individual who wishes to attend the meeting and/or participate in the public comment session should e-mail *nvac@hhs.gov* or call 202–690–5566.

Dated: September 5, 2006.

Bruce Gellin,

Director, National Vaccine Program Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health Emergency Preparedness; Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats [1]

AGENCY: Office of Public Health Emergency Preparedness.

ACTION: Draft HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats.

SUMMARY: The United States faces serious public health threats from the deliberate use of weapons of mass destruction (WMD)—chemical, biological, radiological, or nuclear (CBRN)—by hostile States or terrorists, and from naturally emerging infectious diseases that have a potential to cause illness on a scale that could adversely impact national security. Effective strategies to prevent, mitigate, and treat the consequences of CBRN threats is an integral component of our national security strategy. To that end, the United States must be able to rapidly develop, stockpile, and deploy effective medical countermeasures to protect the American people. The ultimate goal of this HHS Public Health Emergency Medical Countermeasures Enterprise Strategy (*PHEMCE Strategy*) is to establish the foundational elements and guiding principles that will support medical countermeasure availability and utilization for the highest priority CBRN threats facing our nation.

[1] This Strategy excludes pandemic influenza which is addressed in the HHS Pandemic Influenza Plan, a blueprint for pandemic influenza preparation and response. It provides guidance to national, state, and local policy makers and health departments. The HHS Pandemic Influenza Plan includes an overview of the threat of pandemic influenza, a description of the relationship of this document to other Federal plans and an outline of key roles and responsibilities during a pandemic. It is aligned with the .National Strategy for Pandemic Influenza, issued by President Bush November 1, 2005, and the *Implementation Plan for the National Strategy for Pandemic Influenza* which guide our nation's preparedness and response to an influenza pandemic.

DATES: The public is invited to submit comments on the draft HHS *PHEMCE Strategy* up to thirty days from the date of publication in the **Federal Register**. After consideration of the comments submitted, HHS will issue a final *PHEMCE Strategy.*

Comments: Address all comments to Dr. Susan Coller at *PHEMCSTRAT@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Susan Coller, Policy Analyst, Office of Public Health Emergency Medical Countermeasures, Office of Public Health Emergency Preparedness at 330 Independence Ave., SW., Room G640 Washington, DC 20201, or by phone at 202–260–1200.

Overview

The United States faces serious public health threats from the deliberate use of weapons of mass destruction (WMD)—chemical, biological, radiological, or nuclear (CBRN)—by hostile States or terrorists, and from naturally emerging infectious diseases that have a potential to cause illness on a scale that could adversely impact national security. A failure to anticipate these threats, or the lack of a capacity to effectively respond to them could leave an untold number of Americans dead or permanently disabled. Thus, effective strategies to prevent, mitigate, and treat the consequences of CBRN threats are an integral component of our national security strategy. To that end, the United States must be able to rapidly develop, stockpile, and deploy effective medical countermeasures (MCM) to protect the American people.

The key role for development and acquisition of effective medical countermeasures for WMD was previously identified in the *National Strategy to Combat Weapons of Mass Destruction* and *Biodefense for the 21st Century,* the President's blueprint for addressing the nation's biodefense programs. Research and early development support of CBRN MCM by the National Institutes of Health has grown from $53 million in Fiscal Year (FY) 2001 to $1.8 billion in FY 2006. Funding for the Strategic National Stockpile similarly has grown from $52 million in FY01 to $530 million in FY06. Furthermore, on July 21, 2004, President George W. Bush signed into law the Project BioShield Act of 2004 (Project BioShield) to accelerate the research, development, acquisition, and availability of effective medical countermeasures to protect our citizens against CBRN threats. Project BioShield provided $5.6 billion over 10 years to acquire these medical countermeasures.

During its first two years of implementation, Project BioShield acquisitions were guided by a policy and requirements document derived from interagency deliberations in 2003 that involved Cabinet-level Departments and the Executive Office of the President. This document served as the initial strategic plan for acquisition under Project BioShield. Under this strategy, the Department of Health and Human Services (HHS) pursued acquisitions for those highest priority threats for which there were candidate products at relatively advanced stages of development. These products included medical countermeasures for anthrax, smallpox, botulinum toxins and radiological/nuclear agents, the four threat agents deemed by the Department of Homeland Security (DHS) to pose a ''material threat'' to national security. The relatively advanced nature of the products pursued resulted from years of investment, made in large part by the Department of Defense in advance of the BioShield program, as well as aggressive development programs launched by the National Institutes of Health soon after the anthrax attacks in 2001.

Despite these achievements, more can and must be done. HHS will continue to shape and execute a comprehensive, focused MCM program to protect our citizens against CBRN threats today and into the future. On behalf of the Secretary, the Office of Public Health Emergency Preparedness is dedicated to the mission of preventing and mitigating the adverse public health consequences of disasters resulting from these threats. This mission encompasses the breadth of activities required to accomplish the goal including: threat agent and disease surveillance and detection; and research, development, acquisition, storage, deployment and utilization of medical countermeasures.

A focused medical countermeasure program will reflect threat priorities, threat agent characteristics, medical/public health consequence assessments, and the likelihood that effective medical and public health intervention will prevent and mitigate adverse health consequences. Given the expense and time required to develop each countermeasure, and the wide range of pathogens and compounds that potentially could be used in an attack, we must develop a strategy that prioritizes investment in a manner that optimizes our ability to mitigate the public health impact of current and future threats.

The type and magnitude of both CBRN and natural threats are evolving. New diseases emerge and existing diseases change. World-wide travel is

commonplace and more rapid. Advances in biotechnology support the development of new treatments, but make those same tools more widely available to adversaries who might use them to intentionally inflict harm. Nuclear technologies proliferate despite international efforts to contain them, and chemical exposures can result from accidents or deliberate releases. We must, therefore, focus our efforts to meet the evolving nature of these threats by relying on cutting-edge technologies to expand and improve national capacity and capabilities to protect public health in a dynamic environment. This will require unprecedented cooperation among all levels of Government, private industry, academia, international partners and the public.

Approach and Guiding Principles

HHS is undertaking a two-staged approach to develop a Public Health Emergency Medical Countermeasures Enterprise Strategy that will lead to an Implementation Plan for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE Implementation Plan will be a prioritized plan with near-, mid- and long-term goals for research, development and acquisition of medical countermeasures that is consistent with the guiding principles and priority-setting criteria defined in this PHEMCE Strategy.

HHS created the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) in July 2006 [ref: Office of Public Health Emergency Preparedness: Statement of Organization, Functions and Delegations of Authority, 71 FR 38403 (July 6, 2006)]. The PHEMCE is a coordinated interagency effort led by HHS and charged with the responsibility to: (1) Define and prioritize requirements for public health medical emergency countermeasures; (2) coordinate research, early- and advanced product development and procurement activities to address the requirements; and (3) set deployment and use strategies for medical countermeasures held in the Strategic National Stockpile.

The PHEMCE Strategy defines the principles and objectives that will guide our Implementation Plan for the entire PHEMCE-surveillance/detection of threats; research, development, acquisition, storage/maintenance, deployment and utilization of medical countermeasures. The ultimate goal of the PHEMCE Strategy is to establish the foundational elements and guiding principles that will support medical countermeasure availability and utilization for the highest priority CBRN threats facing our nation.

The PHEMCE Strategy will provide a framework for future U.S. Government planning efforts that is consistent with the President's Biodefense for the 21st Century, the National Security Strategy and the National Strategy for Homeland Security. It recognizes that preparing for and responding to CBRN events is not strictly a Federal responsibility, but relies significantly on multiple key stakeholders, including both domestic and international industrial, academic and governmental biomedical research and development communities, Federal, State and local Governments, public health authorities, first responders, and the public.

To address the challenges presented by the diverse CBRN threat spectrum, mitigate the risks associated with MCM development and ensure that our development and acquisition of MCM significantly enhances our response and recovery capabilities, we must utilize the following overarching principles to guide decisions on the development and acquisition of medical countermeasures:

- We must focus our preparations on countering the threat agents that have the highest potential to cause catastrophic public health consequences.
- We must direct investments where medical intervention presents the greatest opportunity to prevent, mitigate, and treat those public health consequences.
- Under HHS leadership, we must align and synchronize efforts on the part of all key stakeholders involved in the PHEMCE towards defending the United States of America against CBRN weapons of mass destruction.
- We must adapt our plans and programs to changes in intelligence, threat assessments, and assessments of medical and public heath consequences including our public health emergency response capabilities, and the progress that is made in the development and availability of candidate medical countermeasures.

To implement programs that most effectively acquire medical countermeasures, including those under Project BioShield, the PHEMCE Strategy addresses the full spectrum of events required from the identification of priority threats, to setting medical countermeasure requirements for those threats, to the ultimate acquisition and effective use of those medical countermeasures. The PHEMCE Strategy builds upon the following four pillars:

1. Threat Identification and Prioritization:

○ HHS will consider the best available intelligence and scientific information to identify and prioritize CBRN threats. HHS' public health consequences assessments and corresponding MCM priorities and requirements will be informed by the DHS Material Threat Determinations which, as defined in the Project BioShield Act, present a material threat sufficient to affect national security.

2. Medical/Public Health Consequence Assessment:

○ HHS will utilize modeling, where available, to complement the subject matter experts' evaluation of the effectiveness of various medical countermeasure strategies and response capabilities.

3. Establishment and Prioritization of Medical Countermeasures Requirements:

○ HHS will establish baseline requirements based on unmitigated consequence assessments.

○ HHS will assess the status of medical countermeasures available and in development including:

■ Holdings of the SNS

■ Relevant commercial products potentially accessible to the USG

■ Candidate medical countermeasures in the developmental pipeline (USG and Industry)

○ HHS will establish Concept of Operations including maintenance, utilization policies and deployment plans for each MCM in the context of all available consequence mitigation strategies.

○ Gap analysis: HHS will assess medical countermeasure requirements vs. candidate and available medical and non-medical countermeasures

○ HHS will define specific medical countermeasure requirements, including product specifications consistent with USG storage plans and operational capabilities for deployment and utilizations by federal, state and local authorities.

4. Establish and Prioritize Near-Term (FY07–08), Mid-Term (FY09–13), and Long-Term (FY14–23) Development, Acquisition, Stockpiling and Maintenance Strategies:

○ HHS will establish a research and development portfolio to address MCM gaps and to meet future acquisition targets (align requirements with priorities).

○ HHS will identify and support critical infrastructure that enables medical countermeasure development such as biocontainment facilities, animal models, workforce training, production, etc.

○ HHS will establish short-, mid-, and long-term acquisition strategies that

incorporate all relevant cost elements for acquisition, storage, maintenance, deployment and utilization of the medical countermeasure.

After publishing a final *PHEMCE Strategy*, HHS will develop and publish an Implementation Plan for this strategy. Several critical policy issues will guide creation of the Implementation Plan. These policies will address both the development and acquisition of MCM to threat agents. These ten strategic policies include:

1. Relative Hierarchy of CBRN Threat Classes (Biological versus Chemical versus Radiological/Nuclear)

The *PHEMCE Implementation Plan* will address the relative value of medical countermeasures across all classes of threat agents. There is general consensus that the greatest potential for medical mitigation exists for biological threat agents. However, HHS also envisions identifying significant, though more limited, opportunities for MCM for radiological, nuclear and chemical threats.

2. Addressing Top Priority versus All Threats

While our primary goal is to prevent the health effects of an attack with WMD, we recognize that despite our best efforts we will not be able to develop and acquire medical countermeasures to prevent and reduce adverse health effects against all threats in all places at all times for all people. Consequently, the *PHEMCE Implementation Plan* will consider all CBRN threats weighing costs, risks, and benefits such as their relative priority, feasibility of use in an event, and cost to mitigate with MCM and non-MCM to develop the best strategy. Recognizing the scope of the threats and the limited resources, the investments will focus on the top priorities for medical mitigation. Where possible, HHS will aim to develop and acquire medical countermeasures that have the potential to address multiple threats, particularly for lower priority threat agents.

3. Traditional, Enhanced, Emerging, and Advanced Threats

There are four classes of biological threat agents: traditional, enhanced, emerging, and advanced (or engineered) threats. These are defined, briefly as:

- Traditional Agents: naturally occurring microorganisms or toxin products with the potential to be weaponized and disseminated to cause mass casualties (*e.g.* anthrax, smallpox, etc.).
- Enhanced Agents: traditional agents that have been modified or selected to circumvent current countermeasures. For example, an enhanced agent could be a bacterial pathogen that is modified to confer resistance to an antibiotic.
- Emerging Agents: naturally occurring organisms that are newly recognized or anticipated to present a public health threat. Recent examples of emerging agents include Severe Acute Respiratory Syndrome (SARS) and West Nile Virus.
- Advanced Agents: novel organisms that have been engineered or newly generated in the laboratory. Ongoing advances in biotechnology are believed to enable the engineering of novel organisms that could be targeted to completely bypass our countermeasures and might even be mistaken as naturally occurring emerging agents.

The *PHEMCE Implementation Plan* will address traditional, enhanced, emerging, and advanced (engineered) threats and develop the best strategy to mitigate risk within time and cost constraints. HHS will continue to support a robust basic research program that will aim to develop broad-spectrum solutions using technologies that enable more flexible next generation interventional concepts and to consider approaches and technologies derived from the commercial drug development sector to support the biodefense mission. However, it is anticipated that near- and mid-term acquisition programs will continue to focus on addressing specific high priority threats with specific medical countermeasures. We will work closely with the intelligence community to ensure that our priorities are consistent with intelligence assessment of the threats most likely to be faced by our nation.

4. Medical Versus Non-Medical Countermeasures

HHS will work closely with interagency partners and in concert with national strategies and directives to guide and coordinate our medical countermeasure efforts with the other aspects of our homeland security strategies and missions to maximize synergies and minimize any gaps in our national defenses. Specifically, the *PHEMCE Implementation Plan* will take into consideration the use of non-medical countermeasures when establishing priorities to complement the use of medical countermeasures.

5. Specific Versus Broad Spectrum or Fixed Versus Flexible Defenses

As is true in the broader biodefense context, a key challenge to the Implementation Plan will be to define the optimal balance between fixed and flexible defenses.[2] While static defenses and the so-called ''one bug-one drug'' approach can be justified for top priority threat agents such as anthrax, with well-recognized potential for catastrophic medical and economic consequences, the uncertainties associated with the CBRN threat environment require that the PHEMCE Strategy also be as flexible as possible, to allow for the best approach for protection of our nation's citizens. Therefore, HHS will support the development of flexible MCM while recognizing that, at least for the immediate future, some agents will require agent-specific MCM.

6. Prevention/Mitigation Versus Treatment

The PHEMCE Implementation Plan will address both medical prevention and treatment alternatives and develop the best strategy considering both costs and benefits. The term ''cost'' in this case goes beyond simple immediate expenditure of funds to also include weighing future opportunity costs. For example, if the United States government purchases a medical countermeasure in the short term it may then miss the opportunity to buy a more effective medical countermeasure in the future due to budgetary constraints. In addition, a medical countermeasure that has a more expensive cost upfront, may be more valuable in the long term if it meets the criteria in utilization during a crisis, that is, easily self administered, no cold-chain storage, or broad spectrum with respect to threat mitigation. As with the definition of costs, benefits also go beyond the simple definition of ''curing disease'' and include concepts such as overall lifecycle of the medical countermeasure including storage, utilization and deployment.

For civilian populations, it is anticipated that, aside from some of the top priority threats, a post-event strategy will be adopted. Pre-event MCM (*e.g.* vaccines) are appropriate for high priority threats and when pre-event MCM are justified. Therapeutics/diagnostics or the use of post-exposure prophylaxis following an event will be the preferred strategy for all other threats. From this perspective, vaccines that provide post-exposure efficacy will be of interest.

[2] ''Bioterrorism—Preparing to Fight the Next War'', David A. Relman, *New England Journal of Medicine*, Vol 354(2):113–115, 2006. In the context of defense against biological threats, a fixed defense is a medical countermeasure intended for use against a specific organism and not useful in scenarios that employ a different organism.

7. Acute Versus Chronic Effects

The *PHEMCE Implementation Plan* will give priority to addressing the acute (immediate to weeks time frame) medical/public health outcomes resulting from CBRN threat agents.

8. First Available Versus Next Generation

The *PHEMCE Implementation Plan* will address both currently available and next generation medical countermeasures and will regularly evaluate on a case-by-case basis strategies for long-term maintenance and/or replacement of medical countermeasures in the SNS. Currently available medical countermeasures will be considered for acquisition if they meet immediate, critical needs and may be effectively deployed under current preparedness plans. Investment to meet particular threats will not however be a singular event, but rather an ongoing process that synchronizes the lifecycle requirements of currently stockpiled medical countermeasures with on-going research and development efforts. This synchronization should ensure that, as current stockpiles age and decline, more appropriate, next generation products will be available for acquisition consideration.

9. General Versus Special Populations

The *PHEMCE Implementation Plan* will address the needs of both general and special populations such as children, the elderly, pregnant women, persons with immunocompromised conditions and persons with disabilities that may impact the efficacy of, or the ability to access, MCM. Given limited available resources, priority will be given to those medical countermeasures that will prevent and treat adverse health effects to the greatest number of individuals. However, efforts will continue to be made to find creative solutions for providing treatment and mitigation of high priority threats to all populations.

10. Domestic Versus International

The *PHEMCE Implementation Plan* will focus on the domestic medical countermeasure needed to protect the homeland, while recognizing that in a global emergency these resources may be utilized by the USG to meet critical international needs and the need to protect the homeland, to the extent feasible, under the framework of the International Health Regulations (2005) that will go into force in June 2007. Additionally, the Implementation Plan will call out and address those instances in which domestic manufacturing capacity is critical to national security.

PHEMCE Strategic Objectives

To achieve the goal of acquiring critical, targeted MCM, HHS will act on the following strategic objectives:

1. Identify and prioritize current and future MCM objectives;

2. Build balanced, effective programs across all phases of the PHEMCE;

3. Increase transparency and predictability in the Nation's civilian MCM priorities;

4. Develop, Recruit, and Support A World-Class Workforce

1. Identify and Prioritize Current and Future MCM Objectives

HHS has made substantial progress toward protecting the Nation from several of the most worrisome bioterrorist threats.[3] Biological threats have significant potential to have a catastrophic impact on public health by causing tens of thousands to millions of casualties in single, multiple, or sequential attacks. There are fewer technical barriers to the acquisition, production and dissemination of biological agents to a large number of people relative to those posed by other CBRN threat classes. In addition, biological threats are unique in that some agents are contagious and have the potential to continue inflicting casualties beyond their original area of release. Therefore, the acquisition of medical countermeasures for priority biological agents presents the greatest opportunity to prevent and mitigate health effects of public health emergencies. When addressing radiological/nuclear and chemical threats emphasis should be on well-defined diagnostics and therapeutic interventions, since the mitigation of the threat will be after the catastrophic event has occurred.

HHS has major stockpiles of antibiotics for use against anthrax, plague, and tularemia, as well as a significant stockpile of smallpox vaccines. These medical countermeasures can be used to protect our citizens from adverse health effects following exposure to these pathogens. The timelines for effective use after a large number of people are exposed are however very demanding and HHS is working with States and localities to enhance our ability to distribute these MCM swiftly enough to be effective in a crisis. HHS also has invested in a growing stockpile of the current anthrax vaccine which is licensed for pre-exposure immunization, as well as the acquisition of a new anthrax vaccine targeted for licensure for both pre-exposure and post-exposure use. Additionally, HHS has contracted for anthrax treatments including polyclonal and monoclonal antibodies. In addition, HHS will include in its overall MCM acquisition strategy the threat of naturally occurring, emerging or re-emerging infectious diseases of which SARS or West Nile Virus represent two examples. Analysis of the threat potential will influence resource allocation towards targeted versus flexible MCM investments. At the same time, long term investments towards the development of broad spectrum platform technologies are expected to enhance the overall threat detection, diagnosis, and disease mitigation capabilities.

In its strategy for future priority setting for acquisition of MCM, HHS recognizes it must focus MCM investments across two separate dimensions.

One dimension is across potential CBRN threat agents. MCM investments must be appropriately targeted across the full range of CBRN agents, informed by the potential gravity of a threat agent, as well as by the probability that such an event might occur. Broad assessments from DHS and the intelligence and scientific community, including both domestic and international perspectives will inform these judgments. Protection against threats must be broad enough to mitigate the impact of major biological, radiological, nuclear and chemical threats and enhance overall security.

A second dimension to consider is the near, mid and long-term MCM needs across time. As we move into the future, both the sophistication of the threat and the sophistication of potential medical countermeasures are expected to increase. The need for and the benefits

[3] In 2000 the Centers for Disease Control and Prevention issued a ranked list of bioterrorism agents. The highest priority, Category A, was assigned to agents that can be easily disseminated or transmitted person-to-person, cause high mortality and major public health impact, might cause public panic and social disruption, and require special action for public health preparedness. The Category A agents (and the diseases they cause) are variola major (smallpox), *Bacillus anthracis* (anthrax), *Yersinia pestis* (plague), *Clostridium botulinum* toxin (botulism), *Francisella tularensis* (tularemia), and two categories of hemorrhagic fever viruses: filoviruses, (Ebola and Marburg) and arenaviruses (Lassa fever, Junin [Argentine hemorrhagic fever] and related viruses). Many other organizations have done rankings of bioterrorism threats and the principle results have roughly been the same. An integrated all WMD hazards risk assessment is necessary for the creation of an overarching guide for setting prioritize across the range of CBRN agents. The Department of Homeland Security will complete and deliver to the Homeland Security Council by January 2008 the results of an all-WMD assessment that builds upon their bioterrorism risk assessment and will integrate chemical, radiological and nuclear threats.

of purchasing large quantities of a currently available MCM must be weighed against the risks and benefits of waiting for a new MCM that could be more effective but will not be available for years. HHS must balance between the risk of an event in the immediate future and the opportunity of a fully refined, advanced MCM in the longer term.

The balancing of these two dimensions will require some difficult tradeoffs. HHS cannot acquire all of the countermeasures that might be available to counter all potential threat agents in each of the near, mid and long-term time frames. Using a more cost-effective and efficient approach, HHS might choose to fund fully the development of a needed MCM, take it through clinical trials, and then purchase only a small stockpile and principally rely on a finely honed, well-planned and exercised surge production capability to swiftly produce enough doses in a national crisis.

For the near-term, HHS will continue to identify MCM opportunities for currently licensed medical treatments and candidate medical treatments already in advanced development that fill near-term vulnerabilities. These will focus on the most worrisome agents, in terms of adverse public health and medical outcomes. We will seek greater robustness in our anthrax and smallpox responses, for example, by using different classes of antibiotics against a bacterial pathogen or focusing on MCM with different mechanisms of action such as vaccines, antimicrobials, and antitoxins which use newer rather than legacy technologies.

For the mid-term, HHS will monitor advances in medical countermeasure technology and seek to provide the needed incentive to pull promising candidate MCM out of the laboratory and turn them into greatly improved medical countermeasures through a more tightly focused advanced development effort. A high priority, for example, will be development of point-of-care assays and diagnostics that can rapidly differentiate microbial pathogens, specific radionuclides, or toxic chemicals that would lead to timely and appropriate medical decisions. Such assays are critical in rapidly separating those who have been exposed and require intervention from the unexposed but ''worried well.'' HHS also will support new MCM manufacturing methods. Just as it has been promoting the development of cell-based production of influenza vaccines to supplement egg-based vaccine preparation methods, the Department will seek other opportunities to promote faster production methods that lend themselves to surge production in a crisis. Furthermore, HHS will support the development of MCM with produce specifications that will facilitate a rapid public health response such as needle-less delivery systems and single dose solutions over multidose strategies.

For the long-term, HHS will strive to develop broad-spectrum countermeasures as well as other new MCM approaches. We, for example, hope to see, over time, improved methods for treating the acute effects of radiation exposure. Replacement of legacy technologies, such as equine heptavalent botulinum antitoxin, may also be needed upon expiration of the current generation products currently being stockpiled.

Prioritizing MCM Based on Product Characteristics

HHS also will select candidate medical countermeasures based on desired product characteristics are most compatible with the concept of operations for public health emergency response. For example, HHS will favor medical countermeasures that people can self-administer, such as oral antibiotics, over those that require a health care worker (doctor or nurse) to administer. Among those that require a health care worker, HHS will favor easily administered medications, such as a simple injection, over those needing longer interventions such as slow-infusion intravenous drugs or multiple interventions. Ideal medical countermeasures will have a low risk of adverse side effects so that their benefits clearly outweigh their risks. Finally, ideal medical countermeasures will include products that can be stored at room temperature and be appropriate for use by the vast majority of citizens. Their use will require little or no screening to identify those patients who cannot use them and hence will most readily facilitate their rapid and broad distribution in a public health emergency.

2. Build Balanced, Effective Programs Across All Phases of the PHEMCE

HHS will assure a balanced, effective program across the PHEMCE and will pursue the broad priorities across the spectrum of research and early development, advanced development, and procurement to ensure a comprehensive, mutually-supportive program.

A strong biodefense research and early development program is currently underway under the leadership of the National Institute of Allergy and Infectious Diseases at the NIH. To supplement this effort, over the next year, and pending the availability of funds, HHS intends to expand its advanced development program. The Department plans to fund and staff this new function to enhance its ability to pursue an aggressive and strategic advanced development program as part of the comprehensive PHEMCE.

HHS is similarly committed to strengthening its execution of MCM procurements. It is expanding the size of procurement staff and is working with DHS to streamline the approval process for use of the Special Reserve Fund authorized in the Project BioShield Act of 2004.

In July 2006, HHS created a strategic planning function in the Office of Public Health Emergency Preparedness. This office will be responsible for carrying out a PHEMCE Strategic Plan that balances investment across CBRN agents and timelines. It also will produce threat-specific plans for the most worrisome bioterrorism agents, identify all the potential junctures for medical intervention post-exposure and present procurement options for the HHS Secretary's decision.

3. Increase Transparency and Predictability in The Nation's Civilian MCM Priorities

HHS will clearly and publicly articulate MCM priorities, the types of MCM it will seek to acquire and the general timelines for acquisition. The development of new medical countermeasures requires effective interactions among Government, the private sector and academia. Private research organizations, pharmaceutical manufacturers, biotechnology companies, and clinical research organizations already have many of the resources and the expertise needed to develop MCM but have been reluctant to make substantial investments in research and development because of market uncertainties.

HHS will promote appropriate discussion of these priorities with all stakeholders, public and private, by convening meetings and workshops with representatives from relevant industries, academia, other Federal departments and agencies, international agencies as appropriate, and other interested persons. In addition, HHS will launch a stakeholder Web portal to enhance industry's access to and communication with the relevant HHS agencies regarding MCM product development.

HHS will work to streamline the regulatory process for medical countermeasures. HHS will facilitate private investment of time, energy and

resources in MCM development by removing or lowering obstacles whenever appropriate, including the application of liability protections where appropriate. HHS will conduct its selection and acquisition process with full transparency while respecting requirements for confidentiality.

4. Develop, Recruit, and Support a World-Class Workforce

A successful PHEMCE will need a highly qualified and accomplished workforce with appropriate technical training, scientific skills, and business experience. HHS is committed to staffing the PHEMCE with outstanding professionals and to creating a supportive work environment.

The Department will recruit outstanding professionals from both the public and private sectors, to build a model program for advanced product development and procurement program that will provide needed products as efficiently and effectively as possible. HHS will recruit career Federal employees for their experience, skills and expertise in research, development, and the regulatory aspects of product development programs as well as management of such government programs. Highly qualified researchers and managers from academia and private industry will compliment their expertise. HHS will facilitate the appointment of these individuals through existing general and senior service programs.

HHS also will develop programs to provide opportunities for information regarding scientific and product development by using such mechanisms as fellowship, sabbatical, internship and exchange programs. This effort will allow private sector individuals to bring new skills and fresh ideas to the program from the biotechnology and pharmaceutical industries. The Department also will create appropriate career paths to assure staff who are working in the PHEMCE have opportunities to continue to grow professionally and assure that excellence remains the hallmark.

HHS will use current Federal hiring practices to offer compensation that attracts the best human capital to meet its mission and challenges. HHS also will accept service from qualified individuals with special expertise who are willing to contribute their skills to advisory boards or committees that the Secretary determines would contribute to the overall program.

Conclusion

This HHS PHEMCE Strategy reflects the new HHS approach to develop and acquire medical countermeasures against CBRN events. It provides strategic direction to the Department, signals the Department's intent and priorities to its Governmental and private partners and will serve to guide development of the PHEMCE Implementation Plan. Consistent with its stated commitment to transparency, predictability, and wide-ranging solicitation of expertise, the Department will engage those partners as it develops specific strategic initiatives to meet its goals and objectives in MCM advanced development, procurement, and delivery. The HHS PHEMCE Strategy underscores the recognition of HHS's top leadership that the President is relying on the Department to craft and execute a program that responsibly protects our fellow citizens from CBRN threats.

Dated: September 5, 2006.

Gerald Parker,

Principal Deputy Assistant Secretary, Office of Public Health Emergency Preparedness.

[FR Doc. E6–14908 Filed 9–7–06; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–223]

Identification of Priority Data Needs for Two Priority Hazardous Substances

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Request for public comments on the identification of priority data needs for two priority hazardous substances, and an ongoing call for voluntary research proposals.

SUMMARY: This notice makes available for public comment the priority data needs for two priority hazardous substances (see Table 1) as part of the continuing development and implementation of the ATSDR Substance-Specific Applied Research Program (SSARP). The notice also serves as a continuous call for voluntary research proposals. The SSARP is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) or CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)]. This research program was initiated in 1991. At that time, a list of priority data needs for 38 priority hazardous substances was announced in the **Federal Register** on October 17, 1991 (56 FR 52178). The list was subsequently revised, based on public comments, and published in final form on November 16, 1992 (57 FR 54150). In 1997, ATSDR finalized the priority data needs for a second list of 12 substances; that priority data needs list was subsequently announced in the **Federal Register** on July 30, 1997 (62 FR 40820). Ten substances constitute the third list of hazardous substances for which priority data needs were identified by ATSDR. The final list of the 10 substances was published on April 29, 2003 (68 FR 22704), after it was subjected to public comment.

The exposure and toxicity priority data needs in this notice were distilled from data needs identified in the Agency's toxicological profiles via a logical scientific approach described in a ''Decision Guide'' published in the **Federal Register** on September 11, 1989 (54 FR 37618). The priority data needs represent essential information to improve the database for conducting public health assessments. Research to address these priority data needs will help determine the types or levels of exposure that may present significant risks of adverse health effects in people exposed to the hazardous substances.

The priority data needs identified in this notice reflect the opinion of the Agency, in consultation with other Federal programs, of the research needed pursuant to ATSDR's authority under CERCLA. They do not represent the priority data needs for any other agency or program.

Consistent with Section 104(i)(12) of CERCLA as amended [42 U.S.C. 9604(i)(12)], nothing in this research program shall be construed to delay or otherwise affect or impair the authority of the President, the Administrator of ATSDR, or the Administrator of EPA to exercise any authority regarding any other provision of law, including the Toxic Substances Control Act of 1976 (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA), or the response and abatement authorities of CERCLA.

In developing this research program, ATSDR has worked with other federal programs to determine common substance-specific data needs, as well as mechanisms to implement research that may include authorities under TSCA and FIFRA, private-sector voluntarism, or the direct use of CERCLA funds.

When deciding the type of research that should be done, ATSDR considers the recommendations of the Interagency Testing Committee established under Section 4(e) of TSCA. Federally funded