



Testimony
Before the Committee on Health,
Education, Labor and Pensions
United States Senate

HHS Bioterrorism and Public Health
Emergency Preparedness

Statement of

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Good morning, Mr. Chairman, Senator Kennedy, and Members of the Committee. I am honored to be here today to update you on the steps the Department of Health and Human Services (HHS) has taken to prepare for the threats of bioterrorism and other possible public health emergencies, including pandemic influenza. The events of September and October 2001 served as a continuing reminder that terrorism – indeed bioterrorism – is a serious threat to our Nation and the world. The Administration and Congress responded forcefully to this threat on a number of fronts, including through the passage and implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Project BioShield Act of 2004. Together, the Administration and Congress provided significant new funding to strengthen our medical and public health capacities to protect our citizens from future attacks.

While public health remains chiefly a state and local responsibility, HHS plays a pivotal leadership role. I am pleased to join you today to update you on the progress we have made.

HHS STRATEGIC PLAN

In the summer of 2003, HHS completed its first strategic plan to counter bioterrorism and other public health emergencies. Since then, HHS has worked

diligently and in close cooperation with State and local public health departments, to implement the strategy. These experiences, in turn, continue to yield improved insights regarding the strategy and its implementation.

HHS updated the strategic plan in the summer of 2005 to capture important lessons learned. The updated plan focuses on the following strategic foci, which compose the overall framework for HHS efforts:

1. Preventing Bioterrorism
2. Enhancing State, Local, and Tribal Preparedness for Bioterrorism and Other Public Health Threats and Emergencies
3. Enhancing HHS Preparedness for Bioterrorism and Other Public Health Threats and Emergencies
4. Acquiring New Knowledge Relevant to Bioterrorism and Other Public Health Threats and Emergencies
5. Developing, Acquiring, and Deploying Priority Medical Countermeasures for Chemical, Biological, Radiological and Nuclear (CBRN) Threats

In keeping with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Plan emphasizes bioterrorism, while recognizing that public health threats and emergencies can ensue from myriad other causes, both naturally occurring and man-made. HHS and its partners therefore must prepare for and respond to all manner of mass casualty incidents. As a consequence, bioterrorism preparedness is not an insular activity for HHS but rather an integral critical component within an all-hazards readiness program. To ensure the

synchronization of HHS' efforts in this area, the Office of Public Health Emergency Preparedness coordinates HHS-wide emergency preparedness activities and serves as the principal point of contact at HHS for other Federal agencies and Departments.

This year, we are proposing roughly \$4.4 billion to prepare for possible bioterrorist and other public health emergencies. This includes:

- An additional \$68 million in the Strategic National Stockpile to expand capabilities to operate, properly store, and deploy the rapidly increasing holdings of these critical repositories
- Approximately \$1.3 billion at CDC and HRSA to continue to improve State and local public health and hospital preparedness
- \$79 million to fund the Mass Casualty Initiative, which includes Federal Medical Stations, Medical Reserve Corps, Healthcare Provider Credentialing and the Commissioned Corps Transformation initiatives, and
- \$160 million to support advanced development of priority medical countermeasures.

This \$4.4 billion is complemented by an additional \$2.3 billion allowance for an emergency appropriation and \$352 million in ongoing efforts in the FY 2007 budget for pandemic influenza activities.

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STATE AND LOCAL PUBLIC HEALTH AND HOSPITAL PREPAREDNESS

Under the President's National Response Plan, HHS leads Federal public health efforts to ensure an integrated and focused national effort to prepare for and respond to emerging biological and other CBRN threats. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the State and local medical and public health response to mass casualty events.

HHS' leadership strategy begins with enhancing the capabilities of State and local public health departments and hospitals. This approach is consistent with experience of emergency responders everywhere; for all emergency incidents – whether naturally occurring, accidental, or terrorist-induced – begin as local matters.

Principally through HHS's Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting. First, the Centers for Disease Control and Prevention (CDC) provides preparedness funding annually to public health departments of all the States, certain major

metropolitan areas, and other eligible entities through cooperative agreements. Second, the Health Resources and Services Administration (HRSA) employs complementary cooperative agreements to provide preparedness funding annually within States for investment primarily in hospitals and other healthcare entities. HHS collaborates with DHS toward ensuring that the guidance associated with the CDC and HRSA awards is coordinated with the guidance associated with those DHS awards that address other aspects of State and local preparedness, such as emergency management and law enforcement. Including the funding we have requested for FY07, CDC and HRSA's total investments in State and local preparedness since 2001 will total almost \$8 billion.

PERFORMANCE MEASURES

HHS through the CDC and HRSA cooperative agreements has undertaken a conscious process to develop performance measures for public health and healthcare preparedness activities. HRSA conducted an expert panel of States and other stakeholders (to include hospitals and hospital associations at the local and national level) in January 2006 to develop a core set of healthcare preparedness measures. These measures are being cross-walked with the public health measures developed by CDC and the Target Capabilities List (TCL) developed by the department of Homeland Security (DHS). The measures will be undergoing a national vetting and review process in the near future and progress towards meeting these measures will be reported during the FY 2006 funding year.

SURVEILLANCE

We are also taking important steps to expand and refine our disease surveillance capabilities. BioSense is a national program designed to advance a new type of biosurveillance at the national, State, and local levels. Using streams of health data and advanced algorithms for analyzing and visualizing these data streams, the new methods supported by BioSense address the needs of monitoring for infectious diseases, for biological and chemical attacks, and for naturally occurring public health emergencies. BioSense supports the situational awareness necessary to confirm and identify possible events, to track and manage their size and spread, and to provide public health and government decision makers the information needed to manage preparedness and response. Though data have been compiled through BioSense for the last few years, there has been a significant time lag in the transmittal and analysis of data. Starting January 1, 2006, CDC has been receiving near “real-time” data from over 30 hospitals in 10 cities. The goal is by the end of 2006 to have over one hundred hospitals in all 31 BioWatch cities participating in BioSense.

In responding to the threat of pandemic influenza with the support of additional funding in fiscal year 2006, CDC plans to further accelerate implementation of the BioSense program in 2006 by increasing the number of participating cities, the number of healthcare systems and real-time clinical data sources within

those cites, and incorporating other existing health data sources of importance in monitoring influenza activity and the effectiveness of emergency response.

HHS FOOD SAFETY EFFORTS

The Bioterrorism Act provided HHS with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. This legislation represents the most fundamental enhancement to our food safety authorities in many years. These additional authorities improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies.

In addition to implementation of the new authorities provided in the Bioterrorism Act, HHS has undertaken numerous other activities to ensure the safety and security of the nation's food supply. We have enhanced coordination with our partners in Federal, state, and local governments, academia, and industry. As an example, FDA USDA, DHS, and the Federal Bureau of Investigation are collaborating with States and private industry to protect the nation's food supply from terrorist threats through the Strategic Partnership Program Initiative. The Initiative involves using a vulnerability assessment tool to identify sector-wide vulnerabilities. It will also identify mitigation strategies and research needs.

TRAINING AND SURGE CAPACITY

An integral part of emergency response is the ability to provide surge capacity to undergird medical and public health systems that may be overwhelmed by mass casualties or displaced persons. A critical new program is the Federal Medical Stations (FMS), which was originally intended to provide a deployable medical capability (equipment, material, pharmaceuticals) to assist hospitals in meeting needed surge requirements. They are designed to be staffed by Federal personnel in support of regional, State, or local venues. Although still in the proof of concept phase, FMS capability was projected into the Gulf in response to Hurricanes Katrina and Rita. Ten 250-bed derivatives of the FMS were created within days of Hurricane Katrina. These units had pared down pharmaceutical lists and were used to support the medical needs of the evacuees, rather than providing hospital surge capacity. While the FMS was designed to be staffed by Federal personnel, they were also adapted during the hurricanes to support state-run medical needs shelters. Current plans are to expand the program to include FMSs that are specifically designed to support the states in providing care to evacuee populations with chronic medical conditions. As we further develop the FMS program we are considering how it can be used to support multiple capabilities. For example, with the growing concerns regarding pandemic influenza, the FMS program is exploring the possibility of using these mobile medical units to support quarantine stations. Our FY 2007 budget seeks \$50 million for FMS.

In the mass casualty setting, the ability to quickly increase the number of health care workers available is a critical component of public health emergency response capacity. HHS' Health Resources and Services Administration (HRSA) has supported efforts to improve personnel surge capacity. Funds are used to allow jurisdictions to develop or enhance Emergency Systems for Advance Registration of Volunteer Health Professionals (ESAR-VHP), authorized under the Public Health Security and Bioterrorism Preparedness and Response Act. ESAR-VHP is designed to help States develop registries of volunteer health professionals whose credentials have been verified in advance of an emergency so that they can be quickly called on and utilized in an emergency. These systems are being developed according to National guidelines, standards and definitions so that States can easily exchange health professionals in an emergency. Once fully developed, these State-based volunteer registries will include up-to-date, verified information on health and medical volunteer identity licensure status, and professional credentials required for practice in hospitals and other facilities. These systems will include Medical Reserve Corps volunteers, State and local personnel, and health professionals working in the private sector.

Our FY 07 budget seeks \$7.6 million for development of a web-based portal that would create the means for integrating the state ESAR-VHP systems into a National system, thereby promoting a more coordinated national deployment of personnel. The portal is intended to not only integrate existing state ESAR-VHP

systems, but to also provide a credentialing service that could assist states with the development of their ESAR-VHP databases.

HRSA also continues to support the Bioterrorism Training and Curriculum Development Program (BTCDDP). This program provides support to health professions schools, health care systems, and other educational entities to equip a workforce of health care professionals to address emergency preparedness and response issues. It is estimated that nearly 225,000 health care professionals have received training to enable them to recognize indications of a terrorist event, treat patients and communities in a safe and appropriate manner, participate in a coordinated multi-disciplinary community response, and alert the public health system rapidly and effectively. HRSA is promoting consistency, collaboration and coordination in healthcare preparedness training through the alignment of curriculum with the National Preparedness goal, adoption and promulgation of competency-based training, evaluation of training and healthcare preparedness through exercises and drills, and establishing a system for disseminating tested materials.

PHS COMMISSIONED CORPS

The Commissioned Corps provides a unique source of well-trained and highly qualified, dedicated public health professionals who are available to respond rapidly to urgent public health challenges and health care emergencies. The Corps' response to Hurricane Katrina is a powerful example of what the Corps

can do. In response to Katrina, we deployed more than 2,000 Corps officers - the largest deployment in the history of the Corps - and we still have personnel in the field providing care in Louisiana today. Transformation is intended to make the force management improvements that are necessary for the Corps to function even more efficiently and effectively. We are now in the process of organizing our officers into teams, providing more training and supplying more equipment so that they can deploy more rapidly and with more capability than is the case presently. All of our officers will be required to meet readiness standards. The President's FY 2007 budget request reflects the importance that has been given to the transformation of the Corps, including an additional \$10 million for strengthening the systems that will allow us to better manage the force.

DEVELOPING, ACQUIRING AND DEPLOYING PRIORITY MEDICAL COUNTERMEASURES

CDC also operates HHS's Strategic National Stockpile (SNS), which contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency severe enough to cause local supplies to run out. Once Federal and local authorities agree that the SNS is needed, medicines and medical supplies can be delivered to any State in the U.S. within 12 hours. Consequently, each State is now required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment.

HHS's National Institutes of Health (NIH) is assigned the lead role in the research and early development of medical countermeasures to prepare for and respond to a biological, chemical, radiological, or nuclear threat agents, and in the conduct of research that will expand our understanding of the human health impact of these agents. The National Institute of Allergy and Infectious Diseases (NIAID) is the NIH institute with primary responsibility for carrying out this assignment.

Thus far, NIAID has used Project BioShield authorities to award \$35.6 million in grants and contracts. The activities supported by these awards will advance development of countermeasures toward possible future procurement with Project BioShield funds. Twelve grants and two contracts have been awarded to support research for therapeutics and a vaccine candidate directed against the CDC Category A agents that cause anthrax, smallpox, tularemia, plague, botulism, and viral hemorrhagic fevers. NIAID has awarded 4 grants and 3 contracts to support research on medical countermeasures against radiological or nuclear terrorist attacks, including countermeasures to protect the immune system against radiation and improved treatments for the elimination of internal radionuclide contamination that can be given by mouth rather than intravenously.

Pandemic Influenza Activities

As you know, last year, the President requested \$7.1 billion in emergency funding for the *National Strategy for Pandemic Influenza*, of which \$6.7 billion was requested for HHS. Congress appropriated \$3.8 billion as the first installment of the President's request to begin these priority activities, and of this amount, \$3.3 billion was provided to HHS. We appreciate the action of Congress on this appropriation as it takes us an essential step forward to become the first generation in history to be prepared for a possible pandemic.

Using the first \$3.3 billion we received in December, we are planning by the end of this year to procure approximately 22-24 million regimens of antivirals at the Federal level. The funding we propose for FY07 will help us come closer to our goal of covering 25% of the American population. This year we will expand our pre-pandemic stockpile of H5N1 vaccine by 1.7 million courses, and will be investing significantly in the domestic development of cell-based technology for influenza vaccine. This, and the proposed FY 07 funding, is necessary to add additional manufacturers to have the domestic capacity to produce enough vaccine for the U.S. population within six months of the first sign of a pandemic.

In March 2006, HHS, through CDC, started allocating \$100 million to help States and other eligible entities enhance preparedness for pandemic influenza. Later this year, we will allocate an additional \$250 million for further State and local preparedness. The Congress has specified that the bulk of funding in this area should be based on performance. In the near future, HHS will apprise the States

as to the contractual arrangement whereby they may purchase additional antiviral drugs, if they so choose, at a 25% subsidy.

As the next step in these efforts, this year's budget includes a \$2.3 billion allowance for the second year of the President's Pandemic Influenza plan. These funds will enable us to meet several important goals, including providing pandemic influenza vaccine to every man, woman and child within six months of detection of sustained human-to-human transmission of a bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness.

Project BioShield

The Project BioShield Act of 2004 (P.L.108-276) ("Project BioShield") is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, development, acquisition, and availability of medical countermeasures to defend against chemical, biological, radiological and nuclear (CBRN) threats.

In exercising the procurement authorities under Project BioShield, HHS has launched acquisition programs to address each of the four threat agents deemed to be Material Threats to the U.S. population by DHS [*Bacillus anthracis*

(anthrax), smallpox virus, Botulinum toxins, and radiological/nuclear agents].

HHS has used the Special Reserve Fund (SRF) to award two contracts for vaccines against anthrax, one contract for a liquid formulation of a drug to protect children from radioactive iodine exposure following nuclear events, and one contract for chelating agents for countering the effects of internal exposure to transuranic radioisotopes.

In addition, negotiations are underway for the acquisition of anthrax therapeutics. With respect to smallpox vaccines, an award will be made for the manufacture and delivery of up to 20 million doses of a next generation attenuated smallpox vaccine, modified vaccinia Ankara (MVA). Additionally, negotiations are underway for procuring 200,000 doses of botulinum antitoxin.

These countermeasures are being added to the SNS that currently includes vaccines, antibiotics to counter infections caused by anthrax, plague, and tularemia, antitoxins, chemical antidotes and radiation emergency medical countermeasures.

However, we recognize that more can and must be done to aggressively and efficiently implement Project BioShield. To this end, I intend to establish a dedicated strategic planning function in HHS that more efficiently integrates biodefense requirements, across the full range of threat agents, with the execution of advanced development and procurement of medical

countermeasures. I will reorganize the Office of Public Health Emergency Preparedness (OPHEP) and assign and empower it as the responsible office to develop and implement a strategic plan for this purpose, and I will ensure that HHS component programs and functions are properly aligned, and that their respective strengths are leveraged, to support OPHEP's efforts. I will also work closely with other departments and agencies to streamline and make more effective the current BioShield interagency governance process. We will make this process more transparent and work to educate the public and industry about our priorities and opportunities. As part of this, HHS will convene an outreach meeting with these external stakeholders later this year.

I applaud the Committee's efforts to support and promote innovation for medical countermeasures, as reflected in S. 1873, the Biodefense and Pandemic Vaccine and Drug Development Act of 2006. However, as presently drafted, I am concerned that S. 1873 would impose an organizational framework on HHS that impairs my ability to implement the strategic approach for medical countermeasures development and procurement that I have outlined, including the functions to be executed by a reorganized OPHEP and a more efficient BioShield interagency governance process. I am committed to ensuring that advanced development of medical countermeasures is properly supported and conducted, and that the procurement and medical countermeasures is timely and efficacious. I would therefore appreciate the opportunity to work with the Committee to further refine S.1873 to ensure that it achieves our mutual

objectives of improving processes that expedite the availability of promising treatments to naturally-occurring infectious diseases or to a chemical, biological, radiological, or nuclear attack.

As part of this, the Administration will work with the Committee on funding for this effort, while preserving the BioShield Special Reserve Fund for medical countermeasures against known and emerging terrorist threats. I also note that the Administration is requesting \$160 million in FY 2007 for advanced development.

CONCLUSION

Thank you once again for inviting me to testify on this important issue.

Maintaining a robust national public health infrastructure to effectively prepare for all emerging threats requires sound collaboration, communication, and clear lines of command and control. Although preparedness depends on plans at the local, state, and federal levels, without the exercise of these plans, we will not be able to know if we are truly prepared. HHS will continue to lead the way towards public health emergency preparedness. As the threat of a pandemic influenza clearly shows however, the scope of the Federal government in responding to pervasive public health emergencies such as a pandemic is limited. States and localities must be prepared to rise to the challenge as well.

I would be happy to take any questions.