Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress

Frank Gottron
Specialist in Science and Technology Policy

Dana A. Shea
Specialist in Science and Technology Policy

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Summary

Reports by congressional commissions, the mention of bioterrorism in President Obama's 2010 State of the Union address, and issuance of executive orders have increased congressional attention to the threat of bioterrorism. Federal efforts to combat the threat of bioterrorism predate the anthrax attacks of 2001 but have significantly increased since then. The U.S. government has developed these efforts as part of and in parallel with other defenses against conventional terrorism. Continued attempts by terrorist groups to launch attacks targeted at U.S. citizens have increased concerns that federal counterterrorism activities insufficiently address the threat.

Key questions face congressional policymakers: How adequately do the efforts already under way address the threat of bioterrorism? Have the federal investments to date met the expectations of Congress and other stakeholders? Should Congress alter, augment, or terminate these existing programs in the current environment of fiscal challenge? What is the appropriate federal role in response to the threat of bioterrorism, and what mechanisms are most appropriate for involving other stakeholders, including state and local jurisdictions, industry, and others?

Several strategy and planning documents direct the federal government's biodefense efforts. Many different agencies have a role. These agencies have implemented numerous disparate actions and programs in their statutory areas to address the threat.

Despite these efforts, congressional commissions, nongovernmental organizations, industry representatives, and other experts have highlighted weaknesses or flaws in the federal government's biodefense activities. Reports by congressional commissions have stated that the federal government could significantly improve its efforts to address the bioterrorism threat.

Congressional oversight of bioterrorism crosses the jurisdiction of many congressional committees. As a result, congressional oversight is often issue-based. Because of the diversity of federal biodefense efforts, this report does not provide a complete view of the federal bioterrorism effort. Instead, this report focuses on four areas under congressional consideration deemed critical to the success of the biodefense enterprise: strategic planning; risk assessment; surveillance; and the development, procurement, and distribution of medical countermeasures.

Congress, through authorizing and appropriations legislation and oversight activities, continues to influence the federal response to the bioterrorism threat. Congressional policymakers may face many difficult choices about the priority of maintaining, shrinking, or expanding existing programs or creating new programs to address identified deficiencies. Augmenting or creating programs may result in additional costs in a time of fiscal challenges. Maintaining or shrinking programs may pose unacceptable risks, given the potential for significant casualties and economic effects from a large-scale bioterror attack.

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Introduction

Reports by congressional commissions, the mention of bioterrorism in President Obama's 2010 State of the Union address, and the issuance of executive orders have increased congressional attention to the threat of bioterrorism.[1] Federal efforts to combat the threat of bioterrorism predate the anthrax attacks of 2001 but have significantly increased since then. The U.S. government has developed these efforts as part of and in parallel with other defenses against conventional terrorism. Continued attempts by terrorist groups to launch attacks targeted at U.S. citizens, including those in transit to U.S. soil,[2] have increased concerns that federal counterterrorism activities, and the investments that underlie them, insufficiently address the threat.

Experts differ in their assessments of the threat posed by bioterrorism. Some claim the threat is dire and imminent.[3] The congressionally mandated Commission on the Prevention of WMD Proliferation and Terrorism concluded that

> unless the world community acts decisively and with great urgency, it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013.
>
> The Commission further believes that terrorists are more likely to be able to obtain and use a biological weapon than a nuclear weapon.[4]

In contrast, other experts assert that the bioterrorism threat is less severe or pressing than that posed by more conventional terrorism or other issues facing the United States.[5] The Scientists Working Group on Biological and Chemical Weapons concluded that

> public health in the United States faces many challenges; bioterrorism is just one. Policies need to be crafted to respond to the full range of infectious disease threats and critical public health challenges rather than be disproportionately weighted in favor of defense against an exaggerated threat of bioterrorism.[6]

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[1] President Obama stated, "And we are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease—a plan that will counter threats at home and strengthen public health abroad." Office of the Press Secretary, The White House, *Remarks by the President in State of the Union Address*, January 27, 2010.

[2] See, for example, the purported attempt by Umar Farouk Abdulmutallab to detonate explosives in mid-flight on Northwest Airlines Flight 253 from Amsterdam, Netherlands, to Detroit, Michigan. See *Indictment in U.S. v. Abdulmutallab*, January 6, 2010. http://www.mied.uscourts.gov/hpc/docs/1.Indictment.pdf

[3] For examples of experts who think the threat of bioterrorism is greater than has been recognized, see Richard Danzig, *Catastrophic Bioterrorism: What Is to Be Done?* Center for Technology and National Security, National Defense University, Washington, DC, August 2003, and The Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008.

[4] The Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008, p. xv.

[5] For examples of experts who downplay the threat posed by bioterrorism, see Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat*, Strategic Studies Institute, U.S. Army War College, Washington, DC, 2005, and Scientists Working Group on Biological and Chemical Weapons, Center for Arms Control and Non-Proliferation, *Biological Threats: A Matter of Balance*, January 26, 2010.

[6] Scientists Working Group on Biological and Chemical Weapons, "Biological Threats: A Matter of Balance," *Bulletin of the Atomic Scientists*, February 2, 2010.

Stakeholders often measure federal efforts against the perceived magnitude of the threat. Thus, those who believe that bioterrorism poses a relatively low threat tend to conclude that the government has done too much. In contrast, those who perceive a greater threat conclude that the federal government needs to do more, whether under existing programs or new ones. Many experts come to mixed conclusions: they regard some programs as effective but identify others as insufficient.

The federal government's biodefense efforts span many agencies and vary widely in their resources, scope, and approach. For example, the Departments of State and Defense have cooperated with foreign governments and nongovernmental organizations to engage in nonproliferation, counterproliferation, and foreign disease outbreak detection efforts.[7] The Departments of State and Commerce have strengthened export controls of materials that could be used for bioterrorism.[8] The Department of Health and Human Services (HHS) has made investments in public health preparedness; response planning;[9] foreign disease outbreak detection;[10] and research, development, and procurement of medical countermeasures against biological terrorism agents (see "Medical Countermeasures" below).[11] The intelligence community has engaged in intelligence gathering and sharing regarding bioterrorism.[12] The Department of Justice performs background checks on people who want to possess certain dangerous pathogens.[13] The Department of Homeland Security (DHS) has engaged in preparedness, response, and recovery-related activities,[14] developed increased capabilities in environmental biosurveillance (see "Biosurveillance" below), and invested in expanding domestic

[7] For information on these topics, see CRS Report RL31559, *Proliferation Control Regimes: Background and Status*, coordinated by Mary Beth Nikitin; CRS Report RL33865, *Arms Control and Nonproliferation: A Catalog of Treaties and Agreements*, by Amy F. Woolf, Mary Beth Nikitin, and Paul K. Kerr; CRS Report RL34327, *Proliferation Security Initiative (PSI)*, by Mary Beth Nikitin; and CRS Report RS22913, *Global Health: USAID Programs and Appropriations from FY2001 through FY2010*, by Tiaji Salaam-Blyther.

[8] Examples of such export control restrictions include the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations (EAR), which are the primary set of U.S. export control regulations, and other multilateral agreements, such as participation in the Australia Group.

[9] For information on these topics, see CRS Report R40159, *Public Health and Medical Preparedness and Response: Issues in the 111th Congress*, by Sarah A. Lister.

[10] CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2011*, by Tiaji Salaam-Blyther.

[11] For example, the National Institute of Allergy and Infectious Diseases (NIAID) developed an extensive research program into potential bioterrorism pathogens. See National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, *NIAID Biodefense Research Agenda for CDC Category A Agents-Progress Report*, August 2003; National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, *NIAID Biodefense Research Agenda for Category B and C Priority Pathogens*, January 2003; and National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, *NIAID Strategic Plan for Biodefense Research-2007 Update*, September 2007. See also Public Health Emergency Medical Countermeasures Enterprise, Biomedical Advanced Research and Development Authority (BARDA), U.S. Department of Health and Human Services, *DRAFT BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement*, July 5, 2007.

[12] For example, the National Counterterrorism Center has established a working group on chemical, biological, radiological, nuclear counterterrorism. See CRS Report R41022, *The National Counterterrorism Center (NCTC)—Responsibilities and Potential Congressional Concerns*, by Richard A. Best Jr. For an overview of homeland security related intelligence issues, see CRS Report RL33616, *Homeland Security Intelligence: Perceptions, Statutory Definitions, and Approaches*, by Mark A. Randol.

[13] For additional information on this program, see CRS Report R40418, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, by Frank Gottron and Dana A. Shea.

[14] For example, see Department of Homeland Security, *National Response Framework: Biological Incident Annex*, January 2008, http://www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf.

bioforensics capabilities.[15] The Environmental Protection Agency (EPA) has explored post-event infrastructure decontamination.[16] Many agencies, jointly or separately, have invested in expanded biodefense infrastructure, including public and private high-containment laboratories for research, diagnostic, and forensics purposes.[17] Lastly, the Executive Office of the President and other executive branch coordinating groups have engaged in risk assessment and strategic planning exercises to coordinate and optimize federal investment against bioterrorism and response capabilities.[18]

Conflicting views of the bioterrorism threat and the breadth of the federal biodefense effort, which crosses congressional committee jurisdictions, complicate congressional oversight of the overall biodefense enterprise. Providing oversight and direction for individual biodefense agencies or programs is easier than addressing the entirety of the biodefense enterprise at once, but such an approach may focus too narrowly to improve the overall effort. An alternative approach identifies key areas or activities that shape federal agency efforts. The Bush Administration identified four such "pillars" as organizing principles for the federal biodefense efforts: threat awareness; prevention and protection; surveillance and detection; and response and recovery.[19] Each of these pillars may have several agencies performing critical parts of the activity. Congressional oversight and direction of biodefense efforts has followed a similar but not identical path. Congress has provided oversight and direction on the basis of both individual agency biodefense activity and on those cross-agency themes and policies deemed most important by congressional policymakers.

Because of the diversity of federal biodefense efforts, this report cannot address all aspects and associated programs related to this issue. Instead, this report focuses on four areas under congressional consideration deemed critical to the success of the biodefense enterprise: strategic planning; risk assessment; surveillance; and the development, procurement, and distribution of

[15] Bioforensics is the scientific analysis of biological evidence. The capability expansion includes the creation of the National Bioforensic Analysis Center as the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack.

[16] For additional information on EPA's research in this area, see http://www.epa.gov/NHSRC/decondeconrh.html.

[17] For more information on this expansion of capacity, see CRS Report R40418, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, by Frank Gottron and Dana A. Shea.

[18] The Obama Administration has released strategy documents addressing biodefense planning and response. See National Security Council, Executive Office of the President, *National Strategy for Countering Biological Threats*, November 2009; Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack," 75 *Federal Register* 737-738, January 6, 2010; and Office of the Press Secretary, The White House, "Executive Order—Optimizing the Security of Biological Select Agents and Toxins in the United States," July 2, 2010. The Bush Administration released a series of homeland security strategies and presidential directives incorporating responses to the bioterrorism threat. Similarly, documents to establish cross-agency coordination, such as that developed by the National Science and Technology Council on foreign animal disease (Subcommittee on Foreign Animal Disease Threats, Committee on Homeland and National Security, National Science and Technology Council, *Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012*, January 2007) or that developed by the Department of Homeland Security to coordinate homeland security research and development (Science and Technology Directorate, Department of Homeland Security, *Coordination of Homeland Security Science and Technology*, December 2007 (Revised January 2008)), have been released. Lastly, the federal government has tested its response capabilities through drills and exercises including responses to bioterrorism. One example is the National Exercise Program (formerly TOPOFF exercises), which included bioterrorism scenarios in several cases. See CRS Report RL34737, *Homeland Emergency Preparedness and the National Exercise Program: Background, Policy Implications, and Issues for Congress*, coordinated by R. Eric Petersen.

[19] The Executive Office of the President, "Biodefense for the 21st Century," *Homeland Security Presidential Directive 10/HSPD-10*, April 28, 2004.

medical countermeasures. This report also focuses on the effectiveness and sufficiency of programs implementing these aspects of the federal biodefense efforts, outside analysts' suggestions for improving the government's efforts, and current issues under congressional consideration. This report does not attempt to address all biodefense issues of potential congressional interest. Although outside the scope of this report, state and local governments, private industry, and our international partners play key roles in defending against the threat of bioterrorism.

Strategic Planning

Although the federal government had previously undertaken efforts to address the bioterrorism threat, the events of September 11, 2001, and the subsequent anthrax mailings led to an increased focus on terrorism in general and especially on biological weapons of mass destruction (WMDs). The Bush Administration established a homeland security apparatus within the White House.[20] Congress and the Bush Administration created the DHS as a focal point in the federal preparedness, response, and recovery to terrorism and imbued it with a variety of new authorities.[21] In addition, the Bush Administration developed a series of national strategies and other guidance documents for homeland security generally and biodefense in specific.[22] Beyond these cross-governmental strategy documents, many agencies developed more focused strategic plans for their individual operations against bioterrorism. The Obama Administration has continued this focus on bioterrorism by issuing additional guidance and directives.[23]

[20] Executive Order 13228 (October 8, 2001) and Homeland Security Presidential Directive-1 (October 29, 2001) established the Office of Homeland Security and the Homeland Security Council and created the position of Assistant to the President for Homeland Security. President Obama ordered a review of the White House organization for counterterrorism and homeland security through Presidential Study Directive 1 (February 23, 2009). The result of this review was reportedly to fold the Homeland Security Council into the National Security Council and merge the staff of the Homeland Security Council and the National Security Council into a single staff (Helene Cooper, "In Security Shuffle, White House Merges Staffs," *New York Times*, May 26, 2009).

[21] The Homeland Security Act of 2002 (P.L. 107-296) created the Department of Homeland Security. For an overview of the process of creating the department, see CRS Report RL31493, *Homeland Security: Department Organization And Management - Legislative Phase*, by Harold C. Relyea.

[22] The Bush Administration released several national strategies to address homeland security for the nation, which included protecting against biological attack as a component. See, for example, Office of Homeland Security, *National Strategy for Homeland Security*, July 2002, and Homeland Security Council, *National Strategy for Homeland Security*, October 2007. The Obama Administration has released a strategy for countering biological threats. See National Security Council, Executive Office of the President, *National Strategy for Countering Biological Threats*, November 2009. Biodefense-related strategies and guidance include a series of presidential directives, such as The White House, "National Strategy to Combat Weapons of Mass Destruction," *Homeland Security Presidential Directive/HSPD-4*, December 2002; The White House, "Defense of United States Agriculture and Food," *Homeland Security Presidential Directive/HSPD-9*, January 30, 2004; The Executive Office of the President, "Biodefense for the 21st Century," *Homeland Security Presidential Directive 10/HSPD-10*, April 28, 2004; The White House, "Medical Countermeasures against Weapons of Mass Destruction," *Homeland Security Presidential Directive/HSPD-18*, January 31, 2007; and The White House, "Public Health and Medical Preparedness," *Homeland Security Presidential Directive/HSPD-21*, October 18, 2007.

[23] For example, National Security Council, Executive Office of the President, *National Strategy for Countering Biological Threats*, November 2009; Department of Health and Human Services, *National Health Security Strategy of the United States of America*, December 2009; Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack," 75 *Federal Register* 737-738, January 6, 2010; and Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," 75 *Federal Register* 39439-39443, July 2, 2010.

Congress has acted to require federal strategic planning activities through provisions of the Homeland Security Act of 2002 (P.L. 107-296), the Pandemic and All-Hazards Preparedness Act (P.L. 109-417), and other legislation. In addition to establishing DHS, Congress has created offices and agencies within other Cabinet departments and assigned them specific planning activities.[24] Finally, Congress established an office within the Executive Office of the President charged with preventing WMD proliferation and terrorism.[25]

Policymakers, analysts, and other experts have criticized federal efforts at strategic planning.[26] Some experts have criticized White House led cross-agency planning as lacking metrics and measures, failing to encompass the full range of threats, and insufficiently meeting stated goals.[27] Policymakers have critiqued efforts by federal agencies to develop multi-agency plans as lacking metrics.[28] Even when considering efforts within individual agencies, experts have levied criticisms of research plans, stating that the correspondence between strategic goals, operational outcomes, and program investments has not been made clear.[29] Agency implementation, translating strategic goals into effective programs and policies, will remain a key component of successful federal biodefense activities.

Options for Congress

Given these criticisms, Congress could choose to recommend changes in the strategic planning process, either government-wide or at the agency level, to address specific deficiencies. For example, Congress, as a body, could enact legislation to require a more robust and transparent government-wide strategic plan that articulates clear goals, metrics and priorities; a periodic comprehensive report detailing biodefense activities government-wide; or the development of a national framework to organize and prioritize biodefense investments.[30] Alternatively, Congress

[24] For example, through the Pandemic and All-Hazard Preparedness Act (P.L. 109-417), Congress created the Biodefense Advanced Research and Development Authority in HHS to plan and support the development of bioterrorism medical countermeasures.

[25] The Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53) created the Office of the United States Coordinator for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, which is to be headed by a Senate-confirmed coordinator.

[26] See, for example, The Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008; National Biodefense Science Board, *Optimizing Industrial Involvement in Medical Countermeasure Development: A Report of the National Biodefense Science Board*, February 2010; and U.S. Government Accountability Office, *Public Health Information Technology: Additional Strategic Planning Needed to Guide HHS's Efforts to Establish Electronic Situational Awareness Capabilities*, GAO-11-99, December 2010.

[27] See, for example, Al Mauroni, *Progress of "Biodefense for the 21st Century" – A Five-Year Evaluation*, 2009.

[28] See, for example, hearings held in the House regarding DHS efforts to develop a cross-governmental homeland security research and development plan. House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, "A Roadmap for Security? Examining the Science and Technology Directorate's Strategic Plan," *Serial No. 110-53*, June 27, 2007; House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, "The Future of Science and Technology at the Department of Homeland Security," *Serial No. 110-102*, April 01, 2008; and House Committee on Science and Technology, Subcommittee on Technology and Innovation, "Developing Research Priorities at DHS's Science and Technology Directorate," *Hearing*, October 27, 2009.

[29] See, for example, National Academy of Public Administration, *Department of Homeland Security Science and Technology Directorate: Developing Technology to Protect America*, June 2009.

[30] The Pandemic and All-Hazards Preparedness Act (P.L. 109-417) requires a strategic plan for countermeasure research and development to be included in the quadrennial National Health Security Strategy. HHS published the draft countermeasure strategy in 2007 and plans to publish the final strategy in the first quarter of 2011. HHS staff, personal (continued...)

might require the Administration to perform internal or external reviews of policies and activities to determine their sufficiency and then direct the Administration to formulate new or revised policies as recommended by the reviews.[31] Congress could also require the creation of implementation plans, linking agency activities with meeting the required, desired strategic goals. Congress might mandate the augmentation of government-wide planning documents, such as the National Response Framework, or the development of a forward-looking planning document, similar to the Quadrennial Homeland Security Review[32] or the National Strategy for Pandemic Influenza and its implementation guide,[33] for cross-agency federal biodefense activities.

Through oversight activities, congressional committees of jurisdiction have a key role in assessing the completeness of ongoing planning. Because of the broad oversight responsibilities of congressional committees, congressional policymakers may identify synergies and duplications between agency efforts more easily than decision-makers within individual agencies.[34] Congress, through its oversight activities, may also identify areas where executive branch resource allocation does not reflect need or congressional intent. A congressional perspective may highlight unnecessary duplication or gaps in federal planning for the various necessary stages of response to a bioterrorism event. Congress may also be able to assess whether current plans appropriately factor in the roles of private industry, states, and our international partners.

Some experts have suggested that Congress might optimize oversight of federal homeland security efforts if fewer committees and subcommittees maintained jurisdiction over homeland security.[35] Proponents with this perspective argue that congressional oversight would become more focused and holistic because of the centralization of oversight authority. Additionally, this might reduce the amount of time homeland security officials spend testifying before Congress. On the other hand, such consolidation might decrease the level of congressional scrutiny, since

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communication with CRS, January 9, 2011. The draft strategy is available at https://www.medicalcountermeasures.gov/BARDA/PHEMCE/enterprise/strategy/bardaplan.aspx.

[31] For example, the HHS *Interim Implementation Guide for the National Health Security Strategy of the United States of America* identifies a series of executive-branch-directed reviews of biodefense to be performed. Additionally, HHS has used select advisory boards to perform reviews or assessments of specific portions of the federal biodefense enterprise. See, for example, reports issued by the National Biodefense Science Board (NBSB) at http://www.hhs.gov/aspr/omsph/nbsb/.

[32] The Implementing Recommendations of the 9/11 Commission Act of 2007 (P.L. 110-53) amended the Homeland Security Act of 2002 to require a quadrennial homeland security review. The first such review was issued in February 2010. See Department of Homeland Security, *Quadrennial Homeland Security Review: A Strategic Framework for a Secure Homeland*, February 2010.

[33] Homeland Security Council, Executive Office of the President, *National Strategy for Pandemic Influenza*, November 2005 and Homeland Security Council, Executive Office of the President, *National Strategy for Pandemic Influenza Implementation Plan*, May 2006.

[34] For example, investigation by the Government Accountability Office identified the duplication and potential waste of anthrax vaccine occurring in the Department of Defense and the Department of Health and Human Services. Government Accountability Office, "Project BioShield: Actions Needed to Avoid Repeating Past Mistakes," *GAO-08-208T*, October 23, 2007.

[35] Both the 9/11 Commission and the Commission on the Prevention of WMD Proliferation and Terrorism recommended that Congress create a single committee in each chamber for oversight and review of homeland security (National Commission on Terrorist Attacks upon the United States, *The 9/11 Commission Report*, p. 421 and Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008, p. 91). Other groups have also called for change in the current congressional oversight of the Department of Homeland Security (Jena Baker McNeill, Heritage Foundation, "Homeland Security Oversight Reform Requires Leadership," *WebMemo 2143*, November 25, 2008).

fewer committees with broader homeland security mandates might have less time and fewer resources to focus on individual agencies and activities.

Risk Assessment

Ideally, a full understanding of the risk posed by bioterrorism would underpin the government's biodefense efforts. By understanding the bioterrorism risk, the federal government could determine the appropriate level of federal response and investment against this risk. The Government Accountability Office (GAO) has called for increased risk assessment activities in biodefense for many years.[36] Unfortunately, the nature of the bioterrorism threat, with its high consequences and low frequency, makes determining the bioterrorism risk difficult. Additionally, the presence of an intelligent adversary who can adapt to the presence of successful countermeasures complicates the use of standard risk assessment techniques.[37] Despite these challenges, risk assessment activities can help agencies use risk-informed decision-making processes to plan, prioritize, and invest wisely. In contrast, investment based on uninformed hypotheses or on an ad hoc basis may allow improperly identified or assessed risks to go unmitigated or result in overinvestment against low-risk events.

The Bush Administration identified bioterrorism risk assessment as a key component of its biodefense strategy. As a consequence, DHS engages in a bioterrorism risk assessment process on a two-year cycle. Other agencies also engage in risk assessment activities, but they vary from DHS's efforts in approach, assumptions, emphasis, and purpose.

Risk assessment processes depend heavily on the information used as input, the quantitative and qualitative factors used to interpret that information, and the robustness of the assessment process. These factors complicate comparisons between bioterrorism risk assessments performed for different purposes or among assessments of other threats. The DHS has begun this comparison on a limited scale,[38] but its use of these risk assessments for planning purposes has been strongly criticized by outside experts. These experts assert that the DHS risk assessments do not adequately address the decision-making process of an intelligent adversary.[39] Regardless of the complexity of the risk assessment methodology, the inherent uncertainties associated with assessing risk in a counterterrorism context likely necessitate retaining some level of flexibility in managing risk.[40]

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[36] For example, the General Accounting Office, now the Government Accountability Office, identified a need for comprehensive threat and risk assessments of chemical and biological attacks in the terrorism context prior to the 2001 anthrax attacks (General Accounting Office, "Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks, *GAO/NSIAD-99*-163, September 1999).

[37] Even defining the adversary presents a challenge. For example, foreign or domestic individuals, cells, or transnational organizations with or without access to state-sponsored resources could each qualify as the adversary. Different definitions of adversary may dramatically alter risk assessments and thus the government efforts to respond to the risk posed.

[38] Homeland Security Directive 18 directs DHS to create a risk assessment that considers chemical, biological, radiological, and nuclear threats.

[39] National Research Council, Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, *Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change*, Washington, DC: National Academies Press, 2008.

[40] For a discussion on DHS's risk assessment processes, see CRS Report RL33858, *The Department of Homeland Security's Risk Assessment Methodology: Evolution, Issues, and Options for Congress*, by Todd Masse, Siobhan (continued...)

Options for Congress

A key question for congressional policymakers is: to what extent should bioterrorism and other risk assessments inform agency and government-wide priorities and policies? Congress could mandate risk-informed decision making based on the intelligence community's assessment of current and future bioterrorism-related threats, endorse a particular risk assessment method, or require the establishment of measures of robustness. It could require agencies to harmonize their risk assessment methodologies or mandate the development of a government-wide risk assessment process rather than individual agency-level assessments. Alternatively, Congress could direct agencies to rely less on the risk assessment process and instead set priorities based on other factors, such as expert judgment.

Biosurveillance

Unlike most other terrorist attacks, a biological attack could infect victims without their knowledge. Days or weeks might pass before victims develop symptoms. Health practitioners treating infected, symptomatic individuals might be the first to identify that a bioterrorism attack had occurred. The Bush Administration prioritized the development and deployment of biosurveillance technologies in an attempt to identify a bioterrorism attack as soon after an attack as possible.[41] The sooner officials identify an attack, the sooner treatment of the exposed individuals could begin. Earlier treatment generally increases the likelihood of individual survival and recovery.[42]

The Bush Administration implemented a number of different detection approaches, including environmental detection, syndromic surveillance,[43] and information sharing.[44] Through these efforts, the federal government aims to identify bioterrorism events at various scales, ranging from large, aerially disseminated releases to smaller releases infecting only a few individuals. The federal government, in collaboration with state and local jurisdictions, enhanced the existing network of public health laboratories to ensure that diagnostic laboratories could correctly handle and analyze clinical samples related to potential bioterrorism events.[45] Similarly, the federal

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O'Neil, and John Rollins.

[41] President Bush announced during the 2003 State of the Union address the deployment of the "nation's first early warning network of sensors to detect biological attack" (Executive Office of the President, The White House, *State of the Union Address*, January 28, 2003).

[42] Computer modeling has shown that the number of casualties and fatalities resulting from a biological attack increases if treatment is delayed. See, for example, L.M. Wein, D.L. Craft, and E.H. Kaplan, "Emergency Response to an Anthrax Attack," *Proc. Natl. Acad. Sci.*, 100(7), 2003, pp. 4346-51.

[43] The term applies to using health-related data that precede diagnosis as a signal of an outbreak or possible bioterrorist attack. See http://www.cdc.gov/ncphi/disss/nndss/syndromic.htm.

[44] These activities included the deployment of the BioWatch program, the development of the Biological Warning and Incident Characterization system, and the establishment of the National Biosurveillance Integration Center through the Department of Homeland Security, the establishment of the BioSense Program through the Centers for Disease Control and Prevention (CDC), and the expansion of the Electronic Surveillance System for Early Notification of Community-based Epidemics, or ESSENCE, program in the Department of Defense.

[45] For more on the Laboratory Response Network, see http://www.bt.cdc.gov/lrn/. For an evaluation the effectiveness of state and federal biosurveillance efforts, see Centers for Disease Control and Prevention, *Strengthening the Nation's Emergency Response State by States*, September 2010.

government has continued to invest in some global health activities partly to help identify when an emerging disease might pose a threat to the United States.[46]

Government and outside experts have both criticized and supported these efforts.[47] Widespread deployment of environmental biosurveillance technologies by the federal government began after the anthrax mailings, and federal efforts to further develop these technologies have also increased. Questions remain regarding the effectiveness of their detection ability, especially in comparison to the innate detection ability of the medical system through astute physicians. A repeated criticism of biosurveillance activities is that the detection system may lack sufficient sensitivity and dependability to allow for a federal response following detection of a bioterrorism event.[48] Technical difficulties persist in making a detection system sufficiently sensitive to detect very low levels of pathogens while maintaining a very low number of false alarms. Frequent false alarms pose a high cost in terms of resource consumption and responder opportunity costs. Additionally, frequent false alarms may lead responders and the public to assume that all alarms are likely false, and thus they may not take alarms seriously. Other widely discussed issues include the extent to which the federal government should protect the population of the United States with such systems, through environmental sensing or other methods, and how the federal government should deploy the limited number of available systems.

Options for Congress

Congress may remain interested in these programs. The DHS has developed and deployed the next generation of environmental detectors more slowly than it originally predicted.[49] Congress may seek to determine whether the current plans for capabilities and coverage of surveillance sufficiently protect the population. Appropriators could provide additional funds and authorizing committees could provide additional oversight or guidance to encourage the completion of the deployment of these detectors. Alternatively, the appropriation committees and the authorizing committees could determine that potential decreases in risk provided by this program does not support continued investment.

Congress may also address concerns about the interactions between DHS and local jurisdictions. Local jurisdictions have identified fiscal burdens from this federal program, and questions remain about their proper role in the response to positive test results.[50] Congress could attempt to

[46] For example, see CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2011*, by Tiaji Salaam-Blyther.

[47] See, for example, Government Accountability Office, "Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing," *GAO-10-171*, December 18, 2009; Government Accountability Office, "Biosurveillance: Preliminary Observations on Department of Homeland Security's Biosurveillance Initiatives," *GAO-08-960T*, July 16, 2008; and National Research Council, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, January 2011.

[48] See, for example, testimony by Tara O'Toole, Director, Center for Biosecurity of University of Pittsburgh Medical Center, before the Senate Committee on Homeland Security and Governmental Affairs, October 23, 2007. Dr. O'Toole is now the DHS Under Secretary for Science and Technology.

[49] House Committee on Appropriations, Subcommittee on Homeland Security, "House Appropriations Subcommittee on Homeland Security Holds Hearing on Biosurveillance Investments," *Hearing Transcript*, February 25, 2010. See also Government Accountability Office, "Department of Homeland Security: Assessments of Selected Complex Acquisitions," *GAO-10-588SP*, June 30, 2010.

[50] National Research Council, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of* (continued...)

alleviate these concerns by providing additional resources to local jurisdictions or by providing additional guidance to DHS regarding its relationships with local jurisdictions.

Medical Countermeasures

Effective medical countermeasures could significantly decrease the impact of a bioterrorist attack.[51] Several federal agencies, described below, have devoted many resources to the development, procurement, and distribution of medical countermeasures that could help respond to a bioterrorist attack. Since 2001, the federal government has often reexamined programs in these areas. Outside observers, Congress, and the executive branch have scrutinized, suggested improvements to, and further refined these policies.[52]

Research and Development

Many potential bioterrorism agents lack available medical countermeasures.[53] To help address this, the federal government invested billions of dollars in research and development that might lead to effective medical countermeasures. The Department of Health and Human Services (HHS) has played a key role in supporting the development of medical countermeasures, mainly through the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA).[54] Additionally, efforts undertaken by the Department of Defense (DOD) to protect warfighters may also contribute to civilian biodefense.[55] As a result of the 2010 Public Health Emergency Medical Countermeasures Enterprise review, HHS has called for the creation of dedicated centers to improve advanced development of medical countermeasures in both HHS and DOD and the establishment of a venture capital entity to spur private sector biodefense research investment.[56]

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Biological Threats: Abbreviated Version, January 2011.

[51] Medical countermeasures include vaccines, antiviral, antibiotic, and other therapeutic medications.

[52] See, for example, Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *Prevention of WMD Proliferation and Terrorism Report Card*, January 2010; National Biodefense Science Board, *Where are the Countermeasures? Protecting America's Health from CBRN Threats*, March 2010; C. Maher and B.D. Lushniak, "Availability of Medical Countermeasures for Bioterrorism Events: US Legal and Regulatory Options," *Clinical Pharmacology & Therapeutics*, 85, June 2009, pp. 669-671; and The White House, *Executive Order - Medical Countermeasures Following a Biological Attack*, December 30, 2009.

[53] For the list of the Department of Health and Human Services top priority needed countermeasures, see Public Health Emergency Medical Countermeasures Enterprise, U.S. Department of Health and Human Services, *HHS Public Health Emergency Medical Countermeasure Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats*, April 2007, p. 10.

[54] See, for example, Public Health Emergency Medical Countermeasures Enterprise, Biomedical Advanced Research and Development Authority (BARDA), U.S. Department of Health and Human Services, *DRAFT BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement*, July 5, 2007.

[55] One such example is the Transformational Medical Technologies (TMT) program, a Department of Defense program to better prepare and protect the warfighter against emerging, genetically engineered, and unknown biothreat agents. For more information on TMT, see https://tmti.jscbis.apgea.army.mil and Chemical and Biological Defense Program, Department of Defense, *Transformational Medical Technologies Initiative (TMTI) – OUSD (AT&L) FY2007*, online at http://www.acq.osd.mil/cp/cbdreports/tmti.pdf.

[56] Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *The Public Health Emergency Medical Countermeasures Enterprise Review Transforming the Enterprise to Meet Long-Range* (continued...)

Some scientists have criticized the federal investment in biodefense countermeasures. They claim that the relative threat of bioterrorism does not justify the large investment in biodefense and that these efforts would provide greater benefits if directed to other areas of research and development, such as more conventional public health threats.[57] Additionally, Congress has questioned the balance of investment among the various stages of research and development, identifying funding gaps that may pose barriers to the conversion of research results into deployable countermeasures. Congress also identified deficiencies in executive branch management of the countermeasure development process. These observations led Congress to establish BARDA to fund and coordinate the conversion of promising research results into deployable products.[58]

Options for Congress

Policymakers often face the challenge of determining the optimal balance of funding between competing stages of the research and development process. While Congress, as a body, has supported a historic increase in biodefense-related basic research funding at NIH, critics have suggested that the federal government has underfunded the critical next stages of research and development that convert promising research results into usable products.[59] Current fiscal pressures will likely exacerbate the difficult decisions regarding appropriate funding levels. Congress may consider whether the federal government appropriately leverages efforts by other stakeholders including state government, academia, and the private sector.[60] Policymakers may also consider whether the federal government should reduce its dominant role in countermeasure research and development in favor of a greater role for investment by industry. Congress may again consider incentive-based approaches, such as tax cuts and credits or patent protections, or demand-based approaches, such as increased funding to support larger contract awards.[61] Alternatively, Congress might conclude that the government needs to take a larger role in developing countermeasures in areas where the private sector has failed to produce desired countermeasures.

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National Needs, August 2010.

[57] For example, Scientists Working Group of Biological and Chemical Weapons, Center for Arms Control and Non-Proliferation, *Biological Threats: A Matter of Balance*, January 26, 2010.

[58] The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA; P.L. 109-417) established the Biomedical Advanced Research and Development Authority.

[59] See, for example, Alliance for Biosecurity, *Letter to President Barack Obama*, September 15, 2009, http://www.allianceforbiosecurity.org/pdf/2277113.pdf, or Center for Biosecurity of the University of Pittsburgh Medical Center, *Letter to President Barack Obama*, March 9, 2009, http://www.upmc-biosecurity.org/website/resources/commentary/2009-03-09-white_house_barda_fy10.html.

[60] For example, Texas A&M University has used state funding and DOD support to join with industrial partners to create a center to train students and to support industrial pharmaceutical and biologics development by providing manufacturing expertise and flexible capacity. See Reeve Hamilton, "Texas A&M Stakes Claim as Leader in Pharmaceuticals," *New York Times*, November 25, 2010.

[61] Previous congresses considered such provisions including S. 975 in the 109th Congress. See CRS Report RL32917, *Bioterrorism Countermeasure Development: Issues in Patents and Homeland Security*, by Wendy H. Schacht and John R. Thomas.

Procurement

As a single entity, the federal government is by far the largest procurer of bioterrorism medical countermeasures. It stockpiles countermeasures and keeps them ready for deployment to respond to a bioterrorism event.[62] The relatively small market for most bioterrorism countermeasures provides little incentive for companies to invest in developing a countermeasure when compared with the larger potential market of other products of the same industry, such as anti-cholesterol drugs. The federal government has experienced difficulties in obtaining desired countermeasures because of this relatively small market. The executive branch and Congress have taken several steps to encourage companies to enter the medical countermeasure field. These activities include providing liability protection to companies developing medical countermeasures, guaranteeing a government market for countermeasures, and more clearly communicating the government's countermeasure needs and priorities.[63] These efforts have met with mixed success.[64] In the face of a need for medical countermeasures against emerging natural threats, such as pandemic influenza, HHS has also invested in medical countermeasure infrastructure to provide a more rapid response.[65] The HHS has also planned a public-private partnership that would create flexible manufacturing infrastructure to lower barriers to desired countermeasure manufacture.[66]

A variety of experts, commissions, and policymakers have characterized the federal government's efforts to partner with private sector countermeasure developers as underfunded, unclear, or insufficient.[67] Given the large costs of bringing a product to market, government assurances of a planned purchase seem insufficient to entice companies into this field. Private companies faced with the potential for liability following adverse reactions to a fielded medical countermeasure expressed reluctance to develop countermeasures. This led Congress to enact measures to protect companies from such liability.[68] Companies and think tanks continue to state that the government should better communicate to developers the countermeasures it would like to procure. Think tanks and industry have also criticized actions they interpret as weakening the government's commitment to guaranteeing a government market by diverting funds designated for that program to other uses.[69] They assert such actions reinforce industry's perception of the government as an

[62] The federal government maintains a Strategic National Stockpile of certain medical countermeasures against national need. This stockpile is regularly rotated and thus serves as a continuing government demand for certain medical countermeasures.

[63] See CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by Frank Gottron.

[64] For such commentary, see Government Accountability Office, "Project BioShield Act: HHS Has Supported Development, Procurement, and Emergency Use of Medical Countermeasures to Address Health Threats," *GAO-09-878R*, July 24, 2009, and Government Accountability Office, "Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities," *GAO-09-820*, July 2009.

[65] CRS Report R40554, *The 2009 Influenza Pandemic: An Overview*, by Sarah A. Lister and C. Stephen Redhead.

[66] Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *The Public Health Emergency Medical Countermeasures Enterprise Review Transforming the Enterprise to Meet Long-Range National Needs*, August 2010.

[67] The Commission on the Prevention of WMD Proliferation and Terrorism, *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, December 2008, and Center for Biosecurity of the University of Pittsburgh Medical Center, *Letter to President Barack Obama*, March 9, 2009, http://www.upmc-biosecurity.org/website/resources/commentary/2009-03-09-white_house_barda_fy10.html.

[68] CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Edward C. Liu.

[69] For a discussion of this issue, see CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by Frank Gottron.

unreliable partner in the development enterprise. In addition, GAO has cautioned against the federal government failing to have and make clear expectations regarding countermeasure and company performance.[70]

Options for Congress

Congress may choose, as it has in some previous years, to use money advance appropriated for countermeasure procurement to support countermeasure development.[71] In addition, policymakers may assess whether previously enacted programs draw new investors into countermeasure manufacturing or whether the federal government must consider other, more novel manufacturing incentives. Congress may also examine whether the procurement prioritization matches the risk assessments and the strategic plans developed by the executive branch. Finally, Congress may provide additional appropriations or create new authorities for HHS, supporting recommendations formed by various assessments of HHS's countermeasure enterprise.[72]

Distribution

Even when effective medical countermeasures against potential bioterrorism pathogens exist, their distribution to individuals affected by an attack remains a challenge. The federal government has attempted to address this need through programs that stockpile and distribute stores of medical countermeasures, the development of alternative distribution mechanisms outside the normal health care setting, and the consideration of other options, such as pre-event distribution or prophylaxis.[73]

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), state and local governments, and industry partners play key roles in distributing emergency medical countermeasures. The FDA regulates distribution of pharmaceuticals and biological products and has certain authorities to permit the emergency use of unapproved products.[74] The CDC maintains the Strategic National Stockpile (SNS) and when requested

[70] Government Accountability Office, "Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine," *GAO-08-88*, October 23, 2007.

[71] Congress has transferred over $1 billion out of the Project BioShield fund for procuring medical countermeasures to support countermeasure research and development and pandemic influenza preparedness. For further discussion of the policy implications of these transfers, see CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by Frank Gottron.

[72] National Biodefense Science Board, *Optimizing Industrial Involvement in Medical Countermeasure Development: A Report of the National Biodefense Science Board*, February 2010; Institute of Medicine, *The Public Health Emergency Medical Countermeasures Enterprise: Innovative Strategies to Enhance Products from Discovery through Approval, An Institute of Medicine Workshop*, February 2010; and Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *The Public Health Emergency Medical Countermeasures Enterprise Review Transforming the Enterprise to Meet Long-Range National Needs*, August 2010.

[73] These programs include the Strategic National Stockpile (see http://www.bt.cdc.gov/stockpile/); the MedKit pilot program of personal medical stockpiles provided by the government and stored at home (see http://www.bt.cdc.gov/agent/anthrax/prep/pdf/medkit-evaluation-summary-2007.pdf), and the use of the U.S. Postal Service to distribute countermeasures (see Executive Order 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack," 75 *Federal Register* 737-738, January 6, 2010).

[74] For more on Emergency Use Authorization, see CRS Report R41033, *Project BioShield: Authorities, Appropriations, Acquisitions, and Issues for Congress*, by Frank Gottron.

delivers it to state and local governments for distribution. State and local governments are responsible for developing and exercising distribution plans.[75] In addition to producing emergency medical countermeasures, industrial partners store some of the SNS and may play a role in state and local distribution plans.

Experts have especially focused on the ability of the federal and state governments to distribute medical countermeasures to those infected in a timely way so as to minimize casualties and fatalities. Much of a successful bioterrorism response relies on providing effective medical countermeasures to the exposed. Experts question whether the federal government can distribute federal stockpiles to states and localities in the midst of an emergency, whether state governments have sufficient manpower or organization to receive federal stockpiles and effectively disseminate them, and whether federal and state governments have sufficiently conceptualized and practiced alternative mechanisms of distribution.[76]

Options for Congress

Congress may face decisions regarding the acceptable ways to disseminate medical countermeasures in an emergency situation, whether the advantages of alternative distribution mechanisms outweigh the potential drawbacks of lowered oversight and control of countermeasure use, and whether the federal government has effectively leveraged private sector resources to improve distribution.

Some experts have suggested the FDA should have new legal authorities and should develop new policy and regulatory frameworks to improve the distribution process during an emergency.[77] Congress may consider whether current FDA authorities are adequate to address medical countermeasure emergency distribution issues and if not whether deficiencies should be addressed through new legislative activity or through solely executive branch action.

Conclusion

While no mass-casualty bioterrorism event has yet occurred in the United States, some experts and policymakers assert that terrorist organizations are attempting to develop such a capability.[78] The federal government has been preparing for a bioterrorism event for many years. Multiple programs in many agencies attempt to prepare for and respond to a bioterrorism event. Whether these programs are sufficient, redundant, excessive, or need improvement has been a topic of much debate. Congress, through oversight activities as well as authorizing and appropriations

[75] For an evaluation of state distribution plans, see Centers for Disease Control and Prevention, *Strengthening the Nation's Emergency Response State by States*, September 2010.

[76] For one view of the state of public health preparedness for bioterrorism, see Trust for America's Health, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism 2010*, December 2010. The Cities Readiness Initiative is a Centers for Disease Control and Prevention program to help local jurisdictions improve their distribution capabilities. See http://emergency.cdc.gov/cri/facts.asp.

[77] For example see, Institute of Medicine, *Medical Countermeasure Dispensing: Emergency Use Authorization and the Postal Model Workshop Summary*, 2010; and Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *The Public Health Emergency Medical Countermeasures Enterprise Review Transforming the Enterprise to Meet Long-Range National Needs*, August 2010.

[78] See, for example, Rolf Mowatt-Larssen, *Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality? A Timeline of Terrorists' Efforts to Acquire WMD*, January 2010.

legislation, continues to influence the federal response to the bioterrorism threat. Congressional policymakers may be faced with many difficult choices about the priority of maintaining, shrinking, or expanding existing programs versus creating new programs to address identified deficiencies. Augmenting such programs may incur additional costs in a time of fiscal challenges while maintaining or shrinking such programs may be deemed as incurring unacceptable risks, given the potential for significant casualties and economic effects from a large-scale bioterror attack.

Author Contact Information

Frank Gottron
Specialist in Science and Technology Policy
fgottron@crs.loc.gov, 7-5854

Dana A. Shea
Specialist in Science and Technology Policy
dshea@crs.loc.gov, 7-6844