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HOMELAND SECURITY

New Department Could Improve Biomedical R&D Coordination but May Disrupt Dual-Purpose Efforts

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Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to be here today to discuss one component—the potential effect on biomedical research—of 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 research, preparedness, and response and that these efforts are fragmented.[1]

The President's proposed Homeland Security Act of 2002[2] would bring many of the federal entities with homeland security responsibilities, including biomedical research and development, into one department. Title III of the proposed legislation would transfer responsibility for certain chemical, biological, radiological, and nuclear research and development programs and activities to the new department.[3] Much of the research in these areas is sponsored by or conducted at the Department of Health and Human Services' (HHS) National Institutes of Health (NIH). The proposal would also transfer the Laboratory Registration/Select Agent Transfer Program—which controls biological agents with the potential for use in bioterrorism—from HHS's Centers for Disease Control and Prevention (CDC) to the new department.

In order to assist the Subcommittee in its consideration of this extensive reorganization of our government, my remarks will focus on the potential effects of a reorganization on biomedical research under Title III of the President's proposal. My testimony today is based largely on our previous and ongoing work on homeland security,[4] as well as a review of the proposed legislation.

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

[2]H.R. 5005, 107th Cong. (2002).

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

[4]See Related GAO Products at the end of this testimony.

In summary, the proposed Department of Homeland Security would 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. GAO has consistently stated that there is a need for a strategic plan and better coordination of existing research and development programs. The new department could improve coordination of the biomedical research and development efforts. We are concerned, however, that the proposed transfer of control and priority setting for research from the organizations where the research would be conducted could be disruptive to dual-purpose programs,[5] which have important synergies that need to be maintained. 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 responsibility. The President's proposal is not sufficiently clear on how both the homeland security and the biomedical research objectives would be accomplished. Because the select agent program's mission fits with homeland security, its transfer to the new department is appropriate.

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

[5]In this testimony, dual-purpose programs refer to biomedical research and development programs that are applicable to both bioterrorism and other health research. For example, NIH supports research to expand knowledge of factors that play a decisive role in determining antibiotic resistance, virulence, and invasiveness of pathogens, as well as those events or processes critical to initiating infection or influencing the severity of disease. This knowledge is useful for both intentional and naturally occurring diseases.

agencies or programs should be included or excluded from the proposed department.[6] 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?
- 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?

In the President's proposal, the new Department of Homeland Security would 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. The new department would carry out its civilian health-related biological, biomedical, and infectious disease defense research and development through agreements with HHS, unless otherwise directed by

[6]U.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).

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 programs conducted by NIH.

NIH supports and carries out biomedical research to study, prevent, and treat infectious and immunologic human diseases. Infectious diseases include those caused by new, emerging, and reemerging infectious agents, including those that are intentionally introduced as an act of bioterrorism. The emphasis of antiterrorism research supported by NIH has been in four areas: (1) design and testing of new diagnostic tools; (2) design, development, and clinical evaluation of therapies; (3) design, development, and clinical evaluation of vaccines; and (4) other basic research, including genome sequencing.[7]

The President's proposal also would transfer the select agent program from HHS to the new department. Currently administered by CDC, this program's mission is ensuring the security of those biologic agents that pose a severe threat to public health and safety and could be used by terrorists. The proposal provides for the new department to consult with appropriate agencies, which would include HHS, in maintaining the select agent list and to consult with HHS in carrying out the program.

[7]Genome sequencing reveals the lineup of paired chemical bases that make up a pathogen's DNA, which contains the genetic code and transmits the hereditary pattern. Sequence information can be exploited in many ways, including demarcating genes, locating therapeutic targets, and identifying mutations that contribute to drug resistance.

Proposed Department Could Improve Coordination of Research and Development Programs

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. The new department also could improve coordination of biomedical research and development efforts. In addition to coordination, the role of the new department would need to include forging collaborative relationships with programs at all levels of government and developing a strategic plan for research and development.

We have previously reported that the limited coordination among federal research and development programs may result in a duplication of efforts.[8] Coordination is hampered 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 help prevent duplication. For example, the Department of Defense's (DOD) Defense Advanced Research Projects Agency was unaware of U.S. Coast Guard plans to develop methods to detect a biological agent on an infected cruise ship and therefore was unable to share information on its research to develop biological detection devices that could have been applicable to buildings infected this way.

The new department would need to develop mechanisms to coordinate and integrate information about ongoing research and development being performed across the government related to chemical, biological, radiological, and nuclear terrorism, as well as harmonize user needs. Although the proposal tasks the new department with coordinating the federal government's "civilian efforts" only, the new department also would need to coordinate with DOD because DOD conducts biomedical research and development efforts designed to detect and respond to weapons of mass destruction. Although DOD's efforts are geared toward protecting armed services members, they may also be applicable to the civilian population. Currently, NIH is working with DOD on biomedical research and development efforts, and it is important for this collaboration to continue. An example of NIH and DOD's efforts is their support of databases to compare the sequences and functions of poxvirus genes. These searchable databases enable researchers to select targets for designing antiviral drugs and vaccines, and serve as repositories for

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

information on well documented poxvirus strains to aid in detection and diagnosis.

The President's proposal could help improve coordination of federal research and development by giving one person the responsibility for a single national research and development strategy that could address coordination, reduce potential duplication, and ensure that 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 the research as well as with state and local authorities.[9] 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.

Transfer of Control Over Dual-Purpose Research and Development Raises Concern

We are concerned about the implications of the proposed transfer of control and priority setting for dual-purpose research programs. 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 arising from their current placement.

The President's proposal would transfer the responsibility for civilian biomedical 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, 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. NIH biodefense research on enhanced immunologic responses to protect against infection and disease is critical in the development of interventions against both naturally occurring and man-made pathogens.

[9] GAO-01-822.

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

There is the potential that the proposal would allow the new department to direct, fund, and conduct research related to chemical, biological, radiological, nuclear, and other emerging threats on its own. This raises the potential for duplication of effort, lack of efficiency, and an increased need for coordination with other departments that would continue to carry out relevant research. Design and implementation of a research agenda is most efficient at the level of the mission agency where scientific and technical expertise resides. Building and duplicating the existing facilities and expertise in the current federal laboratories needed to conduct this research would be inefficient.

Mission of Select Agent Program Is Aligned with New Department

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,[10] 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 include Ebola, anthrax, botulinum, and ricin. The 2002 act expanded the program's requirements to include 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 we stated earlier, one key consideration in

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

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.

Concluding Observations

The President's proposal would address some shortcomings noted earlier in this statement. Better coordination could reduce wasteful duplication and increase efficiency. The mission of the select agent program is aligned with the new department and, therefore, the transfer of the program would enhance efficiency and accountability. However, we are concerned about the broad control the proposal grants to the new department for biomedical research and development. 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 current dual-purpose biomedical research. The President's proposal does not adequately address how to accomplish both objectives or how to maintain a priority-setting role for those best positioned to understand the relevance of biomedical research. We are also concerned that the proposal has the potential to create an unnecessary duplication of federal research capacity.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

Contact and Acknowledgments

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

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