted messages and templates should be distributed to State, local, and tribal governments, and that the Administrator provide those governments with technical assistance related to communications planning.

Subsection “525(e)” directs that the messages and templates developed under this section are exercised.

Subsection “525(f)” directs the Administrator to report to Congress on efforts to carry out this section.

Subsection 221(b) of the bill amends the table of contents of the Homeland Security Act of 2002 (6 U.S.C. § 101).

#### *Section 222. Plume modeling*

This section directs the Secretary of Homeland Security to ensure the rapid development and dissemination of integrated plume models that assess the location and predict the spread of nuclear, radioactive, or chemical fallout of biological agents resulting from an attack or release and that contain protective action guidance. The Secretary of Homeland Security will also establish mechanisms for dissemination by emergency response providers of these plume models to nongovernmental organizations and the public to ensure appropriate response activities. In addition, the Secretary of Homeland Security is required to ensure that DHS exercises the development and dissemination of integrated plume models.

Subsection 222(a) provides definitions for this section, including for the term “plume model,” which means assessment of the location and prediction of the spread of nuclear, radioactive, or chemical fallout and biological pathogens resulting from an explosion or release of nuclear, chemical or biological substances. The term “integrated plume model” incorporates the concept that protective action guidance and other information are also included with the provided plume models.

Subsection 222(b) directs the Secretary of Homeland Security to develop and disseminate integrated plume models to enable rapid response activities following a nuclear, radiological, chemical or biological release. While the integrated plume models are to be provided by the Secretary to appropriate emergency response officials, it is expected that integrated plume models incorporating protective action guidance will be made in a publicly releasable format if public release is deemed appropriate by the emergency response officials in command of the incident response. The integrated plume models should be developed in consultation with other federal agencies, State, local, and tribal governments and nongovernmental organizations involved in the response, sheltering and care of affected individuals.

Subsection 222(c) directs the Secretary of Homeland Security to ensure that the integrated plume models developed pursuant to this section are exercised. Subsection 222(d) instructs the Secretary of Homeland Security to produce a report to Congress detailing the

development of the integrated plume models, lessons learned from exercising these products, and plans for improving future versions.

### Title III—International Measures to Prevent Biological Terrorism

#### Subtitle A—Prevention and Protection Against International Biological Threats

##### *Section 301. International threat assessment: Tier I agent facilities*

This section requires that the DNI lead a review of international biosecurity threats and provide the results to Congress. The review shall assess global biological risks by taking into account the presence and capabilities of foreign terrorist organizations, the location of highest risk agent collections, the location of laboratories with inadequate security and any gaps in knowledge about international biosecurity threats. The report must be submitted no later than six months after enactment of the Act, and should be updated biennially and submitted to specified Congressional committees. The DNI must also submit an unclassified summary and a classified annex no later than six months after enactment of the Act and biennially thereafter to specified Congressional committees. This last requirement will sunset five years after enactment.

##### *Section 302. Strengthening international biosecurity*

This section directs the Secretary of State to provide technical assistance to countries or regions identified by the threat assessment mandated by section 301 in removing, consolidating, and otherwise improving security for Tier I agent collections. The section further directs the Secretary to raise awareness of biological threats internationally, provide physical and other security upgrades to high-risk laboratories, and train countries in biosecurity best practices. Finally, this section requires the Secretary of State to promote research and development collaboration on highly infectious diseases and to provide opportunities for foreign scientists to receive training in the United States on biological safety and security.

##### *Section 303. Promoting secure biotechnology advancement*

Subsection 303(a) directs the Secretary of State to develop a strategy for promoting international adherence to agreements regarding WMD including the Biological Weapons Convention and World Health Organization International Health Regulations.

Subsection 303(b) directs the Secretary to pursue discussions with government, academic and industry representatives in countries with established or emerging biotechnology sectors concerning safeguards to prevent the misuse of biotechnology and initiatives to counter biological terrorism.

#### Subtitle B—Global Pathogen Surveillance

##### *Section 321. Short title*

This section provides the short title of the subtitle as the “Global Pathogen Surveillance Act of 2009.”

*Section 322. Findings; purpose*

This section describes the findings and purpose of this subtitle, namely to enhance the capability of the international community through international health organizations and individual countries, to detect, identify, and contain infectious disease outbreak whether caused by intentional human action or natural sources.

*Section 323. Definitions*

This section provides the definitions used in this subtitle.

*Section 324. Eligibility for assistance*

This section describes the eligibility requirements for developing countries and individuals to receive assistance under this subtitle, including that (1) countries are developing and have agreed to the objective of fully complying with requirements of the World Health Organization on reporting public health information on outbreaks of infectious diseases and to provide pathogen surveillance data to the United States and international health organizations, and (2) individuals do not have a criminal background or ties to any foreign terrorist organization.

*Section 325. Restriction*

This section prohibits the access by foreign nationals participating in programs created by the subtitle to agents that may be used as biological weapons except in a supervised and controlled setting.

*Section 326. Fellowship program*

This section establishes a fellowship program for foreign nationals of eligible developing countries, as defined in section 324, to pursue a Master of Public Health degree or advanced studies in epidemiology, provided that the individuals agree to work in public health or public health-related positions in their home countries for four years. A U.S. citizen may participate on a case-by-case basis provided that individual agrees to work for five years in a public health position in an eligible country or an international health organization.

*Section 327. In-country training in laboratory techniques and disease and syndrome surveillance*

This section directs the Secretary of State to develop short training courses for foreign nationals of eligible developing countries (as defined in section 324) who are laboratory technicians, health care providers, or public health officials on how to identify agents responsible for infectious disease outbreaks, diagnose such diseases, and track and analyze such outbreaks.

*Section 328. Assistance for the purchase and maintenance of public health laboratory equipment and supplies*

This section authorizes the President to assist eligible developing countries, as defined in section 324, in purchasing and maintaining public health laboratory supplies and equipment. Such assistance may be provided only if the country agrees to house, maintain, support, secure, and maximize the use of such supplies and equipment.

*Section 329. Assistance for improved communication of public health information*

This section authorizes the President to assist eligible developing countries, as defined in sections 323 and 324, in purchasing and maintaining communications and information technology necessary to collect, analyze, and transmit public health information. Such assistance may only be provided if the country agrees to house, maintain, support, secure, and maximize the use of such technology.

*Section 330. Assignment of public health personnel to United States missions and international organizations*

This section authorizes an agency head to assign an employee, with the employee's and the Secretary of State's concurrence, to a diplomatic mission or international health organization in order to enhance disease or pathogen surveillance in developing countries.

*Section 331. Expansion of certain United States Government laboratories abroad*

This section permits the Director of the Centers for Disease Control and Prevention and the Secretary of Defense to increase the number of employees and to expand the operations of those agencies' laboratories located in eligible developing countries, as defined in sections 323 and 324, including by increasing the capacity to train foreign nationals at such facilities.

*Section 332. Assistance for international health networks and expansion of field epidemiology training programs*

This section authorizes the President to assist the enhancement of the surveillance and reporting capabilities of the World Health Organization and other international health networks and to establish new international health networks. The section further authorizes the Secretary of Health and Human Services to establish new international Field Epidemiology Training Programs in eligible developing countries, as defined in sections 323 and 324.

*Section 333. Reports*

This section directs the Secretary of State to report to Congress on implementation of this subtitle.

*Section 334. Authorization of appropriations*

This section authorizes appropriations to carry out activities under this subtitle.

Subtitle C—Strengthening the Oversight of Nuclear  
Nonproliferation

*Section 351. Definitions*

This section of the bill defines “appropriate Congressional committees”, “Commission”, “Coordinator”, “Deputy Coordinator”, “highly enriched uranium”, “IAEA”, and “special nuclear material”.



*Section 352. Report on United States nuclear nonproliferation efforts*

Subsection 352(a) instructs the President's Coordinator for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism to submit a report one year after the date of enactment, and annually thereafter, to the appropriate Congressional committees.

Subsection 352(b) describes the content of the report, which requires: (1) a detailed description of the financial incentives used by the U.S. to promote civilian nuclear energy abroad; (2) a statement of U.S. actions to improve the secure civilian storage, and minimize the use and export, of weapons usable highly enriched uranium and the amount the U.S. spends to fuel U.S. civilian reactors with highly enriched uranium; (3) a description of the actions that the U.S. has taken to implement the Energy Development Program mandated by the Nuclear Non-Proliferation Act of 1978; (4) a description of the steps the U.S. has taken to improve the physical security of civilian special nuclear material; (5) an assessment of the capabilities of the International Atomic Energy Agency (IAEA), completed in consultation with all relevant agencies, including the Office of the Director of National Intelligence, to include IAEA's ability to meet its own timely detection and inspection goals, IAEA's ability to actually detect military diversions, and recommendations on updating IAEA definitions of the amount of time it takes, and amount of special nuclear material needed, to convert special nuclear material into a bomb, and recommendations regarding how the U.S. could improve IAEA's capabilities.

Subsection 352(c) requires the President to submit the report in the absence of the Coordinator and Deputy Coordinator.

*Section 353. Report on United States work with IAEA on nuclear nonproliferation*

Subsection 353(a) instructs the Coordinator to submit a report one year after the date of enactment to the appropriate Congressional committees.

Subsection 353(b) describes the content of the report, which shall detail the progress of U.S. work with IAEA's Director General to: (1) establish a safeguards user fee that would require countries with inspected facilities to help cover the costs of IAEA inspections; (2) assess whether the IAEA can meet its own inspection goals, whether those goals afford timely detection to account for a bomb's worth of special nuclear material, whether there are situations in which achieving those goals is not possible, and what corrective actions may be needed to help the IAEA in achieving those goals; (3) promote transparency at suspect sites and encourage member states to track all foreign visitors at safeguarded sites; (4) provide for the acquisition and implementation of near-real-time surveillance equipment in the use of safeguards, including at sites where nuclear fuel rods are located; (5) require that the transfer of items on the Nuclear Suppliers Group dual-use and trigger lists be reported to IAEA in advance and that a system be developed to analyze those transfers.

Subsection 353(c) requires the President to submit the report in the absence of the Coordinator and Deputy Coordinator.

*Section 354. Authorization of appropriations*

This section authorizes appropriations as may be necessary to carry out the reporting requirements for both reports fiscal year 2010 and each year thereafter.

Subtitle D—Energy Development Program Implementation

*Section 361. Findings*

This section of the bill provides Congressional findings, including (1) that Title V of the Nuclear Non-Proliferation Act of 1978 requires the U.S. to work with developing countries in assessing and finding ways to meet their energy needs through alternatives to nuclear energy, and (2) that the Commission on the Prevention of WMD Proliferation and Terrorism recommends that Title V be implemented to help reduce the risk of nuclear proliferation.

*Section 362. Definitions*

This section provides definitions for “appropriate Congressional committees”, “energy development program”, and “Secretary”.

*Section 363. Energy development program implementation*

Subsection 363(a) instructs the Secretary of Energy to develop strategic and implementation plans for the energy development program and to submit them to the appropriate Congressional committees not later than 180 days after the date of enactment.

Subsection 363(b) requires the Secretary to implement the plans not later than 180 days after the date they were submitted to the appropriate Congressional committees.

Subsection 363(c) specifies that Federal employees serving in an exchange capacity in an energy development program are considered to be detailed. These employees shall retain their allowance, privileges, rights, and seniority afforded them by their original employing agency.

Subsection 363(d) authorizes necessary sums to carry out this section for fiscal year 2010 and each fiscal year thereafter.

*Section 364. Reports*

Subsection 364(a) requires that an annual report be submitted by the Secretary of Energy to the appropriate Congressional committees not later than one year after the date of implementation of the plans and every year thereafter.

Subsection 364(b) requires that a report on the Alternative Energy Corps, including how this Corps could be expanded into an international cooperative effort, be submitted by the Secretary to the appropriate Congressional committees not later than one year after the date of the implementation of plans. This latter report is to include an analysis and description of how a Corps of technically trained volunteers could support the search for and use of non-nuclear, indigenous energy sources and the application of suitable technology, including renewable energy technology, in developing countries. The report also is to include a description of other mechanisms that are available to coordinate an international effort to advance the use of suitable technologies in developing countries.

#### Title IV—Government Organization

##### *Section 401. Intelligence on weapons of mass destruction*

This section requires the DNI to develop a strategy for improving intelligence collection, analysis, and dissemination related to WMD, including the relationship between WMD and terrorism. Subsection 401(b) requires that, not later than 120 days after the enactment of this bill, the DNI shall develop and implement the strategy and submit it to the Congressional committees specified in subsection 401(a).

Subsection 401(b) specifies six substantive elements that the strategy must contain, including recruitment of individuals with relevant expertise in WMD intelligence such as scientific and technical knowledge; collaboration with nongovernmental entities; analytic questions and gaps in knowledge to guide collection; development of innovative collection techniques; actions to increase information-sharing and a description of any barriers thereof; and actions to overcome foreign denial and deception. In addition, subsection 401(b) contains five process elements that the strategy must contain, including prioritized objectives and a schedule for meeting them annually for the first five years of the strategy; assignment of roles and responsibilities in the Intelligence Community; a description of the personnel and financial resources necessary to implement the strategy; metrics to measure efficiency and effectiveness; and a schedule for assessing the strategy.

Subsection 401(c) requires that the DNI submit a report every 180 days after submission of the strategy, for a period of three years, to the Congressional committees specified in subsection 401(a). Each report shall include an assessment of the accomplishment of the strategy's objectives, data related to the strategy's metrics, a description of actions taken to implement the strategy, and an assessment of whether resources are sufficient to fulfill the strategy.

##### *Section 402. Intelligence language capabilities and cultural knowledge*

This section requires the DNI to develop a strategy for recruiting employees with critical language skills and cultural backgrounds relevant to counterterrorism or WMD intelligence, including individuals who are first- or second-generation U.S. citizens and U.S. citizens with immediate relatives who are foreign nationals. Subsection 402(b) requires that, not later than 180 days after the enactment of this bill, the DNI shall develop and implement a strategy and submit it to the Congressional committees specified in subsection 402(a).

Subsection 402(b) specifies three substantive elements that the strategy must contain, including the Intelligence Community's need for employees with critical language capabilities and cultural backgrounds relevant to counterterrorism and WMD intelligence over a ten-year period, actions necessary to recruit, train, and retain such individuals, and barriers to effective recruitment, training, and retention, including security clearance processing. In addition, subsection 402(b) contains five process elements that the strategy must contain, including prioritized objectives and a schedule for meeting them annually for the first five years of the strategy; as-

signment of roles and responsibilities in the Intelligence Community; a description of the personnel and financial resources necessary to implement the strategy; metrics to measure efficiency and effectiveness; and a schedule for assessing the strategy.

Subsection 402(c) requires that the DNI submit a report every 180 days after submission of the strategy, for a period of three years, to the Congressional committees specified in subsection 402(a). Each report shall include an assessment of the accomplishment of the strategy's objectives, data related to the strategy's metrics, a description of actions taken to implement the strategy, and an assessment of whether resources are sufficient to fulfill the strategy.

### *Section 403. Counterterrorism technology assessment*

This section strengthens the science and technical capabilities of the Congressional Research Service (CRS) and the Government Accountability Office (GAO) for providing Congress with assessments of counterterrorism technology in order to inform Congress's consideration of legislative proposals on such matters.

Subsection 403(a) defines the term "agency" in this section to mean any department, agency, or instrumentality of the executive branch of the Government.

Subsection 403(b) requires the Director of CRS to establish an interdisciplinary capability in furtherance of CRS's responsibilities to advise Congress concerning technology or technological applications developed or used for counterterrorism. Subsection 403(b) authorizes \$2 million for each of fiscal years 2011 to 2013 for this purpose.

Subsection 403(c) requires the Comptroller General of the United States (the head of GAO) to establish an interdisciplinary capability at GAO to conduct assessments of technology or technological applications that are being developed or are being used, or are available to be used, either by the Executive Branch to counter terrorism or pursuant to a legislative proposal under consideration in Congress or proposed by the Executive Branch. Subsection 403(c) specifies that each assessment of a technology or technological application for counterterrorism shall include its actual or anticipated impact, effectiveness, and efficiency as well as any test results, technological alternatives, actual and anticipated costs and benefits, actual or anticipated countermeasures, and the Executive Branch's own assessment. The interdisciplinary capability shall include personnel with relevant expertise—including science, technology, homeland security, or other fields deemed appropriate—and may include outside experts or consultants. Subsection 403(c) authorizes \$2 million for each of fiscal years 2011 to 2013 for this purpose.

Subsection 403(d) states that the Comptroller General of the United States shall, as appropriate, contract with the National Academy of Sciences to assess technology and technological applications that are being or could be developed for counterterrorism. Subsection 403(d) specifies that each such assessment include determining trends related to the development of technology or technological applications, identifying particular technology or technological applications that may become available or are necessary, and recommending government investments for the development of

technology or technological applications. Subsection 403(d) authorizes \$2 million for each of fiscal years 2011 to 2013 for this purpose.

#### Title V—Emergency Management and Citizen Engagement

##### *Section 501. Improved communications of threat information and alerts*

This section requires the Secretary of Homeland Security, in coordination with the FBI Director, to provide terrorism-related threat and risk assessments to the public. The Secretary of Homeland Security is required to prepare unclassified terrorism-related threat and risk assessments, including guidelines for the public to prevent and respond to acts of terrorism, and to provide State, local, and tribal governments with guidelines on how to disseminate terrorism-related threat and risk information to the public.

Subsection 501(a) finds that the WMD Commission recommended that the federal government practice greater openness of public information so that citizens better understand the threat and risk to them.

To this end, subsection 501(b) amends section 203 of the Homeland Security Act of 2002, as amended, to require that the Secretary of Homeland Security, in coordination with the Attorney General, ensure that information concerning terrorist threats is available to the general public within the United States. To do so, the Secretary of Homeland Security shall prepare unclassified terrorism-related threat and risk assessments on a timely basis. Each assessment shall include guidelines for the general public to prevent and respond to terrorism and be available through publicly accessible communication systems such as DHS's website. The amendment contained within subsection 501(b) also requires the Secretary to provide guidelines to State, local, and tribal governments on disseminating information concerning terrorism threats and risks to the general public.

Subsection 501(c) amends section 201 of the Homeland Security Act of 2002, as amended, to broaden the responsibilities of the Secretary relating to intelligence and analysis and infrastructure protection by mandating that the Secretary disseminate information, as appropriate, not just to governmental and private sector entities with responsibilities related to homeland security but also to the general public in order to assist in deterring, preventing, or responding to terrorism.

Subsection 501(d) requires that the Secretary submit a report to the Senate Homeland Security and Governmental Affairs Committee and the House Homeland Security Committee not later than 180 days after the enactment of this bill on implementation of section 203 of the Homeland Security Act of 2002, as amended, which concerns the Homeland Security Advisory System.

##### *Section 502. Guidelines concerning weapons of mass destruction*

The response to an explosion or release of nuclear, radiological, biological, or chemical material will require specialized procedures and precautions for emergency response providers to respond effectively and safely to a weapon of mass destruction event. The expertise required to develop those specialized procedures often lies at

the federal level, among non-governmental organizations or is dispersed among particular local entities. To be effective, these procedures need to be developed and exercised before an event. This section requires the Secretary of Homeland Security to review existing guidelines and revise or develop new guidelines with State, local, and tribal governments, nongovernmental organizations, and the private sector guidelines for which there is insufficient guidance on responding to a WMD attack.

Subsection 502(a) directs the Secretary of Homeland Security to develop the guidelines in coordination with, and distribute those guidelines to, members of emergency response provider organizations and State, local, and tribal governments.

Subsection 502(b) specifies the minimum contents of the guidelines, to include: the hazardous effects of the WMD agent, the protective practices for the first responder, and how to care for individuals injured or contaminated by the agent.

Subsection 502(c) requires that the guidelines be reviewed and revised if needed at least biennially.

Subsection 502(d) describes the process by which the guidelines are to be developed and revised and includes, among other steps, assessing the appropriateness of existing guidelines for these purposes. The Committee is aware that there have been other efforts to develop such guidelines, such as a terrorism response checklist that the International Association of Fire Chiefs distributes to its members. To the extent there are already existing, relevant guidelines for first responders, the intent of this section is that the Secretary evaluate and, where appropriate, build on such guidelines and not to require the Secretary to start over or to ignore previous efforts that serve as instructive models.

Subsection 502(e) directs that the Secretary of Homeland Security shall consult with other federal agencies, State, local, and tribal governments, and nongovernmental organizations and private industry in developing and revising these guidelines.

Subsection 502(f) requires that an annual report be provided to Congress describing the progress and future development of these guidelines.

Subsection 502(g) provides that “emergency response provider” has the definition given to it in section 2 of the Homeland Security Act of 2002 (6 U.S.C. § 101) and includes Federal, State, and local governmental and nongovernmental emergency public safety, fire, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities.

### *Section 503. Citizen and community preparedness*

This section requires the FEMA Administrator to assist State, local, and tribal governments in promoting individuals’ and communities’ preparedness for natural disasters, acts of terrorism, and other man-made disasters. Such assistance shall include developing guidelines, compiling best practices, providing training materials, and conducting individual and community preparedness outreach efforts. This section also requires the Administrator to appoint a Director of Community Preparedness to oversee the Agency’s activities in this area. Finally, this section permits the Administrator to make grants to States to support individual and community pre-

paredness and authorizes \$15 million in fiscal year 2011 and \$20 million in each of fiscal years 2012 and 2013.

Subsection 503(a) amends Title V of the Homeland Security Act of 2002 (6 U.S.C. §§ 311 et seq.) by adding “Section 526. Citizen and Community Preparedness.”

Subsection “526(a)” of the new section 526 directs the Administrator of the Federal Emergency Management Agency to assist State, local, and tribal governments in promoting individual and community preparedness by developing best practices, guidelines and checklists for prevention and preparedness efforts and conducting individual and community preparedness outreach efforts.

Subsection “526(b)” directs the FEMA Administrator to coordinate with private sector and nongovernmental organizations in promoting preparedness.

Subsection “526(c)” directs the Administrator to work with and provide support to volunteer preparedness programs, including those sponsored by nongovernmental organizations.

Subsection “526(d)” directs the Administrator to appoint a Director of Community Preparedness to coordinate and oversee the individual and community preparedness efforts of the Federal Emergency Management Agency.

Subsection “526(e)” authorizes appropriations for grants to States to support individual and community preparedness programs through 2013.

Subsection 503(b) of the bill amends the authorities and responsibilities of the Federal Emergency Management Agency Administrator in section 504(a) of the Homeland Security Act of 2002 (6 U.S.C. §§ 314(a)) to include enhancing and promoting the preparedness of individuals and communities for natural disasters, acts of terrorism, and other man-made disasters.

Subsection 503 (c) is a conforming amendment to the table of contents of the Homeland Security Act of 2002 (6 U.S.C. §§ 101 et seq.).

## V. EVALUATION OF REGULATORY IMPACT

Pursuant to the requirements of paragraph 11(b)(1) of rule XXVI of the Standing Rules of the Senate, the Committee has considered the regulatory impact of this bill. S. 1649 would impose additional security mandates on certain laboratories and personnel currently regulated under the National Select Agent Program. At the same time, it would reduce the regulatory burden on other currently regulated laboratories and personnel, and remove some completely from the National Select Agent Program and its requirements. Also, laboratories and personnel that work on certain agents that pose a minimal level of concern may face additional registration requirements without security mandates. And entities that receive, synthesize, or handle DNA from the Variola virus will face new regulations. To the extent that State, local, or tribal governments operate laboratories subject to the bill’s requirements, they would see increased or decreased regulation along the lines of that experienced by private sector laboratories. Those institutions, however, and like private sector labs, would benefit from grant funding authorized to offset those costs. State, local, and tribal governments would also benefit from grant programs intended to strengthen individual and community preparedness.

In light of the fact that the bill both increases and decreases regulatory requirements and that the precise impact of the new requirements cannot be calculated prior to the issuance of the new regulations required by the bill, the Committee agrees with CBO, as expressed in its cost estimate included in section VI below, that although the new federal regulations would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act, the types of restrictions, the number of entities regulated under such regulations, and the final costs cannot currently be estimated. Nor, as CBO notes, can it be determined whether these costs would exceed the annual thresholds for intergovernmental or private-sector mandates.

With respect to personal privacy, S. 1649 requires additional personnel reliability measures that may have an impact on the personal privacy of certain individuals who are already required to register under the National Select Agent Program, undergo credit checks, and submit to a federal background check.

Finally, because a determination of any additional paperwork or recordkeeping resulting from the bill depends on requirements of the future regulations and the number of entities those regulations will affect, the Committee could not estimate the amount of any such paperwork or recordkeeping, or the time and financial costs required of the affected parties.

#### VI. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

NOVEMBER 19, 2010.

Hon. JOSEPH I. LIEBERMAN,  
*Chairman, Committee on Homeland Security and Governmental Affairs, U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1649, the WMD Prevention and Preparedness Act of 2009.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

#### *S. 1649—WMD Prevention and Preparedness Act of 2009*

Summary: CBO estimates that S. 1649 would authorize the appropriation of \$945 million over the 2011–2015 period for programs in the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), and other agencies to address the threat of weapons of mass destruction.

Assuming appropriation of the necessary amounts, CBO estimates that implementing S. 1649 would cost \$720 million over the 2011–2015 period. Enacting the bill could have an insignificant effect on revenues; therefore, pay-as-you-go procedures apply. Enacting S. 1649 would not affect direct spending.

S. 1649 would impose intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) because it would require public and private laboratories and other facilities to comply with new security standards. The number of entities that would be affected and the types of security measures to



be required would depend on future regulatory actions; therefore, CBO cannot estimate the costs of the mandate. Consequently, CBO cannot determine whether the costs would exceed the annual thresholds for intergovernmental or private-sector mandates (\$70 million and \$141 million, respectively, in 2010 dollars adjusted annually for inflation).

**Estimated cost to the Federal Government:** The estimated budgetary impact of S. 1649 is shown in the following table. The costs of this legislation fall within budget functions 150 (international affairs), 270 (energy), 350 (agriculture), 450 (community and regional development), 550 (health), 750 (administration of justice), and 800 (general government).

	By fiscal year, in millions of dollars—					
	2011	2012	2013	2014	2015	2011–2015
CHANGES IN SPENDING SUBJECT TO APPROPRIATION <sup>a</sup>						
DHS Programs:						
Estimated Authorization Level .....	112	117	118	78	29	454
Estimated Outlays .....	38	52	65	69	75	299
HHS Programs:						
Estimated Authorization Level .....	84	69	63	65	66	347
Estimated Outlays .....	32	74	66	62	64	298
Other Programs:						
Estimated Authorization Level .....	31	31	31	25	26	144
Estimated Outlays .....	18	26	29	25	25	123
Total Changes:						
Estimated Authorization Level .....	227	217	212	168	121	945
Estimated Outlays .....	88	152	160	156	164	720

<sup>a</sup> In addition to the costs shown above, enacting S. 1649 could affect revenues, but CBO estimates that any such effects would be insignificant.

Note: DHS = Department of Homeland Security; HHS = Department of Health and Human Services.

**Basis of estimate:** For this estimate, CBO assumes that the bill will be enacted before the end of 2010, that the necessary amounts will be appropriated near the start of each fiscal year, and that spending will follow historical patterns for similar activities.

#### *Spending subject to appropriation*

**DHS Programs.** CBO estimates that S. 1649 would authorize the appropriation of \$454 million over the 2011–2015 period for several DHS programs and activities. Assuming appropriation of the necessary amounts, CBO estimates that outlays would total \$299 million over that time period.

S. 1649 would authorize the appropriation of \$50 million annually over the 2011–2014 period for the Federal Emergency Management Agency (FEMA) to make grants to state, local, and tribal governments and nonprofit institutions to improve security at laboratories that contain certain toxins. The bill also would authorize the appropriation of \$15 million in 2011 and \$20 million for each of 2012 and 2013 for FEMA to make grants to states to help individuals and communities prepare for natural disasters, acts of terrorism, and other catastrophes. CBO estimates that implementing those grant programs would cost \$107 million over the 2011–2015 period and an additional \$148 million after 2015.

The legislation would authorize the appropriation of \$20 million annually over the 2011–2013 period for DHS to establish a program to distribute antidotes and medical countermeasures to emer-

agency-response providers and their families. CBO estimates that this program would cost \$60 million over the 2011–2014 period.

S. 1649 would authorize appropriations for the existing National Bioforensics Analysis Center, which collects, stores, and analyzes evidence from acts of bioterrorism and other crimes. The bill would authorize the appropriation of such sums as may be necessary for the center. For fiscal year 2010, the Congress appropriated about \$17 million for the National Bioforensics Analysis Center. CBO estimated future funding levels by adjusting the 2010 level for anticipated inflation. We estimate that this provision would cost about \$86 million over the 2011–2015 period.

In addition, S. 1649 would require DHS to establish regulations for instituting security measures at laboratories that contain certain toxins and to enforce those measures. The bill would require DHS to establish guidelines for emergency service personnel to improve the response to incidents involving weapons of mass destruction. The legislation also would require the department to develop and disseminate plume models (assessments of the spread of radioactive and other fallout from weapons of mass destruction) to appropriate emergency-response officials. Based on the costs of similar activities, CBO estimates that it would cost DHS about \$46 million to carry out these provisions over the next five years.

HHS Programs. CBO estimates that implementing S. 1649 would require the appropriation of \$347 million over the 2011–2015 period for activities to be conducted by the Department of Health and Human Services; resulting outlays would total \$298 million over the five-year period.

S. 1649 would modify and expand the requirement for the Secretaries of HHS and Agriculture to create a tiered list of certain toxins considered threats to the United States; that list was established in an executive order issued on July 2, 2010 (Executive Order 13546). The bill would require those agencies to provide DHS with a list of locations that store those toxins. DHS would develop and enforce the security regulations for facilities that contain those toxins.

S. 1649 also would require the Secretary of HHS to:

- Establish a list of biological toxins that could pose a threat to the health of individuals, animals, or plants, and maintain a database of the laboratories that possess those toxins, the individuals in contact with them, and any facilities that could be misused for the purpose of developing a biological weapon;
- Ensure that the appropriate agencies have access to the databases that maintain information regarding dangerous toxins; and
- Regulate the distribution, synthesis, and handling of variola virus DNA, which is used by research entities to prevent or treat smallpox.

Based on information from HHS and accounting for overlapping activities specified in the executive order, CBO estimates that those provisions would cost \$36 million over the 2011–2015 period.

S. 1649 would require HHS to establish and implement a strategy for dispensing antidotes or other countermeasures to mitigate the effects of a terrorist attack with chemical, biological, radiological, or nuclear materials. Those activities would overlap to a considerable degree with activities under Executive Order 13527,

issued on December 30, 2009; that order requires the Secretaries of DHS and HHS to establish mechanisms for providing medical countermeasures following a biological attack.

The legislation also would:

- Direct each agency in the executive branch to develop a plan to dispense countermeasures to its employees in certain facilities. The Secretary of HHS would review and approve those plans and establish a set of best practices applicable for entities in the private sector.
- Expand an existing program established by HHS that uses the U.S. Postal Service to deliver medical countermeasures in the event of an emergency. The program would be expanded to five cities in the first year and 15 cities in the second year, contingent upon the voluntary participation of additional jurisdictions.
- Require HHS to conduct a pilot program to study the feasibility of providing personal medical kits to the public. The medical kits would include antibiotics and other medical countermeasures as determined by HHS.

Based on information from HHS and accounting for activities already required by that executive order, CBO estimates that implementing those provisions would cost \$262 million over the 2011–2015 period.

Other Programs. CBO estimates that S. 1649 would authorize the appropriation of \$144 million over the 2011–2015 period for other programs and activities. Assuming appropriation of the necessary amounts, we estimate that outlays over that period would total \$123 million.

The bill would authorize the Department of State to provide assistance to foreign countries that are deemed to be at high risk for biological threats. The State Department currently engages with about 30 such countries to address biological threats and already meets many of the bill's requirements. Based on information from the department, CBO estimates that the department would require additional appropriations of about \$14 million a year to meet certain new requirements under the bill and that implementing those requirements would cost \$52 million over the 2011–2015 period. Those new requirements would be to assist countries in securing dangerous pathogens, ensuring the reliability of laboratory personnel, collaborating in bioforensics, adhering to international agreements on biological weapons, and purchasing and maintaining communications equipment and information technology.

The bill also would require the Secretary of Energy to provide assistance to developing countries to help them use more renewable energy and less petroleum fuels. Recently, the Department of Energy has initiated an international program called the Energy Development in Island Nations (EDIN) initiative. That program promotes the use of clean energy in Iceland, New Zealand, and the U.S. Virgin Islands. Based on information from the Department of Energy on the cost of expanding that program to additional countries, CBO estimates that implementing this provision would require additional appropriations of about \$10 million a year and, assuming that the increased efforts would start immediately, we estimate that costs would total \$48 million over the 2011–2015 period.

S. 1649 would authorize the appropriation of \$6 million annually over the 2011–2013 period for the Congressional Research Service

and the Government Accountability Office to study and assess how advances in technology might be used to combat terrorism. CBO estimates that implementing this provision would cost \$18 million over the 2011–2014 period.

Finally, S. 1649 would authorize a number of activities intended to enhance the ability of the international community to detect, identify, and contain outbreaks of infectious diseases. Based on information from the Department of Agriculture, CBO estimates that under those initiatives an expansion of activities already carried out by the department with Foreign Animal Disease Funds would cost approximately \$5 million over the next five years.

Revenues. S. 1649 could increase revenues because the legislation would establish civil penalties for violating the regulations established by DHS and HHS. Civil fines are recorded as revenues and deposited in the Treasury. CBO estimates that any additional revenues would not be significant because of the small number of cases likely to be affected.

Pay-as-you-go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The changes in revenues that are subject to those pay-as-you-go procedures are shown in the following table.

	By fiscal year, in millions of dollars—											
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2011–2015	2011–2020
	NET INCREASE OR DECREASE (–) IN THE DEFICIT											
Statutory Pay-As-You-Go Im-												
pact .....	0	0	0	0	0	0	0	0	0	0	0	0

Intergovernmental and private-sector impact: Under current law, laboratories must register with the National Select Agent Registry if they possess, use, or transfer certain materials or toxins. They also must comply with security standards for conducting risk assessments. S. 1649 would impose additional duties on laboratories if they possess, use, or transfer certain materials or toxins that are designated as tier I threats. Those laboratories would be required to comply with new security standards in addition to new standards for conducting background checks, training personnel, and performing vulnerability assessments.

S. 1649 also would require all individuals, laboratories, or other facilities that possess, use, or transfer certain biological agents or toxins to register with the Secretary of DHS.

Finally, the bill would require entities that currently receive, synthesize, or handle DNA from the Variola virus to meet new requirements determined by the Secretary. Those new requirements would determine who is qualified to receive the DNA, establish rules regarding distribution of the DNA, place limits on the amount of DNA provided to laboratories, place limits on the synthesis of the DNA, and enforce any other regulations deemed necessary by the Secretary.

The requirement to comply with the new federal regulations would impose intergovernmental and private-sector mandates as defined in UMRA. The Secretary of HHS, in coordination with the Secretary of DHS, would have broad authority to add or remove materials from the list of tier I threats or registry agents at any

time. Because the number of entities that would be affected and the types of limits and security measures required would depend on those future regulations, CBO cannot estimate the cost of the mandates. Consequently, CBO cannot determine whether the costs would exceed the annual thresholds for intergovernmental or private-sector mandates (\$70 million and \$141 million in 2010, respectively, adjusted annually for inflation).

Grant funding authorized by the bill for enhancing security at laboratories would benefit certain state, local, and tribal governments, including public institutions of higher education.

Previous CBO estimate: On October 26, 2010, CBO transmitted a cost estimate for H.R. 5498, the WMD Prevention and Preparedness Act of 2010, as ordered reported by the House Committee on Homeland Security on June 23, 2010. We estimated that implementing H.R. 5498 would cost \$455 million over the 2011–2015 period, assuming appropriation of the necessary amounts, and that enacting that legislation also would reduce direct spending by \$23 million over the 2011–2020 period. There are many differences between the bills and the cost estimates reflect those differences.

Estimate prepared by: Federal Costs: DHS—Mark Grabowicz; HHS—Stephanie Cameron and Andrea Noda; Department of Agriculture—Greg Hitz; Department of State—Sunita D'Monte; Department of Energy—Raymond Hall.

Impact on State, local, and Tribal governments: Lisa Ramirez-Branum.

Impact on the private sector: Sarah Axeen.

Estimate approved by: Theresa Gullo, Deputy Assistant Director for Budget Analysis.

#### VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 1649 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in *italic*, and existing law in which no change is proposed is shown in roman):

### **PUBLIC HEALTH SERVICE ACT**

Public Law 78–410

\* \* \* \* \*

## **TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE**

### **PART B—FEDERAL-STATE COOPERATION**

\* \* \* \* \*

#### **SEC. 319N. NATIONAL MEDICAL COUNTERMEASURE DISPENSING STRATEGY.**

(a) *DEFINITIONS.—In this section—*

(1) *the term “appropriate committees of Congress” means—*

(A) *the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education, Labor, and Pensions of the Senate; and*

(B) the Committee on Homeland Security, the Committee on Energy and Commerce, and the Committee on Oversight and Government Reform of the House of Representatives;

(2) the term “dispense” means to provide medical countermeasures to an affected population in response to a threat or incident;

(3) the term “medical countermeasure” means a drug (as that term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act), a device (as that term is defined in section 201(h) of such Act), or a biological product (as that term is defined in section 351 of this Act), to—

(A) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency; or

(B) diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device; and

(4) the term “public health emergency” means a public health emergency declared by the Secretary under section 319.

(b) STRATEGY.—The Secretary, in coordination with the Secretary of Homeland Security and the Postmaster General, shall develop, coordinate, and maintain a National Medical Countermeasure Dispensing Strategy (referred to in this section as the “National MCM Dispensing Strategy”).

(c) CONTENTS.—The National MCM Dispensing Strategy shall—

(1) encompass all aspects of the Federal role in dispensing medical countermeasures (referred to in this section as “MCMs”) and describe methods by which the Federal Government may assist State, local, and tribal governments to dispense MCMs;

(2) address a variety of geographical areas, population densities, and demographics;

(3) create a multilayered approach for the dispensing of MCMs that includes redundancies;

(4) address—

(A) a staffing plan for dispensing MCMs, including—

(i) for MCM dispensing locations; and

(ii) for dispensing through the United States Postal Service;

(B) requirements for timeliness of MCM dispensing;

(C) appropriateness, effectiveness, and efficiency of differing methods of MCM dispensing;

(D) measures and evaluations of MCM dispensing effectiveness and efficiency;

(E) liability issues associated with MCM dispensing, considering—

(i) the volunteer force;

(ii) medical personnel;

(iii) potential adverse reactions to medications;

(iv) participating employees of the United States Postal Service; and

(v) security personnel;

(F) security issues, including—

(i) partnerships with law enforcement; and

(ii) necessary levels of security to protect MCM dispensing locations and related personnel, participating employees of the United States Postal Service, and transportation of MCMs;

(G) communications issues, including—

(i) communications between the Federal, State, local, and tribal government officials that may be involved in dispensing MCMs;

(ii) communications between the government and private sector; and

(iii) the creation of prescribed messages or message templates so that information about how people can acquire MCMs can be disseminated quickly in anticipation of or in the immediate aftermath of a biological attack or a naturally occurring disease outbreak;

(H) transportation of MCMs to dispensing locations;

(I) implementation and operations of dispensing plans;

(J) necessary levels of Federal technical assistance in developing MCM dispensing capabilities;

(K) measures that are necessary in order so that actions taken pursuant to the National MCM Dispensing Strategy will comply with applicable requirements of the Federal Food, Drug, and Cosmetic Act and of section 351 of this Act; and

(L) any other topics that the Secretary determines appropriate; and

(5) be exercised regularly in various jurisdictions.

(d) *COORDINATION.*—Where appropriate, the Secretary, in coordination with the Secretary of Homeland Security and the Postmaster General, shall coordinate with State, local, and tribal government officials, private sector, and nongovernmental organizations in development of the National MCM Dispensing Strategy.

(e) *REPORTS TO CONGRESS.*—

(1) *IN GENERAL.*—The Secretary, in coordination with the Secretary of Homeland Security and the Postmaster General, shall—

(A) not later than 180 days after the date of enactment of this section, submit the National MCM Dispensing Strategy to the appropriate committees of Congress; and

(B) not later than 180 days after the submission of the Strategy under subparagraph (A), submit an implementation plan for such Strategy to the appropriate committees of Congress.

(2) *STATUS REPORT.*—Not later than 1 year after the submission of the implementation plan under paragraph (1)(B), the Secretary, in coordination with the Secretary of Homeland Security and the Postmaster General, shall submit to the appropriate committees of Congress a report describing the status of the activities taken pursuant to the implementation plan.

## PUBLIC HEALTH SERVICE ACT

\* \* \* \* \*

**SEC. 351A. [42 U.S.C. § 262a] ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.**

**(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—**

**(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—**

(A) **IN GENERAL.**—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) **CRITERIA.**—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) *the suitability of the agent or toxin to be used in a biological attack;*

[(III)] (IV) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

[(IV)] (V) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

**(2) TIER I AGENTS.—**

(A) **DESIGNATION OF TIER I AGENTS.**—*Not later than 180 days after the date of enactment of the Weapons of Mass Destruction Prevention and Preparedness Act of 2009, the Secretary, in coordination with the Secretary of Homeland Security, shall by regulation designate as a “Tier I agents” those agents and toxins—*

*(i) for which the Secretary of Homeland Security has issued a Material Threat Determination under section 319F–2(c)(2) regarding the agent or toxin, unless the Secretary of Health and Human Services determines, in coordination with the Secretary of Homeland Security, that such designation is unwarranted; or*

*(ii) that meet the criteria under subparagraph (B).*

(B) **CRITERIA.**—*In determining whether to designate an agent or toxin as a Tier I agent under subparagraph (A), the Secretary, in coordination with the Secretary of Homeland Security, shall consider—*

*(i) whether the agent or toxin has clear potential to be used effectively in a biological attack that causes significant casualties;*

*(ii) information available from any biological or bioterrorism risk assessments conducted by the Depart-*



ment of Homeland Security or relevant assessments by other agencies; and

(iii) such other criteria and information that the Secretary determines appropriate and relevant.

(C) *INCLUSION OF AGENTS AND TOXINS NOT PREVIOUSLY LISTED.*—All agents or toxins designated by the Secretary as Tier I agents shall be included on the list maintained by the Secretary pursuant to paragraph (1).

(D) *EVALUATION OF TIER I AGENTS.*—The Secretary, in coordination with the Secretary of Homeland Security, shall—

(i) on an ongoing basis, consider the inclusion of additional agents or toxins on the list of Tier I agents, as appropriate; and

(ii) at least biennially, review the list of Tier I agents to determine whether any agents or toxins should be removed from the list.

[(2)] (3) *BIENNIAL REVIEW.*—The Secretary shall review and republish the [list under paragraph (1)] lists under paragraphs (1) and (2) biennially, or more often as needed, and shall by regulation revise the [list as necessary in accordance with such paragraph] lists as necessary in accordance with such paragraphs.

(b) \* \* \*

(c) \* \* \*

(d) *REGISTRATION; IDENTIFICATION; DATABASE.*—

(1) *REGISTRATION.*—Regulations under subsections (b) and (c) of this section shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6) of this section.

(2) *IDENTIFICATION; DATABASE.*—Regulations under subsections (b) and (c) of this section shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(3) *FEDERAL AGENCY ACCESS.*—The Secretary shall ensure access to the database established pursuant to paragraph (2) by the Secretary of Agriculture, the Secretary of Homeland Security, the Attorney General, the Secretary of Energy, the Secretary of Defense, and any other Federal agency that the Secretary determines appropriate.

(e) *SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.*—

(1) *IN GENERAL.*—Regulations under subsections (b) and (c) of this section shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent

or toxin poses to public health and safety (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose. *In identifying whether an individual is within a category specified in subparagraph (B)(ii)(II), the Attorney General shall consult with the Secretary of Homeland Security to determine if the Department of Homeland Security possesses any information relevant to the identification of such an individual by the Attorney General.*

(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18)

or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50).

(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) of this section shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

(A) INDIVIDUALS.—Regulations under subsections (b) and (c) of this section shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) OTHER PERSONS.—Regulations under subsections (b) and (c) of this section shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this

subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) REVIEW.—

(A) ADMINISTRATIVE REVIEW.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) of this section shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5.

(B) CERTAIN PROCEDURES.—

(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocutory appeal and expedited consideration).

(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judicial proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under [subsection (h)] *subsection (i)* of this section shall not be disclosed under section 552 of title 5.

(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) LABORATORY AND FACILITY REGISTRATION AND DATABASE.—

(1) IN GENERAL.—*The Secretary, in coordination with the Secretary of Homeland Security and the Secretary of Agriculture, shall by regulation establish criteria defining characteristics, features, or equipment that could facilitate the misuse of a laboratory or other facility for the purposes of developing a biological weapon, which may include—*

*(A) technology that is particularly suitable to the development of an effective biological weapon, such as technology that would enable synthesis of Tier I agents;*

*(B) features that would enable an individual to develop a biological weapon while escaping detection; and*

*(C) such other characteristics as the Secretary determines appropriate.*

(2) REGISTRY AGENTS.—

*(A) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall establish and maintain by regulation a list of biological agents and toxins that have the potential to pose a severe threat to public, animal, or plant health but for which the potential to be used in a biological attack has not been established.*

*(B) DESIGNATION.—Agents listed pursuant to subparagraph (A) shall be designated as “Registry Agents”.*

*(C) EXCLUSION OF SELECT AGENTS.—In determining whether to designate a biological agent or toxin as a Registry Agent, the Secretary shall exclude agents or toxins listed pursuant to subsection (a)(1) of this section and section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.*

(3) REGULATIONS GOVERNING REGISTRATION AND DATABASE.—

*(A) REGULATIONS REQUIRING REGISTRATION.—The Secretary shall by regulation require the registration with the Secretary of laboratories or other facilities that—*

*(i) meet the criteria established pursuant to paragraph (1); or*

*(ii) possess, use, or transfer Registry Agents designated under paragraph (2).*

*(B) DATABASE.—The Secretary shall maintain a national database that includes the locations of each laboratory or other facility required to be registered under this subsection, the criteria established pursuant to paragraph (1) that are applicable to the laboratory or facility, the Registry Agents that are possessed or used at or transferred by the laboratory or facility, and the name of the person that owns or controls the laboratory or facility.*

(C) *ADDITIONAL REGISTRATION REQUIREMENTS.*—An individual who possesses, uses, or transfers Registry Agents at a location other than a laboratory or other facility shall be required to register with the Secretary pursuant to this subsection.

(4) *PENALTIES.*—In addition to any other penalties that may apply under law, any person who violates any provision of this subsection shall be subject to the United States for a civil penalty in an amount not to exceed \$25,000 in the case of an individual and \$50,000 in the case of any other person.

(5) *ACCESS TO DATABASE.*—The Secretary shall make the database established under paragraph (3) available to the Secretary of Homeland Security, the Secretary of Agriculture, the Secretary of Defense, the Attorney General, and such agencies as the Secretary determines appropriate.

(6) *BIOSECURITY AND BIOSAFETY BEST PRACTICES.*—The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall promote biosecurity and biosafety best practices to entities registered under paragraph (3).

(7) *DISCLOSURE OF INFORMATION.*—No Federal agency shall disclose under section 552 of title 5, United States Code, any information contained in the database established pursuant to paragraph (3).

[(f)] (g) *INSPECTIONS.*—The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) of this section to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e) of this section.

[(g)] (h) *EXEMPTIONS.*—

(1) *CLINICAL OR DIAGNOSTIC LABORATORIES.*—Regulations under [subsections (b) and (c)] *subsections (b), (c), and (f)* of this section shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(2) *PRODUCTS.*—

(A) *IN GENERAL.*—Regulations under subsections (b) and (c) of this section shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) of this section to a specific product is necessary to protect public health and safety.

(B) *RELEVANT LAWS.*—For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

(i) The Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq.].

(ii) Section 262 of this title.

(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. §§ 151–159).

(iv) The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. §§ 136 et seq.].

(C) INVESTIGATIONAL USE.—

(i) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) of this section when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) of this section to such product is not necessary to protect public health and safety.

(ii) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) of this section shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

(3) PUBLIC HEALTH EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) AGRICULTURAL EMERGENCIES.—Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such

exemption remains necessary, provide one extension of an additional 30 days.

**[(h)] (i) DISCLOSURE OF INFORMATION.—**

(1) **NONDISCLOSURE OF CERTAIN INFORMATION.**—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) of this section for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d) of this section, or any other compilation of the registration or transfer information submitted under subsections (b) and (c) of this section to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c) of this section, or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under **[(subsection (f))] subsection (g)** of this section that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) **COVERED AGENCIES.**—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) **OTHER EXEMPTIONS.**—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection



552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) **RULE OF CONSTRUCTION.**—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c) of this section; or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) **DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.**—This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

[(i)] (j) **CIVIL MONEY PENALTY.**—

(1) **IN GENERAL.**—In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) of this section shall be subject to the United States for a civil money penalty in an amount not exceeding \$250,000 in the case of an individual and \$500,000 in the case of any other person.

(2) **APPLICABILITY OF CERTAIN PROVISIONS.**—The provisions of section 1320a–7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a–7a(j)(2) of this title, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

[(j)] (k) **NOTIFICATION IN EVENT OF RELEASE.**—Regulations under subsections (b) and (c) of this section shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released

listed agent or toxin is an overlap agent or toxin (as defined in **[subsection (l)]** *subsection m* of this section), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

**[(k)]** *(l)* **REPORTS.**—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) of this section (relating to theft or loss) and **[subsection (j)]** *subsection (k)* of this section (relating to releases).

**[(l)]** *(m)* **DEFINITIONS.**—For purposes of this section:

(1) The terms “biological agent” and “toxin” have the meanings given such terms in section 178 of title 18.

(2) The term “listed agents and toxins” means biological agents and toxins listed pursuant to subsection (a)(1) of this section.

(3) The term “listed agents or toxins” means biological agents or toxins listed pursuant to subsection (a)(1) of this section.

(4) The term “overlap agents and toxins” means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1) of this section; and

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term “overlap agent or toxin” means a biological agent or toxin that—

(A) is listed pursuant to subsection (a)(1) of this section; and

(B) is listed pursuant to section 8401(a)(1) of title 7.

(6) The term “person” includes Federal, State, and local governmental entities.

(7) The term “registered person” means a person registered under regulations under subsection (b) or (c) of this section.

(8) The term “restricted person” has the meaning given such term in section 175b of title 18.

**[(m)]** *(n)* **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.

## **HOMELAND SECURITY ACT OF 2002**

Public Law 107–296

\* \* \* \* \*

### **TITLE II—INFORMATION ANALYSIS AND INFRASTRUCTURE PROTECTION**

#### **Subtitle A—Directorate For Information Analysis And Infrastructure Protection; Access To Infor- mation**

\* \* \* \* \*

**SEC. 201. [6 U.S.C. § 121] INFORMATION AND ANALYSIS AND INFRASTRUCTURE PROTECTION.**

(a) \* \* \*

\* \* \* \* \*

(d) RESPONSIBILITIES OF SECRETARY RELATING TO INTELLIGENCE AND ANALYSIS AND INFRASTRUCTURE PROTECTION.—

(1) \* \* \*

\* \* \* \* \*

(8) To disseminate, as appropriate, information analyzed by the Department within the Department, to other agencies of the Federal Government with responsibilities relating to homeland security, [and to agencies of State and local governments and private sector entities with such responsibilities in order to assist in the deterrence, prevention, preemption of, or response to, terrorist attacks against the United States.] *to State, local, tribal, and private entities with such responsibilities, and, as appropriate, to the general public, in order to assist in deterring, preventing, or responding to acts of terrorism against the United States.*

\* \* \* \* \*

**SEC. 203. [6 U.S.C. § 124] HOMELAND SECURITY ADVISORY SYSTEM.**

(a) \* \* \*

(b) \* \* \*

(c) *TERRORISM THREAT AWARENESS.*—

(1) *TERRORISM THREAT AWARENESS.*—*The Secretary, in coordination with the Attorney General, shall ensure that information concerning terrorist threats is available to the general public within the United States.*

(2) *THREAT BULLETINS.*—

(A) *IN GENERAL.*—*Consistent with the requirements of subsection (b), the Secretary shall on a timely basis prepare unclassified terrorism related threat and risk assessments.*

(B) *REQUIREMENTS.*—*Each assessment required under subparagraph (A) shall—*

*(i) include guidelines for the general public for preventing and responding to acts of terrorism; and*

*(ii) be made available on the website of the Department and other publicly accessible websites, communication systems, and information networks.*

(3) *GUIDELINES FOR STATE, LOCAL, AND TRIBAL GOVERNMENTS.*—*The Secretary shall provide to State, local, and tribal governments written guidelines on how to disseminate information about terrorism-related threats and risks to the general public within their jurisdictions.*

(4) *USE OF EXISTING RESOURCES.*—*The Secretary shall use websites, communication systems, and information networks in operation on the date of an assessment under this subsection to satisfy the requirements of paragraph (2)(B)(ii).*

\* \* \* \* \*

## TITLE III—SCIENCE AND TECHNOLOGY IN SUPPORT OF HOMELAND SECURITY

\* \* \* \* \*

### SEC. 318. ENHANCED BIOSECURITY MEASURES.

(a) *DEFINITIONS.*—*In this section:*

(1) *LISTED AGENT.*—*The term ‘listed agent’ means an agent or toxin included on—*

(A) *the list established and maintained by the Secretary of Health and Human Services under section 351A(a)(1) of the Public Health Service Act (42 U.S.C. § 262a(a)(1)); or*

(B) *the list established and maintained by the Secretary of Agriculture under section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(a)(1)).*

(2) *PERSON.*—*The term ‘person’ has the meaning given that term in section 351A(l)(6) of the Public Health Service Act (42 U.S.C. § 262a(l)(6)).*

(3) *TIER I AGENT.*—*The term ‘Tier I agent’ means an agent or toxin designated as a Tier I agent under section 351A(a)(2) of the Public Health Service Act (42 U.S.C. § 262a(a)(2)) or section 212(a)(2) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(a)(2)).*

(b) *REGULATIONS.*—*The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, shall through a negotiated rule making under subchapter III of chapter 5 of title 5, United States Code, establish enhanced biosecurity measures for persons that possess, use, or transfer Tier I agents, which shall include—*

(1) *standards for personnel reliability programs;*

(2) *standards for biosecurity training of responsible officials, laboratory personnel, and support personnel employed by such persons;*

(3) *standards for performing laboratory risk assessments;*

(4) *risk-based laboratory security performance standards; and*

(5) *any other security standards jointly determined necessary by the Secretary and the Secretary of Health and Human Services.*

(c) *NEGOTIATED RULEMAKING COMMITTEE.*—*The negotiated rule-making committee established by the Secretary under subsection (b) shall include representatives from—*

(1) *the Department;*

(2) *the Department of Health and Human Services;*

(3) *the Department of Agriculture;*

(4) *the Department of Defense;*

(5) *the Department of Energy;*

(6) *the Department of Justice;*

(7) *for profit research institutions;*

(8) *academic research institutions;*

(9) *nonprofit research institutions; and*

(10) *other interested parties, as the Secretary determines appropriate.*

(d) *TIME REQUIREMENT.*—*The procedures for the negotiated rule-making conducted under subsection (b) shall be conducted in a timely manner to ensure that—*

(1) any recommendations with respect to proposed regulations are provided to the Secretary not later than 6 months after the date of enactment of this section; and

(2) a final rule is promulgated not later than 12 months after the date of enactment of this section.

(e) **FACTORS TO BE CONSIDERED.**—In developing proposed and final standards under subsection (b), the Secretary and the negotiated rulemaking committee shall consider factors including—

(1) the recommendations of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (established under section 1851 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Public Law 110–53; 121 Stat. 501)), the National Science Advisory Board for Biosecurity (established under section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417; 120 Stat. 2851)), the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and any working group established under Executive Order 13486 (74 Fed. Reg. 2289) relating to strengthening laboratory biosecurity; and

(2) how any disincentives to biological research arising from enhanced biosecurity measures can be minimized.

(f) **IMPLEMENTATION OF ENHANCED BIOSECURITY MEASURES.**—

(1) **ENFORCEMENT.**—The Secretary, in consultation as appropriate with the Secretary of Health and Human Services and the Secretary of Agriculture, shall enforce the standards promulgated under subsection (b).

(2) **TRAINING PROGRAMS.**—The Secretary of Health and Human Services, in consultation with the Secretary, shall develop or approve training programs that meet the standards promulgated under subsection (b).

(3) **HARMONIZATION OF REGULATIONS.**—

(A) **REGULATIONS UNDER PUBLIC HEALTH SERVICE ACT.**—Not later than 120 days after the Secretary promulgates regulations or amendments thereto pursuant to this section, the Secretary of Health and Human Services shall amend regulations promulgated under the Select Agent Program under section 351A(b)(1) of the Public Health Service Act (42 U.S.C. § 262a(b)(1)) to ensure that such regulations do not overlap or conflict with the regulations promulgated by the Secretary under this section.

(B) **REGULATIONS UNDER AGRICULTURE BIOTERRORISM PROTECTION ACT OF 2002.**—Not later than 120 days after the Secretary promulgates regulations or amendments thereto pursuant to this section, the Secretary of Agriculture shall amend regulations promulgated under the Select Agent Program under section 212(b)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(b)(1)) to ensure that such regulations do not overlap or conflict with the regulations promulgated by the Secretary under this section.

(4) **PENALTIES.**—

(A) **CIVIL MONEY PENALTY.**—In addition to any other penalties that may apply under law, any person who violates any provision of regulations promulgated under subsection (b) shall be subject to a civil money penalty in an amount

not exceeding \$250,000 in the case of an individual and \$500,000 in the case of any other person that possesses, uses, or transfers a Tier I agent.

**(B) INTERMEDIATE SANCTIONS.—**

(i) **IN GENERAL.**—If the Secretary determines that a person has violated any provision of regulations promulgated under this section, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (A).

(ii) **TYPES OF SANCTIONS.**—The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(I) directed plans of correction;

(II) civil money penalties in an amount not to exceed \$10,000 for each violation of, or for each day of substantial noncompliance with, the regulations promulgated under this section;

(III) payment for the costs of onsite monitoring;

or

(IV) any combination of the actions described in subclauses (I), (II), and (III).

**(C) SUSPENSION OF RESEARCH AND FUNDING.—**

(i) **IN GENERAL.**—If the Secretary determines that a person has violated any provision of the regulations promulgated under subsection (b) and that the violation has endangered security, the Secretary may suspend the authority of the person to possess, use, or transfer Tier I agents until the violation has been remedied.

(ii) **NOTICE.**—If the Secretary suspends the authority of a person to possess, use, or transfer Tier I agents under clause (i), the Secretary shall notify each executive agency that provides funding for research on Tier I agents by the person.

(iii) **SUSPENSION.**—If the head of an executive agency receives notice under clause (ii), the head of the executive agency may suspend the provision of funds to the person for research on Tier I agents.

(iv) **RULE OF CONSTRUCTION.**—Nothing in this subparagraph shall be construed to limit or modify the authority to suspend the authority of a person to possess, use, or transfer Tier I agents, or to suspend funding for research under any other provision of law.

**(D) PROCEDURES.**—The Secretary shall develop and implement procedures with respect to when and how penalties or intermediate sanctions are to be imposed under this paragraph. Such procedures shall provide for notice to the person, a reasonable opportunity to respond to the proposed penalty or intermediate sanction, and appropriate procedures for appealing determinations relating to the imposition of a penalty or intermediate sanction.

**(5) SIMULTANEOUS LABORATORY INSPECTIONS.—**

**(A) INSPECTIONS BY THE DEPARTMENT OF HOMELAND SECURITY.**—The Secretary shall have the authority to inspect persons subject to the regulations promulgated under sub-

section (b) to ensure compliance with the regulations by such persons.

(B) *SIMULTANEOUS INSPECTIONS.*—All Federal agencies conducting inspections of a person to ensure compliance with regulations promulgated under subsection (b), regulations promulgated under section 351A(b)(1) of the Public Health Service Act (42 U.S.C. § 262a(b)(1)), regulations promulgated under section 212(b)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(b)(1)), or security standards applicable under a contract between a Federal agency and the person shall be conducted simultaneously to the extent practicable.

(C) *JOINT INSPECTION PROCEDURES.*—Federal agencies conducting simultaneous inspections of a person under this paragraph shall cooperate, to the maximum extent practicable, to ensure that the inspections are conducted efficiently and in a manner that minimizes the administrative burden on the person.

(D) *INSPECTION REPORTS.*—Any report of inspection of a person conducted by a Federal agency to enforce regulations promulgated under subsection (b), regulations promulgated under section 351A(b)(1) of the Public Health Service Act (42 U.S.C. § 262a(b)(1)), regulations promulgated under section 212(b)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(b)(1)), or security standards applicable under a contract between the Federal agency and the person shall be made available to any other Federal agency that enforces any such regulations with respect to the person or that funds research of a Tier I agent or a listed agent by the person.

**SEC. 319. BIOSECURITY INFORMATION SHARING.**

(a) *IN GENERAL.*—Consistent with the responsibilities under section 201(d), the Secretary shall ensure that State, local, and tribal governments have access to relevant safety and security information relating to biological laboratories and facilities in or in close proximity to the jurisdiction of the State, local, or tribal government, as the Secretary determines appropriate.

(b) *ACCESS TO INFORMATION IN DATABASES.*—In carrying out this section, the Secretary may utilize information from the national databases established under subsections (d)(2) and (f)(3) of section 351A of the Public Health Service Act (42 U.S.C. § 262a) and section 212(d)(2) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. § 8401(d)(2)).

(c) *CLASSIFIED AND SENSITIVE INFORMATION.*—The Secretary shall ensure that any information disseminated under this section is disseminated consistent with—

- (1) the authority of the Director of National Intelligence to protect intelligence sources and methods under the National Security Act of 1947 (50 U.S.C. §§ 401 et seq.) and related procedures or similar authorities of the Attorney General concerning sensitive law enforcement information;
- (2) section 552a of title 5, United States Code (commonly referred to as the Privacy Act of 1974); and
- (3) other relevant laws.

**SEC. 320. PERSONAL MEDKITS FOR EMERGENCY RESPONSE PROVIDERS AND MEMBERS OF PREPAREDNESS ORGANIZATIONS.**

(a) **DEFINITIONS.**—*In this section—*

(1) *the term ‘appropriate committees of Congress’ means—*

(A) *the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education, Labor, and Pensions of the Senate; and*

(B) *the Committee on Homeland Security and the Committee on Energy and Commerce of the House of Representatives;*

(2) *the term ‘immediate family member’ means an individual who is a cohabitating family member or domestic partner;*

(3) *the term ‘preparedness organization’ means an organization that contributes to State or local preparedness for an emergency or major disaster (as those terms are defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. §5122)), including Community Emergency Response Teams, the Medical Reserve Corps, the Fire Corps, and the citizen preparedness programs of the American Red Cross;*

(4) *the term ‘medkit’ means a cache of antibiotics and other medical countermeasures to be used during a public health emergency;*

(5) *the term ‘medkit program’ means the program established under subsection (b); and*

(6) *the term ‘public health emergency’ means a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. §247d).*

(b) **ESTABLISHMENT.**—*The Secretary, in coordination with the Secretary of Health and Human Services and in a manner that complies with applicable requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301 et seq.) and of section 351 of the Public Health Service Act (42 U.S.C. §262), shall establish a program to distribute medkits to emergency response providers, members of preparedness organizations, and immediate family members of an emergency response provider or member of a preparedness organization.*

(c) **MEDKIT PROGRAM COMPONENTS.**—

(1) **IN GENERAL.**—*An emergency response provider, member of a preparedness organization, or immediate family member of an emergency response provider or member of a preparedness organization participating in the medkit program shall—*

(A) *register with the Secretary;*

(B) *before the distribution of a medkit, receive training regarding—*

(i) *the proper use and dosing of medical countermeasures;*

(ii) *reporting of the use of a medkit;*

(iii) *the proper storage of a medkit; and*

(iv) *any other topic determined appropriate by the Secretary;*

(C) *before the distribution of a medkit, undergo appropriate medical screening; and*



(D) report the use of a medkit within a reasonable time period, as established by the Secretary.

(2) INVENTORY.—The Secretary shall conduct an annual inventory of medkits distributed under the medkit program.

(d) AUTHORIZATION AND CONTENTS.—

(1) IN GENERAL.—The Secretary shall coordinate with the Secretary of Health and Human Services and the Commissioner of Food and Drugs to—

(A) seek an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 360bbb–3), if needed, to allow distribution and use of medkits under the medkit program; and

(B) establish the appropriate contents for medkits distributed under the medkit program.

(2) CONTENT CONSIDERATION.—In establishing the appropriate contents for medkits under paragraph 20 (1)(B), the Secretary, in coordination with the Secretary of Health and Human Services, shall—

(A) consider information available from any biological or bioterrorism risk assessments conducted by the Department of Homeland Security or other relevant assessments by other departments or the intelligence community;

(B) consider the criteria described in section 351A(a)(1)(B) of the Public Health Service Act (42 U.S.C. § 262a(a)(1)(B));

(C) consult with relevant private and public organizations; and

(D) consider such other criteria and information that the Secretary, in coordination with the Secretary of Health and Human Services, determines appropriate.

(e) REPORT.—Not later than 180 days after the date of enactment of this section, the Secretary shall submit to the appropriate committees of Congress a report on the implementation of this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Secretary to carry out this section, \$20,000,000 for each of fiscal years 2011 through 2013.

#### **SEC. 321. BIOFORENSICS CAPABILITIES AND STRATEGY.**

(a) DEFINITIONS.—In this section—

(1) the term ‘appropriate committees of Congress’ means—

(A) the Committee on Homeland Security and Governmental Affairs, the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, the Committee on Agriculture, Nutrition, and Forestry, and the Committee on Armed Services of the Senate; and

(B) the Committee on Homeland Security, the Committee on the Judiciary, the Committee on Energy and Commerce, the Committee on Agriculture, and the Committee on Armed Services of the House of Representatives;

(2) the term ‘bioforensic’ means the scientific discipline dedicated to analyzing evidence from a bioterrorism act, biological agent or toxin based criminal act, or inadvertent biological agent or toxin release for attribution purposes;

(3) the term ‘National Bioforensics Analysis Center’ means the National Bioforensics Analysis Center established under subsection (b);

(4) the term 'national bioforensics repository collection' means the national bioforensics repository collection established under subsection (c)(1); and

(5) the term 'national bioforensics strategy' means the national bioforensics strategy developed under subsection (d)(1).

(b) NATIONAL BIOFORENSICS ANALYSIS CENTER.—There is in the Department a National Bioforensics Analysis Center which shall—

(1) serve as the lead Federal facility to conduct and facilitate bioforensic analysis in support of the executive agency with primary responsibility for responding to the biological incident;

(2) maintain the national bioforensics repository collection as a reference collection of biological agents and toxins for comparative bioforensic identifications; and

(3) support threat agent characterization studies and bioforensic assay development.

(c) NATIONAL BIOFORENSIC REPOSITORY COLLECTION.—

(1) IN GENERAL.—The National Bioforensics Analysis Center shall maintain a national bioforensics repository collection.

(2) ACTIVITIES.—The national bioforensics repository collection shall—

(A) receive, store, and distribute biological threat agents and toxins and related biological agents and toxins;

(B) serve as a reference collection for comparative bioforensic identifications; and

(C) support threat agent characterization studies and bioforensic assay development.

(3) PARTICIPATION.—

(A) IN GENERAL.—The Secretary, the Attorney General, the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, and the head of any other appropriate executive agency with a biological agent or toxin collection that is useful for the bioforensic analysis of biological incidents, performance of biological threat agent characterization studies, or development of bioforensic assays shall provide samples of relevant biological agents and toxins, as determined by the Secretary, in consultation with the head of the executive agency possessing the agent or toxin, which shall not include any variola virus, to the national bioforensics repository collection.

(B) OTHER BIOLOGICAL AGENTS AND TOXINS.—The Secretary shall encourage the contribution of public and private biological agent and toxin collections to the national bioforensics repository collection that were collected or created with support from a Federal grant or contract and that support the functions described in paragraph (2).

(4) ACCESS.—The Secretary shall—

(A) provide an executive agency that submits a biological agent or toxin to the national bioforensics repository collection with access to the national bioforensics repository collection; and

(B) establish a mechanism to provide public and private entities with access to the national bioforensics repository collection, as appropriate, for scientific analysis of a biological agent or toxin in the national bioforensics repository

collection, with appropriate protection for intellectual property rights.

(5) *REPORT.*—

(A) *IN GENERAL.*—Not later than 180 days after the date of enactment of this section, the Secretary, in consultation with the Attorney General, the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, and the head of any other appropriate executive agency that will participate in or contribute to the national bioforensics repository collection, shall submit to the appropriate committees of Congress a report regarding the national bioforensics repository collection.

(B) *CONTENTS.*—The report submitted under subparagraph (A) shall—

(i) discuss the status of the establishment of the national bioforensics repository collection;

(ii) identify domestic and international biological agent and toxin collections that would prove useful in carrying out the functions of the national bioforensics repository collection;

(iii) examine any access or participation issues affecting the establishment of the national bioforensics repository collection or the ability to support bioforensic analysis, threat characterization studies, or bioforensic assay development, including—

(I) intellectual property concerns;

(II) access to collected or created biological agent or toxin collections funded by a Federal grant or contract;

(III) costs for the national bioforensics repository collection associated with accessing domestic and international biological agent and toxin collections;

(IV) costs incurred by domestic and international biological agent and toxin collections to allow broad access or contribute biological agents or toxins to the national bioforensics repository collection; and

(V) access to the national bioforensics repository collection by public and private researchers to support threat characterization studies and bioforensic assay development; and

(iv) other issues determined appropriate by the Secretary.

(d) *NATIONAL BIOFORENSIC STRATEGY.*—

(1) *IN GENERAL.*—The Secretary, in coordination with the Attorney General, the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, and the head of any other appropriate executive agency, as determined by the Secretary, shall develop, coordinate, and maintain a national bioforensics strategy.

(2) *CONTENTS.*—The national bioforensics strategy shall—

(A) provide for a coordinated approach across all executive agencies with responsibilities for analyzing evidence from a bioterrorism act, biological agent or toxin based

*criminal act, or inadvertent biological agent or toxin release for attribution purposes;*

*(B) describe the roles and responsibilities of all relevant executive agencies;*

*(C) establish mechanisms, in coordination with State, local, and tribal governments, for coordinating with law enforcement agencies in analyzing bioforensic evidence;*

*(D) include guidance for collecting, processing, and analyzing samples; and*

*(E) provide for a coordinated approach across all executive agencies to support threat agent characterization research, funding, and assay development.*

(3) *REPORT.*—Not later than 180 days after the date of enactment of this section, the Secretary, in consultation with the Attorney General, the Secretary of Health and Human Services, the Secretary of Agriculture, the Secretary of Defense, and the head of any other appropriate executive agency, as determined by the Secretary, shall submit to the appropriate committees of Congress the national bioforensics strategy.

(e) *AUTHORIZATION OF APPROPRIATIONS.*—There are authorized to be appropriated such sums as may be necessary to carry out this section.

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## TITLE V—EMERGENCY PREPAREDNESS AND RESPONSE

\* \* \* \* \*

### SEC. 504. [6 U.S.C. § 314] AUTHORITY AND RESPONSIBILITIES

(a) *IN GENERAL.*—The Administrator shall provide Federal leadership necessary to prepare for, protect against, respond to, recover from, or mitigate against a natural disaster, act of terrorism, or other man-made disaster, including—

(1) \* \* \*

\* \* \* \* \*

*(20) enhancing and promoting the preparedness of individuals and communities for natural disasters, acts of terrorism, and other man-made disasters;*

[(20)] (21) carrying out all authorities of the Federal Emergency Management Agency and the Directorate of Preparedness of the Department as transferred under section 315 of this title; and

[(21)] (22) otherwise carrying out the mission of the Agency as described in section 313(b) of this title.

\* \* \* \* \*

### SEC. 525. COMMUNICATIONS PLANNING.

(a) *INCORPORATION OF COMMUNICATIONS PLANS.*—

(1) *IN GENERAL.*—The Secretary, acting through the Administrator of the Federal Emergency Management Agency, shall incorporate into each operational plan developed under sections 653(a)(4) and 653(b) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. § 701 note) a communica-

tions plan for providing information to the public related to preventing, preparing for, protecting against, and responding to imminent natural disasters, acts of terrorism, and other man-made disasters, including incidents involving the use of weapons of mass destruction and other potentially catastrophic events.

(2) *CONSULTATION.*—In developing communications plans under paragraph (1), the Administrator shall consult with State, local, and tribal governments and coordinate, as the Administrator considers appropriate, with other Federal departments and agencies that have responsibilities under the National Response Framework and other relevant Federal departments and agencies.

(b) *PRESCRIPTED MESSAGES AND MESSAGE TEMPLATES.*—

(1) *IN GENERAL.*—As part of the communication plans, the Administrator shall develop prescribed messages or message templates, as appropriate, to be included in the plans to be provided to State, local, and tribal officials so that those officials can quickly and rapidly disseminate critical information to the public in anticipation or in the immediate aftermath of a disaster or incident.

(2) *DEVELOPMENT AND DESIGN.*—The prescribed messages or message templates shall—

(A) be developed, as the Administrator determines appropriate, in consultation with State, local, and tribal governments and in coordination with other Federal departments and agencies that have responsibilities under the National Response Framework and other relevant Federal departments and agencies;

(B) be designed to provide accurate, essential, and appropriate information and instructions to the population directly affected by a disaster or incident, including information related to evacuation, sheltering in place, and issues of immediate health and safety; and

(C) be designed to provide accurate, essential, and appropriate technical information and instructions to emergency response providers and medical personnel responding to a disaster or incident.

(c) *COMMUNICATIONS FORMATS.*—In developing the prescribed messages or message templates required under subsection (b), the Administrator shall develop each such prescribed message or message template in multiple formats to ensure delivery—

(1) in cases where the usual communications infrastructure is unusable as a result of the nature of a disaster or incident; and

(2) to individuals with disabilities or other special needs and individuals with limited English proficiency in accordance with section 616 of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. § 701 note).

(d) *DISSEMINATION AND TECHNICAL ASSISTANCE.*—The Administrator shall ensure that all prescribed messages and message templates developed under this section are made available to State, local, and tribal governments so that those governments may incorporate them, as appropriate, into their emergency plans. The Administrator shall also make available relevant technical assistance to those governments to support communications planning.

(e) *EXERCISES.*—To ensure that the prescribed messages or message templates developed under this section can be effectively utilized in a disaster or incident, the Administrator shall incorporate such prescribed messages or message templates into exercises conducted under the National Exercise Program described in section 648 of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. §701 note).

(f) *REPORT.*—Not later than 1 year after the date of the enactment of this section, the Administrator shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives a copy of the communications plans required to be developed under this section, including prescribed messages or message templates developed in conjunction with the plans and a description of the means that will be used to deliver such messages in a natural disaster, act of terrorism, or other manmade disaster.

**SEC. 526. INDIVIDUAL AND COMMUNITY PREPAREDNESS.**

(a) *IN GENERAL.*—The Administrator shall assist State, local, and tribal governments in improving and promoting individual and community preparedness for natural disasters, acts of terrorism, and other man-made disasters, including incidents involving the use of weapons of mass destruction and other potentially catastrophic events, by—

(1) developing guidelines and checklists of recommended actions for individual and community prevention and preparedness efforts and disseminating such guidelines and checklists to communities and individuals;

(2) disseminating the guidelines developed under section 502 of the Weapons of Mass Destruction Prevention and Preparedness Act of 2009 to communities and individuals, as appropriate;

(3) compiling and disseminating information on best practices in individual and community preparedness;

(4) providing information and training materials in support of individual and community preparedness efforts;

(5) conducting individual and community preparedness outreach efforts; and

(6) such other actions as the Administrator determines appropriate.

(b) *COORDINATION.*—Where appropriate, the Administrator shall coordinate with private sector and nongovernmental organizations to promote individual and community preparedness.

(c) *SUPPORT FOR VOLUNTARY PROGRAMS.*—In carrying out the responsibilities described in subsection (a), the Administrator shall, where appropriate, work with and provide support to individual and community preparedness programs, such as the Community Emergency Response Team Program, Fire Corps, Medical Reserve Corps Program, Volunteers in Police Service, USAonWatch-Neighborhood Watch, and other voluntary programs, including those sponsored by nongovernmental organizations.

(d) *DIRECTOR.*—The Administrator shall appoint a Director of Community Preparedness to coordinate and oversee the individual and community preparedness efforts of the Agency.

(e) *GRANTS.*—

(1) *IN GENERAL.*—*The Administrator may make grants to States to support individual and community preparedness efforts, including through the Citizen Corps Program.*

(2) *APPROPRIATIONS.*—*There are authorized to be appropriated for grants under this section—*

*(A) \$15,000,000 for fiscal year 2011;*

*(B) \$20,000,000 for fiscal year 2012; and*

*(C) \$20,000,000 for fiscal year 2013.*

## **AGRICULTURAL BIOTERRORISM PROTECTION ACT OF 2002**

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## **TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS**

\* \* \* \* \*

### **Subtitle B—Department of Agriculture**

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#### **SEC. 212. [7 U.S.C. §8401] REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.**

(a) **REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.**—

(1) **LIST OF BIOLOGICAL AGENTS AND TOXINS.**—

(A) **IN GENERAL.**—The Secretary of Agriculture shall by regulation establish and maintain a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

(B) **CRITERIA.**—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) **CONSIDER**—

(I) the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;

(II) the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;

(III) *the suitability of the agent or toxin to be used in a biological attack;*

[(III)] (IV) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and

[(IV)] (V) any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

(2) **TIER 1 AGENTS.**—

(A) *DESIGNATION OF TIER AGENTS.*—Not later than 180 days after the date of enactment of the Weapons of Mass Destruction Prevention and Preparedness Act of 2009, the Secretary, in coordination with the Secretary of Homeland Security, shall by regulation designate as ‘Tier I agents’ those agents and toxins—

(i) for which the Secretary of Homeland Security has issued a Material Threat Determination under section 319F–2(c)(2) of the Public Health Service Act (42 U.S.C. §247d–6b(c)(2)) regarding the agent or toxin, unless the Secretary of Agriculture determines, in coordination with the Secretary of Homeland Security, that such designation is unwarranted; or

(ii) that meet the criteria under subparagraph (B).

(B) *CRITERIA.*—In determining whether to designate an agent or toxin as a Tier I agent under subparagraph (A), the Secretary, in coordination with the Secretary of Homeland Security, shall consider—

(i) whether the agent or toxin has clear potential to be used effectively in a biological attack that causes catastrophic consequences;

(ii) information available from any biological or bioterrorism risk assessments conducted by the Department of Homeland Security or relevant assessments by other agencies; and

(iii) such other criteria and information that the Secretary determines appropriate and relevant.

(C) *INCLUSION OF AGENTS AND TOXINS NOT PREVIOUSLY LISTED.*—All agents or toxins designated by the Secretary as Tier I agents shall be included on the list maintained by the Secretary pursuant to paragraph (1).

(D) *EVALUATION OF TIER I AGENTS.*—The Secretary, in coordination with the Secretary of Homeland Security, shall—

(i) on an ongoing basis, consider the inclusion of additional agents or toxins on the list of Tier I agents, as appropriate; and

(ii) at least biennially, review the list of Tier I agents to determine whether any agents or toxins should be removed from the list.

[(2)] (3) *BIENNIAL REVIEW.*—The Secretary shall review and republish the [list under paragraph (1)] lists under paragraphs (1) and (2) biennially, or more often as needed, and shall by regulation revise the [list as necessary in accordance with such paragraph] lists as necessary in accordance with such paragraphs.

(b) \* \* \*

(c) \* \* \*

(d) *REGISTRATION; IDENTIFICATION; DATABASE.*—

(1) \* \* \*

(2) \* \* \*

(3) *FEDERAL AGENCY ACCESS.*—The Secretary shall ensure access to the database established pursuant to paragraph (2) by the Secretary of Health and Human Services, the Secretary of Homeland Security, the Attorney General, the Secretary of En-



*ergy, the Secretary of Defense, and any other Federal agency that the Secretary determines appropriate.*

(e) \* \* \*

(f) \* \* \*

(g) EXEMPTIONS.—

(1) OVERLAP AGENTS AND TOXINS.—

(A) \* \* \*

\* \* \* \* \*

(E) PUBLIC HEALTH EMERGENCIES.—Upon request of the Secretary of Health and Human Services, after the granting by such Secretary of an exemption under **[351A(g)(3)] 351A(h)(3)** of title 42 pursuant to a finding that there is a public health emergency, the Secretary of Agriculture may temporarily exempt a person from the applicability of the requirements of this section with respect to an overlap agent or toxin, in whole or in part, to provide for the timely participation of the person in a response to the public health emergency. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that upon request of the Secretary of Health and Human Services, the Secretary of Agriculture may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

## MINORITY VIEWS OF SENATOR CARL LEVIN

I commend the Homeland Security and Governmental Affairs Committee for its focus on security threats that could pose a risk to our Nation and our way of life, including threats from weapons of mass destruction (WMD). The evolving threat of bioterrorism requires a carefully coordinated and integrated whole-of-government approach, both to stay ahead of the threat and to ensure that our own crucial biological research and development capabilities are not impaired.

It is with those priorities in mind that I oppose some of the provisions contained in S. 1649, the “Weapons of Mass Destruction Prevention and Preparedness Act of 2009.” After taking into account the views of the Administration and outside experts, and considering the full range of significant Administration actions on biosecurity—both before and after the bill was reported by the committee—I cannot support this legislation in its current form.

S. 1649 would duplicate efforts in many areas that are in critical need of unification, it would complicate important biosecurity and biosafety regulations without providing clear security gains, and it still is not supported by crucial stakeholders in and out of government. The main thrust of the bill would run contrary to key recommendations of the very commission that triggered this legislation. These serious shortcomings have not been addressed in this legislation, and that is why I voted against the bill while it was before this committee. Preventing and mitigating a biological attack is sufficiently important and complex that we must take the time to get it right as we seek to improve our bio-security and safety.

If this legislation moves forward, I look forward to working with this committee as well as other colleagues in the Senate to improve this legislation, to consider suggested Administration, outside expert, and other Senate Committees’ changes. I am confident that such additional work could produce a bill that is much more effective, is more consistent with current law, policy, and stakeholder views, and helps strengthen regulation without hindering critical research and development to protect our Nation.

According to Senators Lieberman and Collins, S. 1649 was motivated by the December 2008 report of the Commission on the Prevention of WMD Proliferation and Terrorism (WMD Commission), *World at Risk*, and was intended to implement its major recommendations. One of the key recommendations that the WMD Commission made, repeatedly and explicitly, was that the Department of Health and Human Services (HHS) should have the lead federal responsibility for regulating and overseeing dangerous biological agents. Unfortunately, S. 1649 runs contrary to that key recommendation, and would give that responsibility to the Department of Homeland Security (DHS). This is a major shortcoming of the proposed legislation.

Senators Lieberman and Collins have stated that there will be opportunities to continue to work with the Administration, other committees, and Senators as the bill moves toward Senate consideration. I welcome that commitment, since I believe the Senate should consider changes to the legislation based on current circumstances and consider changes based on recommendations of the Administration and the outside scientific community.

For example, since S. 1649 was reported out of committee on November 4, 2009, the Administration has taken a number of significant actions on biosecurity, as had been expected. These actions—such as the July 2, 2010 Executive Order 13456 on “Optimizing the Security of Biological Select Agents and Toxins in the United States,” and the December 30, 2009 Executive Order 13527 on “Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack”—would obviate much of the legislation contained within S. 1649.

Also, since the markup of S. 1649, the Administration has completed a number of important interagency reviews of biosecurity and biosafety issues and has produced many recommendations and policy decisions to improve the security of the Nation against biological threats. In addition, a number of important reports and studies have been published recently with carefully considered recommendations for improving our security against potential biological threats. I believe it is critical for Congress to consider fully these actions and recommendations before acting on legislation concerning biosecurity and biosafety.

I would encourage my colleagues to review carefully the current state of efforts to counter bioterrorism before considering legislation on this issue. This is a technically complex issue with potential pitfalls as well as opportunities for improvement. I believe we should fully consider the results of the Administration’s substantial recent efforts and its official views, as well as the various reports that have been published in the last 18 months, and the views of outside scientific groups, before legislating in this area. Such consideration would ensure that any changes we make would enhance our security while not causing unintended consequences.

It is my hope that considering these substantial recent actions and recommendations would provide a useful path forward to continue to improve our Nation’s safety and security without sacrificing the critical scientific expertise and research capabilities that are integral to our safety and security. I commend my colleagues on their efforts, and I look forward to working with them and other members of the Senate on these very important issues in the future.

CARL LEVIN.

