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Testimony

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HOMELAND SECURITY

New Department Could Improve Coordination but Transferring Control of Certain Public Health Programs Raises Concerns

Statement for the Record by Janet Heinrich Director, Health Care—Public Health Issues



Mr. Chairman and Members of the Committee:

I appreciate the opportunity to submit this statement for the record on the proposed creation of the Department of Homeland Security. Since the terrorist attacks of September 11, 2001, and the subsequent anthrax incidents, there has been concern about the ability of the federal government to prepare for and coordinate an effective public health response to such events, given the broad distribution of responsibility for that task at the federal level. Our earlier work found, for example, that more than 20 federal departments and agencies carry some responsibility for bioterrorism preparedness and response and that these efforts are fragmented. Emergency response is further complicated by the need to coordinate actions with agencies at the state and local level, where much of the response activity would occur.

The President's proposed Homeland Security Act of 2002² would bring many of these federal entities with homeland security responsibilities including public health preparedness and response—into one department. in an effort to mobilize and focus assets and resources at all levels of government. The aspects of the proposal concerned with public health preparedness and response would involve two primary changes to the current system, which are found in Title V of the proposed legislation. First, the proposal would transfer certain emergency preparedness and response programs from multiple agencies to the new department. Second, it would transfer the control over, but not the operation of, other public health preparedness assistance programs, such as providing emergency preparedness planning assistance to state and local governments, from the Department of Health and Human Services (HHS) to the new department.³ Title III of the proposed legislation would also transfer responsibility for certain chemical, biological, radiological, and nuclear research and development programs and activities to the new department.4

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¹U.S. General Accounting Office, *Bioterrorism: Federal Research and Preparedness Activities*, GAO-01-915 (Washington, D.C.: Sept. 28, 2001).

²H.R. 5005, 107th Cong. (2002).

 $^{^3}$ These changes are primarily covered by Sections 502 and 505, respectively, in Title V of the President's proposed legislation.

⁴These changes are primarily covered by Sections 301, 302, and 303 of the President's proposed legislation.

In order to assist the Committee in its consideration of this extensive reorganization of our government, this statement focuses on Titles III and V of the President's proposal and the implications of (1) the proposed transfer of specific public health preparedness and response programs currently housed in HHS into the new department, (2) the proposed transfer of control over certain other public health preparedness assistance programs from HHS to the new department, and (3) the proposed transfer of responsibility for research and development on chemical, biological, radiological, and nuclear threats to the new department. The statement is based largely on our previous and ongoing work on homeland security, 5 as well as a review of the proposed legislation.

In summary, we believe that the proposed reorganization has the potential to repair the fragmentation we have noted in the coordination of public health preparedness and response programs at the federal, state, and local levels. As we have recommended, the proposal would institutionalize the responsibility for homeland security in federal statute. We expect that, in addition to improving overall coordination, the transfer of programs from multiple agencies to the new department could reduce overlap among programs and facilitate response in times of disaster. However, we have concerns about the proposed transfer of control of public health assistance programs that have both basic public health and homeland security functions from HHS to the new department. These dual-purpose programs have important synergies that we believe should be maintained. We are concerned that transferring control over these programs, including priority setting, to the new department has the potential to disrupt some programs that are critical to basic public health responsibilities. We do not believe that the President's proposal is sufficiently clear on how both the homeland security and the public health objectives would be accomplished. The proposed Department of Homeland Security would also be tasked with developing national policy for and coordination of the federal government's civilian research and development efforts to counter chemical, biological, radiological, and nuclear threats. However, we are concerned that the proposed transfer of control and priority setting for research from the organizations where the research would be conducted could also be disruptive to dual-purpose programs.

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⁵See Related GAO Products at the end of this testimony.

Background

In response to global challenges the government faces in the coming years, we have a unique opportunity to create an extremely effective and performance-based organization that can strengthen the nation's ability to protect its borders and citizens against terrorism. There is likely to be considerable benefit over time from restructuring some of the homeland security functions, including reducing risk and improving the economy, efficiency, and effectiveness of these consolidated agencies and programs. Realistically, however, in the short term, the magnitude of the challenges that the new department faces will clearly require substantial time and effort, and will take additional resources to make it fully effective.

The Comptroller General has testified that the Congress should consider several very specific criteria in its evaluation of whether individual agencies or programs should be included or excluded from the proposed department. Those criteria include the following:

- Mission Relevancy: Is homeland security a major part of the agency or program mission? Is it the primary mission of the agency or program?
- Similar Goals and Objectives: Does the agency or program being considered for the new department share primary goals and objectives with the other agencies or programs being consolidated?
- Leverage Effectiveness: Does the agency or program being considered for the new department promote synergy and help to leverage the effectiveness of other agencies and programs or the new department as a whole? In other words, is the whole greater than the sum of the parts?
- Gains Through Consolidation: Does the agency or program being considered for the new department improve the efficiency and effectiveness of homeland security missions through eliminating duplications and overlaps, closing gaps, and aligning or merging common roles and responsibilities?

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⁶U.S. General Accounting Office, *Homeland Security: Proposal for Cabinet Agency Has Merit, but Implementation Will Be Pivotal to Success*, GAO-02-886T (Washington, D.C.: June 25, 2002).

- Integrated Information Sharing/Coordination: Does the agency or program being considered for the new department contribute to or leverage the ability of the new department to enhance the sharing of critical information or otherwise improve the coordination of missions and activities related to homeland security?
- Compatible Cultures: Can the organizational culture of the agency or program being considered for the new department effectively meld with the other entities that will be consolidated? Field structures and approaches to achieving missions vary considerably between agencies.
- Impact on Excluded Agencies: What is the impact on departments losing components to the new department? What is the impact on agencies with homeland security missions left out of the new department?

Federal, state, and local government agencies have differing roles with regard to public health emergency preparedness and response. The federal government conducts a variety of activities, including developing interagency response plans, increasing state and local response capabilities, developing and deploying federal response teams, increasing the availability of medical treatments, participating in and sponsoring exercises, planning for victim aid, and providing support in times of disaster and during special events such as the Olympic games. One of its main functions is to provide support for the primary responders at the state and local level, including emergency medical service personnel, public health officials, doctors, and nurses. This support is critical because the burden of response falls initially on state and local emergency response agencies.

The President's proposal would transfer the Laboratory Registration/ Select Agent Transfer Program—which controls biological agents with the potential for use in bioterrorism—from HHS to the new department. Currently administered by the Centers for Disease Control and Prevention (CDC), the program's mission is the security of those biologic agents that have the potential for use by terrorists. The proposal provides for the new department to consult with appropriate agencies, which would include HHS, in maintaining the select agent list.

In addition, the President's proposal transfers control over many of the programs that provide preparedness and response support for the state

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and local governments to a new Department of Homeland Security. Among other changes, the proposed legislation transfers HHS's Office of the Assistant Secretary for Public Health Emergency Preparedness to the new department. Included in this transfer is the Office of Emergency Preparedness (OEP), which currently leads the National Disaster Medical System (NDMS)⁷ in conjunction with several other agencies and the Metropolitan Medical Response System (MMRS).⁸ The Strategic National Stockpile, currently administered by CDC, would also be transferred, although the Secretary of HHS would still manage the stockpile and continue to determine its contents.

Under the President's proposal, the new department would also be responsible for all current HHS public health emergency preparedness activities carried out to assist state and local governments or private organizations to plan, prepare for, prevent, identify, and respond to biological, chemical, radiological, and nuclear events and public health emergencies. Although not specifically named in the proposal, this would include CDC's Bioterrorism Preparedness and Response program and the Health Resources and Services Administration's (HRSA) Bioterrorism Hospital Preparedness Program. These programs provide grants to states and cities to develop plans and build capacity for communication, disease surveillance, epidemiology, hospital planning, laboratory analysis, and other basic public health functions. Except as otherwise directed by the President, the Secretary of Homeland Security would carry out these activities through HHS under agreements to be negotiated with the Secretary of HHS. Further, the Secretary of Homeland Security would be authorized to set the priorities for these preparedness and response activities.

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⁷In the event of an emergency, NDMS has response teams that can provide support at the site of a disaster. These include specialized teams for burn victims, mental health teams, teams for incidents involving weapons of mass destruction, and mortuary teams that can be deployed as needed. About 2,000 civilian hospitals have pledged resources that could be marshaled in any domestic emergency under the system.

⁸MMRS is a program that provides support for local community planning and response capabilities for mass casualty and terrorist incidents in metropolitan areas.

⁹The stockpile, previously called the National Pharmaceutical Stockpile, consists of two major components. The first component is the 12-Hour Push Packages, which contain pharmaceuticals, antidotes, and medical supplies and can be delivered to any site in the United States within 12 hours of a federal decision to deploy assets. The second component is the Vendor Managed Inventory.

The new Department of Homeland Security would also be responsible for conducting a national scientific research and development program, including developing national policy and coordinating the federal government's civilian efforts to counter chemical, biological, radiological, and nuclear weapons or other emerging terrorist threats. Its responsibilities would also include establishing priorities and directing and supporting national research and development and procurement of technology and systems for detecting, preventing, protecting against, and responding to terrorist acts using chemical, biological, radiological, or nuclear weapons. Portions of the Departments of Agriculture, Defense, and Energy that conduct research would be transferred to the new Department of Homeland Security. The Department of Homeland Security would carry out its civilian health-related biological, biomedical, and infectious disease defense research and development through agreements with HHS, unless otherwise directed by the President. As part of this responsibility, the new department would establish priorities and direction for programs of basic and applied research on the detection, treatment, and prevention of infectious diseases such as those conducted by the National Institutes of Health (NIH).

Transfer of Certain Public Health Programs Has Potential to Improve Coordination The transfer of federal assets and resources in the President's proposed legislation has the potential to improve coordination of public health preparedness and response activities at the federal, state, and local levels. Our past work has detailed a lack of coordination in the programs that house these activities, which are currently dispersed across numerous federal agencies. In addition, we have discussed the need for an institutionalized responsibility for homeland security in federal statute. ¹⁰

The proposal would transfer the Laboratory Registration/Select Agent Transfer Program from HHS to the new department. The select agent program, recently revised and expanded by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 11 generally requires the registration of persons and laboratory facilities possessing specific biologic agents and toxins—called select agents—that have the potential to pose a serious threat to public health and safety. Select agents include approximately 40 viruses, bacteria, rickettsia, fungi, and toxins. Examples

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¹⁰U.S. General Accounting Office, *Homeland Security: Responsibility and Accountability for Achieving National Goals*, GAO-02-627T (Washington, D.C.: Apr. 11, 2002).

¹¹Pub. L. No. 107-188, §§ 201-204, 116 Stat. 594, 637-647 (2002).

include Ebola, anthrax, botulinum, and ricin. The 2002 act expanded the program to cover facilities that possess the agents as well as the facilities that transfer the agents.

The mission of the select agent program appears to be closely aligned with homeland security. As stated earlier, one key consideration in evaluating whether individual agencies or programs should be included or excluded from the proposed department is the extent to which homeland security is a major part of the agency or program mission. By these criteria, the transfer of the select agent program would enhance efficiency and accountability.

The President's proposal also provides the potential to consolidate programs, thereby reducing the number of points of contact with which state and local officials have to contend. However, coordination would still be required with multiple agencies across departments. Many of the agencies involved in these programs have differing perspectives and priorities, and the proposal does not sufficiently clarify the lines of authority of different parties in the event of an emergency, such as between the Federal Bureau of Investigation (FBI) and public health officials investigating a suspected bioterrorist incident.

We have reported that many state and local officials have expressed concerns about the coordination of federal public health preparedness and response efforts. ¹² Officials from state public health agencies and state emergency management agencies have told us that federal programs for improving state and local preparedness are not carefully coordinated or well organized. For example, federal programs managed by the Federal Emergency Management Agency (FEMA), Department of Justice (DOJ), OEP, and CDC all currently provide funds to assist state and local governments. Each program conditions the receipt of funds on the completion of a plan, but officials have told us that the preparation of multiple, generally overlapping plans can be an inefficient process. ¹³ In addition, state and local officials told us that having so many federal entities involved in preparedness and response has led to confusion,

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¹²U.S. General Accounting Office, *Bioterrorism: Federal Research and Preparedness Activities*, GAO-01-915 (Washington, D.C.: Sept. 28, 2001).

¹³U.S. General Accounting Office, Combating Terrorism: Intergovernmental Partnership in a National Strategy to Enhance State and Local Preparedness, GAO-02-547T (Washington, D.C.: Mar. 22, 2002).

making it difficult for them to identify available federal preparedness resources and effectively partner with the federal government.

The proposed transfer of numerous federal response teams and assets to the new department would enhance efficiency and accountability for these activities. This would involve a number of separate federal programs for emergency preparedness and response, whose missions are closely aligned with homeland security, including FEMA; certain units of DOJ; and HHS's Office of the Assistant Secretary for Public Health Emergency Preparedness, including OEP and its NDMS and MMRS programs, along with the Strategic National Stockpile. In our previous work, we found that in spite of numerous efforts to improve coordination of the separate federal programs, problems remained, and we recommended consolidating the FEMA and DOJ programs to improve the coordination.¹⁴ The proposal places these programs under the control of the Under Secretary for Emergency Preparedness and Response, who could potentially reduce overlap and improve coordination. This change would make one individual accountable for these programs and would provide a central source for federal assistance.

The proposed transfer of MMRS, a collection of local response systems funded by HHS in metropolitan areas, has the potential to enhance its communication and coordination. Officials from one state told us that their state has MMRSs in multiple cities but there is no mechanism in place to allow communication and coordination among them. Although the proposed department has the potential to facilitate the coordination of this program, this example highlights the need for greater regional coordination, an issue on which the proposal is silent.

Because the new department would not include all agencies with public health responsibilities related to homeland security, coordination across departments would still be required for some programs. For example, NDMS functions as a partnership among HHS, the Department of Defense (DOD), the Department of Veterans Affairs (VA), FEMA, state and local governments, and the private sector. However, as the DOD and VA programs are not included in the proposal, only some of these federal organizations would be brought under the umbrella of the Department of Homeland Security. Similarly, the Strategic National Stockpile currently

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¹⁴U.S. General Accounting Office, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Washington, D.C., Sept. 20, 2001).

involves multiple agencies. It is administered by CDC, which contracts with VA to purchase and store pharmaceutical and medical supplies that could be used in the event of a terrorist incident. Recently expanded and reorganized, the program will now include management of the nation's inventory of smallpox vaccine. Under the President's proposal, CDC's responsibilities for the stockpile would be transferred to the new department, but VA and HHS involvement would be retained, as well as continuing review by experts of the contents of the stockpile to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered.

Although the proposed department has the potential to improve emergency response functions, its success depends on several factors. In addition to facilitating coordination and maintaining key relationships with other departments, these factors include merging the perspectives of the various programs that would be integrated under the proposal and clarifying the lines of authority of different parties in the event of an emergency. As an example, in the recent anthrax events, local officials complained about differing priorities between the FBI and the public health officials in handling suspicious specimens. According to the public health officials, FBI officials insisted on first informing FBI managers of any test results, which delayed getting test results to treating physicians. The public health officials viewed contacting physicians as the first priority in order to ensure that effective treatment could begin as quickly as possible.

New Department's Control of Essential Public Health Capacities Raises Concern The President's proposal to shift the responsibility for all programs assisting state and local agencies in public health emergency preparedness and response from HHS to the new department raises concern because of the dual-purpose nature of these activities. These programs include essential public health functions that, while important for homeland security, are critical to basic public health core capacities. ¹⁵ Therefore, we are concerned about the transfer of control over the programs, including

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¹⁵The recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 mandated development of a preparedness plan for state and local governments building on core public health capacities, to include effective public health surveillance and reporting mechanisms, appropriate laboratory readiness, properly trained and equipped public health and medical personnel, and communications networks that can effectively disseminate relevant information in a timely and secure manner. Pub. L. No. 107-188, §101, 116 Stat. 594, 596 (adding section 2801 to the Public Health Service Act).

priority setting, that the proposal would give to the new department. We recognize the need for coordination of these activities with other homeland security functions, but the President's proposal is not clear on how the public health and homeland security objectives would be balanced.

Under the President's proposal, responsibility for programs with dual homeland security and public health purposes would be transferred to the new department. These include such current HHS assistance programs as CDC's Bioterrorism Preparedness and Response program and HRSA's Bioterrorism Hospital Preparedness Program. Functions funded through these programs are central to investigations of naturally occurring infectious disease outbreaks and to regular public health communications, as well as to identifying and responding to a bioterrorist event. For example. CDC has used funds from these programs to help state and local health agencies build an electronic infrastructure for public health communications to improve the collection and transmission of information related to both bioterrorist incidents and other public health events. 16 Just as with the West Nile virus outbreak in New York City, which initially was feared to be the result of bioterrorism, 17 when an unusual case of disease occurs public health officials must investigate to determine whether it is naturally occurring or intentionally caused. Although the origin of the disease may not be clear at the outset, the same public health resources are needed to investigate, regardless of the source.

States are planning to use funds from these assistance programs to build the dual-purpose public health infrastructure and core capacities that the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 stated are needed. States plan to expand laboratory capacity, enhance their ability to conduct infectious disease surveillance and epidemiological investigations, improve communication among public health agencies, and develop plans for communicating with

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¹⁶These include the Health Alert Network (HAN), a nationwide system that facilitates the distribution of health alerts, dissemination of prevention guidelines and other information, distance learning, national disease surveillance, electronic laboratory reporting, and Epi-X, a secure Web-based disease surveillance network for federal, state, and local epidemiologists that provides tools for searching, tracking, discussing, and reporting on diseases and is therefore a key element in any disease investigation.

¹⁷U.S. General Accounting Office, West Nile Virus Outbreak: Lessons for Public Health Preparedness, GAO/HEHS-00-180 (Washington, D.C.: Sept. 11, 2000).

the public. States also plan to use these funds to hire and train additional staff in many of these areas, including epidemiology.

Our concern regarding these dual-purpose programs relates to the structure provided for in the President's proposal. The Secretary of Homeland Security would be given control over programs to be carried out by HHS. The proposal also authorizes the President to direct that these programs no longer be carried out through agreements with HHS, without addressing the circumstances under which such authority would be exercised. We are concerned that this approach may disrupt the synergy that exists in these dual-purpose programs. We are also concerned that the separation of control over the programs from their operations could lead to difficulty in balancing priorities. Although the HHS programs are important for homeland security, they are just as important to the day-to-day needs of public health agencies and hospitals, such as reporting on disease outbreaks and providing alerts to the medical community. The current proposal does not clearly provide a structure that ensures that the goals of both homeland security and public health will be met.

Transfer of Control and Priority Setting over Dual-Purpose Research and Development Raises Concern

The proposed Department of Homeland Security would be tasked with developing national policy for and coordinating the federal government's civilian research and development efforts to counter chemical, biological, radiological, and nuclear threats. In addition to coordination, we believe the role of the new department should include forging collaborative relationships with programs at all levels of government and developing a strategic plan for research and development. However, we have many of the same concerns regarding the transfer of responsibility for the research and development programs that we have regarding the transfer of the public health preparedness programs. We are concerned about the implications of the proposed transfer of control and priority setting for dual-purpose research. For example, some research programs have broad missions that are not easily separated into homeland security research and research for other purposes. We are concerned that such dual-purpose research activities may lose the synergy of their current placement in programs. In addition, we see a potential for duplication of capacity that already exists in the federal laboratories.

We have previously reported that while federal research and development programs are coordinated in a variety of ways, coordination is limited,

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raising the potential for duplication of efforts among federal agencies. ¹⁸ Coordination is limited by the extent of compartmentalization of efforts because of the sensitivity of the research and development programs, security classification of research, and the absence of a single coordinating entity to ensure against duplication. For example, DOD's Defense Advanced Research Projects Agency was unaware of U.S. Coast Guard plans to develop methods to detect biological agents on infected cruise ships and, therefore, was unable to share information on its research to develop biological detection devices for buildings that could have applicability in this area.

The new department will need to develop mechanisms to coordinate and integrate information on research and development being performed across the government related to chemical, biological, radiological, and nuclear terrorism, as well as user needs. We reported in 1999 and again in 2001 that the current formal and informal research and development coordination mechanisms may not ensure that potential overlaps, gaps, and opportunities for collaboration are addressed. 19 It should be noted, however, that the President's proposal tasks the new department with coordinating the federal government's "civilian efforts" only. We believe the new department will also need to coordinate with DOD and the intelligence agencies that conduct research and development efforts designed to detect and respond to weapons of mass destruction. In addition, the first responders and local governments possess practical knowledge about their technological needs and relevant design limitations that should be taken into account in federal efforts to provide new equipment, such as protective gear and sensor systems, and help set standards for performance and interoperability. Therefore, the new department will have to develop collaborative relationships with these organizations to facilitate technological improvements and encourage cooperative behavior.

The President's proposal could help improve coordination of federal research and development by giving one person the responsibility for creating a single national research and development strategy that could address coordination, reduce potential duplication, and ensure that

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¹⁸GAO-01-822.

¹⁹U.S. General Accounting Office, *Chemical and Biological Defense: Coordination of Nonmedical Chemical and Biological R&D Programs*, GAO/NSIAD-99-160 (Washington, D.C.: Aug. 16, 1999), and GAO-01-822.

important issues are addressed. In 2001, we recommended the creation of a unified strategy to reduce duplication and leverage resources, and suggested that the plan be coordinated with federal agencies performing research as well as state and local authorities.²⁰ The development of such a plan would help to ensure that research gaps are filled, unproductive duplication is minimized, and that individual agency plans are consistent with the overall goals.

The President's proposal would also transfer the responsibility for civilian health-related biological defense research and development programs to the new department, but the programs would continue to be carried out through HHS. These programs, now primarily sponsored by NIH, include a variety of efforts to understand basic biological mechanisms of infection and to develop and test rapid diagnostic tools, vaccines, and antibacterial and antiviral drugs. These efforts have dual-purpose applicability. The scientific research on biologic agents that could be used by terrorists cannot be readily separated from research on emerging infectious diseases. For example, NIH-funded research on a drug to treat cytomegalovirus complications in patients with HIV is now being investigated as a prototype for developing antiviral drugs against smallpox. Conversely, research being carried out on antiviral drugs in the NIH biodefense research program is expected to be useful in the development of treatments for hepatitis C.

The proposal to transfer responsibility to the new department for research and development programs that would continue to be carried out by HHS raises many of the same concerns we have with the structure the proposal creates for public health preparedness programs. Although there is a clear need for the new department to have responsibility for setting policy, developing a strategy, providing leadership, and overall coordinating of research and development efforts in these areas, we are concerned that control and priority-setting responsibility will not be vested in those best positioned to understand the potential of basic research efforts or the relevance of research being carried out in other, non-biodefense programs.

In addition, the proposal would allow the new department to direct, fund, and conduct research related to chemical, biological, radiological, nuclear, and other emerging terrorist threats on its own. This raises the potential for duplication of efforts, lack of efficiency, and an increased need for

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²⁰GAO-01-822.

coordination with other departments that would continue to carry out relevant research. We are concerned that the proposal could result in a duplication of capacity that already exists in the current federal laboratories.

Concluding Observations

Many aspects of the proposed consolidation of response activities are in line with our previous recommendations to consolidate programs, coordinate functions, and provide a statutory basis for leadership of homeland security. The transfer of the HHS medical response programs has the potential to reduce overlap among programs and facilitate response in times of disaster. However, we are concerned that the proposal does not provide the clear delineation of roles and responsibilities that is needed. We are also concerned about the broad control the proposal grants to the new department for research and development and public health preparedness programs. Although there is a need to coordinate these activities with the other homeland security preparedness and response programs that would be brought into the new department, there is also a need to maintain the priorities for basic public health capacities that are currently funded through these dual-purpose programs. We do not believe that the President's proposal adequately addresses how to accomplish both objectives. We are also concerned that the proposal would transfer the control and priority setting over dualpurpose research and has the potential to create an unnecessary duplication of federal research capacity.

Contact and Acknowledgments

For further information about this statement, please contact me at (202) 512-7118. Robert Copeland, Marcia Crosse, Greg Ferrante, and Deborah Miller also made key contributions to this statement.

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