

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 3, 2007.

**A. Federal Reserve Bank of Richmond** (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *PSB Holding Corp.*, Preston, Maryland; to engage *de novo* through its subsidiary, Community Bank Mortgage Corporation, Easton, Maryland, in the origination and sale of residential mortgage loans to the secondary market, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, March 14, 2007.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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**BILLING CODE 6210-01-S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Assistant Secretary for Preparedness and Response; HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats

**AGENCY:** Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services.

**ACTION:** Notice.

**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. This *HHS Public Health Emergency Medical Countermeasures Enterprise Strategy (HHS PHEMCE Strategy)* establishes the goals and objectives that HHS will employ to ensure that medical countermeasures are available for effective use against the highest priority CBRN threats facing the Nation. The *HHS PHEMCE Strategy* considers the full spectrum of medical countermeasures-related activities, including research, development, acquisition, storage/maintenance, deployment, and utilization. The *HHS PHEMCE Strategy* is consistent with the President's *Biodefense for the 21st Century* and aligned with the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction*.

**DATES:** This notice is effective as of March 14, 2007.

**FOR FURTHER INFORMATION CONTACT:** Dr. Susan Collier, Policy Analyst, Office of Public Health Emergency Medical Countermeasures, Office of the Assistant Secretary for Preparedness and Response at 330 Independence Ave., SW., Room G640, Washington, DC 20201 or by phone: 202-260-1200.

### Introduction

The United States faces serious public health threats from the deliberate use of chemical, biological, radiological, or nuclear (CBRN) weapons of mass destruction (WMD) by hostile states or terrorists, and from naturally emerging infectious diseases that have the potential to cause illness on a scale that could adversely impact national security. The type and magnitude of both CBRN and naturally-occurring threats are evolving. Chemical exposures can result from accidents as well as deliberate releases. Advances in biotechnology support the development of new medical treatments, but also make those same tools more widely available to adversaries who might use them to modify biological organisms with the intention to inflict harm. New diseases, like Severe Acute Respiratory Syndrome (SARS), emerge; and regionally endemic diseases, like West Nile Fever and Rift Valley Fever, are introduced into susceptible populations. Nuclear technologies may proliferate despite international efforts to contain them.

A failure to anticipate these threats or the lack of a capacity to effectively prevent them could leave an untold number of Americans dead or permanently disabled. The United States must be able to effectively develop, stockpile, and rapidly deploy

critical medical countermeasures to prevent, mitigate, and treat the adverse health consequences of threats both natural and manmade. Given the diverse and dynamic nature of these threats, and the expense and time required to develop threat agent-specific medical countermeasures, a strategy must be developed that prioritizes investment and optimizes the ability to protect the Nation.

### The Role of the Department of Health and Human Services in Public Health Preparedness

Within the Federal government, the Department of Health and Human Services (HHS) leads the research, development, acquisition, deployment, and use of effective medical countermeasures to protect the civilian population from WMD. This key role was identified in the *National Strategy to Combat Weapons of Mass Destruction*,<sup>1</sup> *Biodefense for the 21st Century*,<sup>2</sup> and the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction*,<sup>3</sup> which together are the President's blueprint for addressing the Nation's CBRN defense programs.

Within HHS, multiple operating and staff divisions work together to develop and implement strategies to prevent and control disease, injury, illness, and disability from terrorist threats and naturally-occurring diseases capable of negatively impacting Government and social systems. In July 2006, HHS created the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).<sup>4</sup> The PHEMCE is a coordinated, intra-agency effort led by the Office of the Assistant Secretary for Preparedness and Response<sup>5</sup> (ASPR) and includes three HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The mission of the PHEMCE is to: (1) Define and prioritize requirements for public health emergency medical countermeasures; (2) integrate and coordinate research, early and late stage product development, and procurement activities addressing the requirements; and (3) set deployment and use

<sup>1</sup> <http://www.whitehouse.gov/news/releases/2002/12/WMDStrategy.pdf>.

<sup>2</sup> <http://www.whitehouse.gov/homeland/20040430.html>.

<sup>3</sup> <http://www.whitehouse.gov/news/releases/2007/02/20070207-2.html>.

<sup>4</sup> **Federal Register**, Vol. 71, No. 129, Thursday, July 6, 2006, Notices.

<sup>5</sup> Formerly the Office of Public Health Emergency Preparedness; changed to reflect the Pandemic and All-Hazards Preparedness Act enacted on December 19, 2006 (P.L. 109-417).

strategies for medical countermeasures held in the Strategic National Stockpile (SNS).

Many resources throughout HHS have already been coordinated in support of medical countermeasure preparedness. Funding support by the NIH for basic research, product development, and clinical research of CBRN medical countermeasures has grown from \$53 million in Fiscal Year 2001 (FY01) to \$1.8 billion in FY06. Funding for the SNS 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).<sup>6</sup> The purpose of Project BioShield is to accelerate the research, development, acquisition, and availability—including through use of the Emergency Use Authorization (EUA)—of safe and effective medical countermeasures to protect the United States from CBRN threats. Project BioShield created a \$5.6 billion special reserve fund for use over 10 years (FY04—FY13) to acquire these medical countermeasures.

During its first two years of implementation, Project BioShield acquisitions were guided by requirements derived from interagency deliberations in 2003 that involved Cabinet-level Departments and the Executive Office of the President. Under this initial strategy, 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<sup>7</sup>—the four threat agents initially determined by the Department of Homeland Security (DHS) to pose a material threat to national security.<sup>8</sup> The relatively

<sup>6</sup> [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_cong\\_public\\_laws&docid=f:publ090.108.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ090.108.pdf).

<sup>7</sup> To date, contracts have been awarded using the Project BioShield special reserve fund for the purchase of anthrax therapeutics, anthrax vaccines, botulism antitoxin, a pediatric formulation of potassium iodide (a drug that blocks absorption of radioactive iodide in the thyroid gland), and Calcium- and Zinc-DTPA (two forms of a decorporation agent to remove transuranic radionuclides from the body). The SNS also contains enough smallpox vaccine to protect every American, antibiotics for anthrax, adult (tablet) formulations of potassium iodide, the decorporation agent Prussian Blue, and additional supplies for treating the burn and blast injuries that could be associated with a nuclear event.

<sup>8</sup> The Project BioShield Act of 2004 requires the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services and the heads of other agencies, as appropriate, to determine which current and emerging CBRN threats present a material threat against the United

advanced nature of the products pursued resulted from years of earlier investment made in large part by NIH and the Department of Defense (DOD).

In addition to the achievements made to date, more can and must be done. The National Strategy for *Medical Countermeasures against Weapons of Mass Destruction* provides guiding principles to align United States Government (USG) programs and funding mechanisms that support the research, development, acquisition, deployment, and utilization of medical countermeasures for current and future CBRN threats. In accordance with the National Strategy, HHS will continue its commitment to shape and execute a focused medical countermeasures program to protect the Nation's citizens against high priority CBRN threats where medical countermeasures can have the greatest impact. The NIH will continue its existing research and development efforts to identify medical countermeasures for known as well as emerging diseases. HHS will use the Biomedical Advanced Research and Development Authority (BARDA) in the Pandemic and All-Hazards Preparedness Act (Pub. L. 109–417) to provide direct investment in medical countermeasure advanced research and development. Finally, HHS will use the Project BioShield special reserve fund and the Strategic National Stockpile resources to acquire, store, maintain and deploy top priority medical countermeasures.

#### Medical Countermeasure Preparedness For CBRN Threats: A Two-Stage Approach

To fulfill the mission of the ASPR to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters, HHS through the PHEMCE is undertaking a two-stage approach to planning that aims to solicit stakeholder input and to efficiently integrate the requirements for, and the advanced development and acquisition of, medical countermeasures for priority CBRN threat agents.

#### Stage One

The first stage is development of this *Public Health Emergency Medical Countermeasures Enterprise Strategy*<sup>9 10</sup>

States population sufficient to affect national security.

<sup>9</sup> A draft of this *HHS PHEMCE Strategy* was published in the **Federal Register** on September 8, 2006, for public comment and was presented and discussed at the 2006 BioShield Stakeholders Workshop on September 25–26, 2006. The *HHS PHEMCE Strategy* reflects input received from the stakeholders representing industry, academia, other

(*HHS PHEMCE Strategy*). The *HHS PHEMCE Strategy* establishes the goals and objectives that HHS will employ to ensure that the most appropriate medical countermeasures are developed and acquired for use against the highest priority CBRN threats facing the Nation. This *HHS PHEMCE Strategy* considers the full spectrum of medical countermeasures-related activities, including research, development, acquisition, storage/maintenance, deployment, and utilization.

#### Stage Two

The second stage in this process is the development of the *HHS PHEMCE Implementation Plan*. This document, to be published in early 2007, will outline the medical countermeasure programs that 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. The *HHS PHEMCE Implementation Plan* will incorporate valuable lessons learned from the initial implementation of Project BioShield; consider new authorities made available in the Pandemic and All-Hazards Preparedness Act; and outline HHS near-, mid- and long-term goals for research, development, and acquisition of medical countermeasures, consistent with the goals defined in this *HHS PHEMCE Strategy*. The *HHS Implementation Plan* will be reviewed at least biennially and revised to reflect changes in the threat scope and the availability of new or improved countermeasures.

While ASPR leads the execution of the *HHS PHEMCE Implementation Plan*, HHS recognizes that developing, acquiring, and utilizing medical countermeasures to prepare for and respond to CBRN events will require significant resources and unprecedented

non-governmental organizations, and State, local, and Federal governments. Additional information on the Workshop is available at [www.hhs.gov/aspr/ophemc/bioshield/workshop.html](http://www.hhs.gov/aspr/ophemc/bioshield/workshop.html).

<sup>10</sup> This *HHS PHEMCE Strategy* excludes pandemic influenza, which is addressed in the *HHS Pandemic Influenza Plan*, a blueprint for pandemic influenza preparation and response that provides guidance to Federal, 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 the *HHS Pandemic Influenza Plan* 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 George W. Bush on November 1, 2005, and the *Implementation Plan for the National Strategy for Pandemic Influenza*, which guides the Nation's preparedness and response to an influenza pandemic.[0] Additional information is available at [www.pandemicflu.gov](http://www.pandemicflu.gov).

cooperation among many stakeholders, including Federal counterparts outside HHS,<sup>11</sup> private industry (domestic and international), State and local governments, frontline first responders and healthcare workers, academia, and the public.

#### Four Strategic Goals

To address the challenges presented by the diverse CBRN threat spectrum, to mitigate the financial and programmatic risks associated with medical countermeasure development and acquisition, and to ensure that the development and acquisition of medical countermeasures significantly enhances the Nation's response and recovery capabilities, the following four strategic goals and underlying objectives will guide critical funding allocation decisions.

##### *Goal 1. Identify and Prioritize Programs for the Development and Acquisition of Medical Countermeasures*

While a primary goal of HHS is to prepare the Nation to prevent and respond to the health effects of natural and manmade disasters, constraints of both time and financial resources do not allow for the development and acquisition of medical countermeasures to prevent and mitigate all threats, in all places, at all times, and for all people. Consequently, several factors must be considered when developing the most appropriate strategies for high priority CBRN threats. The prioritization of medical countermeasure development and acquisition programs that will be delineated in the *HHS PHEMCE Implementation Plan* will be informed by the following three objectives.

##### Objective 1. Establish the Relative Hierarchy of the Chemical, Biological, Radiological, and Nuclear Threat Classes

In the process of determining the most effective ways to mitigate and treat the effects of the CBRN threats, it is essential to understand that the three threat classes (i.e., chemical, biological, and radiological/nuclear) are distinct in their feasibility of use and in their potential public health consequences. HHS recognizes that the overall strategy for protection against these threats must be broad enough to effectively mitigate the public health impact of a major chemical, biological, radiological, or

nuclear event, while focusing preparations on developing and acquiring medical countermeasures to protect against the threat agents that have the greatest potential to cause catastrophic public health consequences and for which medical intervention will be effective, feasible, and pragmatic. Threat identification and prioritization to inform medical countermeasure development and acquisition is a collaborative effort between HHS and DHS. DHS has the lead in considering the best available intelligence and scientific information to identify and prioritize CBRN threats. DHS uses this as the basis for issuing determinations about which agents present a material threat sufficient to affect national security. DHS then provides HHS with estimates of the numbers of potentially exposed individuals using plausible, high-consequence scenarios for each threat. To inform subsequent medical and public health consequence assessments, HHS combines this data with medical consequence modeling, subject matter expert evaluations, domestic and international intelligence information, and information on current State and local response capabilities. The *HHS PHEMCE Implementation Plan* will consider all of these inputs when establishing the HHS medical countermeasure priorities and requirements.

##### Objective 2. Prioritize Gaps in the Research, Development, and Acquisition of Medical Countermeasures

HHS is committed to investing in research and development of medical countermeasures that will provide the most benefit for preventing or treating the effects of exposure to CBRN threats. HHS will apply the following specific guidelines and principles when evaluating potential investments.

*Medical<sup>12</sup> versus Non-Medical<sup>13</sup> Countermeasures.* HHS will address the relative value of medical countermeasures and non-medical countermeasures, both within each class of threat agent and across all classes of threat agents. The *HHS PHEMCE Implementation Plan* will be developed with the overall goal of creating—through investments in research, development, and acquisitions—a

portfolio that optimizes public health preparedness using the best combined strategies to prevent, mitigate, and treat the effects of a catastrophic CBRN event.

*Prevention and Mitigation versus Treatment.* HHS will address both medical prevention and medical treatment alternatives for public health preparedness. Given cost/benefit and implementation considerations, *post-event* diagnostics, prophylaxis, and/or treatment are likely to be the preferred strategies for most threats; however, *pre-event* medical countermeasures (such as vaccines) may still be appropriate for some high priority threats.

*Acute versus Chronic.* Many CBRN agents have the potential to cause acute health consequences. In addition to relieving these acute consequences, early mitigation and treatment may prevent subsequent chronic health effects. The *HHS PHEMCE Implementation Plan*, therefore, will give priority to addressing the acute (immediate to weeks timeframe) medical and/or public health outcomes resulting from CBRN threat agents, while acknowledging that some threats, despite early interventions, may cause long-term health consequences.

*Specific versus Broad-spectrum.* The USG must be capable of responding to a wide variety of potential challenges, including traditional as well as novel biological agents that are highly communicable, associated with a high rate of morbidity or mortality, and potentially without known countermeasure at the time of discovery. Identified in the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction* is the spectrum of potential biological threat agents that pose such risks. These include threats that are traditional (i.e., naturally occurring microorganisms or toxin products with the potential to be disseminated to cause mass casualties, such as anthrax and plague); enhanced (i.e., a traditional agent that has been modified or selected to circumvent current countermeasures, such as an engineered, antibiotic-resistant, bacterial pathogen[0]); emerging (i.e., a naturally occurring organism that is newly recognized or anticipated to present a public health threat, such as Severe Acute Respiratory Syndrome-associated coronavirus [SARS-CoV][0][0]); or advanced (i.e., a novel organism that has been engineered or newly generated in the laboratory and that could be targeted to bypass traditional countermeasures or produce a more severe or otherwise enhanced spectrum of disease).

Medical countermeasure acquisitions planned in the near-term will continue

<sup>11</sup> Partners include Department of Defense (DOD), Department of Homeland Security (DHS), Department of Labor (DOL), Department of Transportation (DOT), Department of State (DOS), Department of Veterans Affairs (DVA), Department of Energy (DOE), and Department of Agriculture (USDA).

<sup>12</sup> Includes both pharmaceutical medical countermeasures (e.g., vaccines, antibiotics, antitoxins) and non-pharmaceutical medical countermeasures (e.g., ventilators, devices, personal protective equipment such as face masks and gloves).

<sup>13</sup> Includes elements such as contact and transmission interventions, social distancing, and community shielding.

to focus on addressing specific, high-priority threats with specific medical countermeasures. Where available, HHS will pursue development and acquisition of medical countermeasures that address multiple threats, as is the case with the current stockpile of antibiotics that are effective against multiple bacterial threat agents. A key challenge for the *HHS PHEMCE Implementation Plan*, however, will be to define the optimal balance between fixed and flexible defenses<sup>14</sup> to best prepare for the future.

Fixed defenses (the so-called “one bug—one drug” approach) for medical counter-measure development can be time-consuming and expensive. To date, however, this has been the preeminent path for addressing current threats. This approach has been successful in part because it presents industry with clearly defined targets for product development. At the same time, however, the uncertainties associated with the CBRN threat environment require that the *HHS PHEMCE Implementation Plan* support the development of flexible defenses to allow for innovations in medical countermeasure design that may result in enhanced products. For example, the benefit of broad-spectrum pharmaceuticals and platform technologies<sup>15</sup> will extend beyond their ability to counter current biological threat agents and will allow for rapid response to future threats. In addition, development of broad-spectrum medical countermeasures and platform technologies may also contribute to the mitigation and treatment of the health effects associated with chemical and radiological/nuclear threats. Therefore, HHS will support the development of flexible medical countermeasures including broad-spectrum pharmaceuticals and diagnostics, while recognizing that, at least for the immediate future, some threats will require agent-specific medical countermeasures.

The NIH will continue its existing research and development efforts to identify medical countermeasures for known as well as emerging diseases. HHS will use the Biomedical Advanced Research and Development Authority (BARDA) in the Pandemic and All-

Hazards Preparedness Act to provide direct investment in medical countermeasure advanced research and development. Finally, HHS will use the Project BioShield special reserve fund and the Strategic National Stockpile resources to acquire, store, maintain, and deploy top priority medical countermeasures. HHS will work to ensure that its internal agencies, including ASPR, NIH, FDA, and CDC, continue to present industry with clear and comprehensive guidelines for HHS expectations regarding the development, approval, and utilization policies for fixed and flexible defenses.

*General versus Special Populations.* The *HHS PHEMCE Implementation Plan* will address the medical countermeasure needs of both the general population and those special populations (e.g., children, the elderly, pregnant women, immunocompromised individuals, and persons with disabilities) for whom efficacy or dosing have not been determined, to whom FDA licensure has not been extended, or for whom the use of a countermeasure is medically contraindicated. Given the limited availability of resources, priority will be given to those medical countermeasures that will prevent and treat adverse health effects for the greatest number of individuals. Meanwhile, HHS will continue its dedication to finding treatment and mitigation solutions for high priority threats to all populations.

*Concept of Operations.* HHS will develop, and select for acquisition, candidate medical countermeasures based on desired product characteristics that are most compatible with the current Concept of Operations (CONOPs) for public health emergency response at the Federal, State, and local levels. For each medical countermeasure, HHS will establish civilian CONOPs, including maintenance, utilization policies, and deployment plans in the context of available consequence mitigation strategies. When feasible, HHS will identify and integrate existing CONOPs developed by its Federal partners.<sup>16</sup> Consistent with previously issued material threat determinations, HHS will define specific medical countermeasure requirements, including product specifications consistent with USG storage plans and operational

capabilities for deployment<sup>17</sup> and utilization by Federal, State, and local authorities. For example, HHS will favor medical countermeasures that people can self-administer (e.g., oral antibiotics) over those that require administration by a health care worker. For those medical countermeasures that do require a health care worker, HHS will favor easily administered medications (e.g., a simple single injection) over medications that require intravenous administration, continuous medical monitoring, or prolonged courses. Preferred medical countermeasures will include products that can be stored at room temperature, have a minimum 5-year shelf-life, and are appropriate for use by the vast majority of the at-risk population.

*Domestic versus International.* The *HHS PHEMCE Implementation Plan* will focus on medical countermeasures needed to protect the domestic civilian population. In a global emergency, however, the USG may utilize these resources, as feasible and as appropriate, to meet critical international needs.

Objective 3. Establish and Prioritize Near-Term, Mid-Term, and Long-Term Development and Acquisition Programs

HHS will achieve the optimal state of public health preparedness by synchronizing its near-term, mid-term, and long-term investments in the research, development, and acquisition of existing as well as novel medical countermeasures to effectively prevent, mitigate, and treat the dynamic nature of the threat scope. The *HHS PHEMCE Implementation Plan* will address both existing and next generation medical countermeasures. HHS will regularly evaluate, on a case-by-case basis, investment strategies for long-term maintenance and/or replacement of medical countermeasures in the SNS. HHS will establish a research and development portfolio that will meet future top priority countermeasure gaps.

Building on the existing USG infrastructure, HHS will identify and support the critical framework necessary to enable medical countermeasure development, including biocontainment facilities, animal models, workforce training and education, and product manufacturing. HHS will establish strategies that consider the total life-cycle costs<sup>18</sup> of

<sup>14</sup> Relman DA. Bioterrorism—Preparing to Fight the Next War, *NEJM*, 2006, 354(2):113–115. 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.

<sup>15</sup> Platform technologies are methods for developing and producing medical countermeasures that are rapidly adaptable to multiple threats.

<sup>16</sup> DOD will separately develop its medical countermeasure CONOPs for military populations and will work to integrate DOD medical countermeasure requirements and product development plans with HHS strategies for addressing civilian requirements.

<sup>17</sup> Deployment includes the transportation and distribution system (both vehicular equipment and human capital) needed to distribute the medicines and supplies.

<sup>18</sup> Relevant cost elements including development, acquisition, storage, maintenance, deployment,

each medical countermeasure and will employ the following guidelines and principles to evaluate potential investments in the near-term, the mid-term, and the long-term.

*Near-term Strategies (FY07–08).*

Recognizing the broad spectrum of CBRN threats and the limited resources available, all investments will focus on those threats with the highest possibility for medical mitigation. Currently available medical countermeasures will be considered for acquisition if they meet immediate, critical needs and if they can be deployed effectively under current preparedness plans. HHS will continue to invest in research and development activities to identify additional indications for currently approved<sup>19</sup> products. Furthermore, HHS will continue to support candidate medical countermeasures already in advanced development that have the potential to address current vulnerabilities. These efforts will focus on the highest priority gaps in terms of adverse public health and medical outcomes.

*Mid-term Strategies (FY09–13).* HHS will monitor advances in medical countermeasure technology and will provide, through a narrowly focused advanced development effort, the support needed to pull promising candidate medical countermeasures through the development pipeline. It will be accepted that some of these candidate countermeasures and platforms may not be deemed suitable for further investment as additional data become available; however, this approach is expected to result in a net expansion of the pool of medical countermeasure candidates. HHS also will work with the private sector to support new technologies for medical countermeasure manufacturing that may be utilized for both CBRN and commercial interests. Furthermore, HHS will support the development of point-of-care assays and diagnostics, and other medical countermeasure products that facilitate a rapid public health response, such as those with needle-less delivery systems or single dose solutions.

*Long-term Strategies (FY14–23).* HHS will maintain its commitment to providing appropriate resources to address those threat agents deemed by DHS to pose the greatest risks to national security. In addition to these

known dangers, HHS will continue to work to protect the Nation from unknown threats. HHS will also continue its support of the development of novel, broad-spectrum medical countermeasures as well as innovative approaches to countermeasure deployment logistics, including manufacturing processes, delivery systems, storage requirements, and distribution tactics. Maintenance in the SNS of products made with existing technologies will be evaluated in the context of availability of next generation products and of products made with modernized manufacturing technologies. Existing technologies will continue to be evaluated for applicability to producing novel medical countermeasures.

*Goal 2. Build Balanced, Effective Programs Across the HHS Public Health Emergency Medical Countermeasures Enterprise*

The HHS PHEMCE will build and maintain a balanced and effective medical countermeasure research, development, and acquisition program. Currently, a robust research and early development program exists under the leadership of the NIH. In the coming years, HHS will expand on this foundation to enhance its ability to pursue an aggressive, integrated, and strategic advanced development program using authorities provided in the Pandemic and All-Hazards Preparedness Act. The prioritization of threat-specific medical countermeasures will be reflected in corresponding changes in the NIH's research and development funding allocations. Furthermore, HHS will enhance its ability to pursue an aggressive and strategic advanced development program as part of the comprehensive PHEMCE. ASPR will coordinate biodefense research and development at NIH, CDC, and FDA; synchronize funding streams for advanced development; and utilize scientific capital and technological capability from all Federal government agencies to ensure that the necessary medical countermeasure solutions are available to respond to and minimize critical public health needs.

Similarly, HHS will strengthen its execution of medical countermeasure procurements. It is expanding its acquisition staff and has worked with DHS to streamline the approval process for use of the special reserve fund authorized in the Project BioShield Act of 2004. For current and future medical countermeasures, HHS will continue to establish, in partnership with State and local authorities, CONOPs that include

maintenance, utilization policies, and deployment plans in the context of available consequence mitigation strategies.

*Goal 3. Increase Transparency and More Actively Engage the Private Sector*

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 medical countermeasures; however, they have been reluctant to make substantial investments in research and development because of market uncertainties. HHS will clearly and publicly articulate its medical countermeasure development and acquisition priorities, as well as the general timelines associated with addressing these priorities.

HHS will enhance communication between the Federal government and external stakeholders through several mechanisms, including this *HHS PHEMCE Strategy*, the soon-to-be-released *HHS PHEMCE Implementation Plan*, the PHEMCE Stakeholder Workshops, and a dedicated Web site, [MedicalCountermeasures.gov](http://MedicalCountermeasures.gov). HHS's annual Stakeholder Workshops will educate the public and promote appropriate discussion of these priorities with public and private stakeholders. As needed, HHS will also convene other meetings and workshops with representatives from relevant industries, academia, and other Federal departments and agencies (including the Government and Sector Coordinating Councils involved in the development of the National Infrastructure Protection Plan), international agencies as appropriate, and other interested persons.

In 2007, HHS will launch [MedicalCountermeasures.gov](http://MedicalCountermeasures.gov), a secure Web site designed to enhance industry's access to and rapid communication with the relevant USG agencies regarding medical countermeasure development. [MedicalCountermeasures.gov](http://MedicalCountermeasures.gov) will provide frequent updates on Federal medical countermeasure activities, and will feature upcoming events, pre-solicitation notices, key Federal resources, announcements, and links to related USG Web sites. Conversely, stakeholders will be able to use [MedicalCountermeasures.gov](http://MedicalCountermeasures.gov) to submit information on their products in development as well as to request meetings with USG departments or agencies.

utilization, industrial warm-base, and disposal of expired items.

<sup>19</sup>The term "approved" is used broadly in this report to refer to products and uses that FDA has approved, licensed, or cleared under sections 505, 510(k), and 515 of the Federal Food, Drug, and Cosmetic Act or that FDA has licensed under section 351 of the Public Health Service Act.

As required by the Pandemic and All-Hazards Preparedness Act, HHS will establish the National Biodefense Science Board (NBSB) to provide expert advice and guidance to the HHS Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future CBRN agents, whether naturally occurring, accidental, or deliberate. The membership of the NBSB will be comprised of the Nation's preeminent scientific, public health, and medical experts; Federal officials as the Secretary may determine are necessary to support the functions of the Board; individuals representing the pharmaceutical, biotechnology, and device industries; individuals representing academia; and other members as determined appropriate by the Secretary, including a practicing healthcare professional and a representative from a healthcare consumer organization.

With diligent respect for confidentiality concerns and Federal regulations, HHS will increase the transparency and public visibility of processes by which it selects and acquires medical countermeasures. Acknowledging industry's risky investments of time, energy, and resources, HHS will foster medical countermeasure development by removing or lowering obstacles whenever appropriate, including through the application of liability protections under the Public Readiness and Emergency Preparedness Act (PREP Act)<sup>20</sup> and, as appropriate and necessary, more flexible contracting procedures. In addition to granting the HHS Secretary limited antitrust exemption authorities regarding medical countermeasure research and development, the Pandemic and All-Hazards Preparedness Act allows the Secretary to make milestone-based awards and payments to biotechnology companies and pharmaceutical manufacturers.

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

A successful PHEMCE relies on a highly qualified and accomplished workforce with appropriate technical training, scientific skills, and business management experience—both within the public and the private sectors. HHS is committed, as is each of its Federal partners in this endeavor, to continued staffing of the PHEMCE with

outstanding professionals and to maintaining a work environment conducive to high performance. The Department will continue to recruit outstanding professionals from both the public and private sectors to build a model program for advanced product development, procurement, and delivery that will provide needed products as efficiently and effectively as possible. HHS will recruit Federal employees (civil service and the U.S. Public Health Service) 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, clinicians, and managers from academia and private industry will complement their expertise. HHS will facilitate the appointment of these individuals through existing general and senior service programs.

HHS also will develop programs to train professionals at all career stages in the foundations of the PHEMCE, utilizing mechanisms such as fellowships, sabbaticals, internships, 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 provide PHEMCE staff with opportunities to continue to grow professionally, to retain outstanding staff, and to ensure that excellence remains a PHEMCE hallmark.

HHS will use all available Federal hiring practices and all Pandemic and All-Hazards Preparedness Act authorities to offer compensation that attracts the best human capital to meet its mission and challenges. HHS also will identify qualified individuals with special expertise who are willing to serve on 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 the development, acquisition, and use of medical countermeasures against CBRN threats. It provides strategic direction to the Department, signals the Department's intents and priorities to its Governmental and private partners, and guides the development of the *HHS PHEMCE Implementation Plan*. Consistent with its stated commitment to transparency, predictability, and wide-ranging solicitation of expertise, the Department will continue to engage stakeholders as it develops specific

strategic initiatives to meet its goals and objectives for the advanced development, procurement, and delivery of medical countermeasures. The *HHS PHEMCE Strategy* underscores the commitment by the top leadership of HHS to achieve the vision articulated in the President's *National Strategy for Medical Countermeasures against Weapons of Mass Destruction*. It seeks to craft and execute a robust, integrated, and end-to-end Public Health Emergency Medical Countermeasure Enterprise that provides the Nation with an "all hazards" capability to protect against, respond to, and enable recovery from chemical, biological, radiological, or nuclear attacks upon the public health.

Dated: March 15, 2007.

**Gerald Parker,**

*Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institute for Occupational Safety and Health; Notice of Public Input Opportunity**

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) announces the following availability of opportunity for the public to provide input regarding the draft document, "Long-Term Field Evaluation (LTFE) Program Concept."

NIOSH is the Federal agency responsible for conducting research and making recommendations for the approval for self-contained, self-rescuer (SCSR) closed circuit escape respirators, Title 42, Code of Federal Regulations (CFR), Part 84.

The LTFE program for self-contained self-rescuers (SCSRs) for miners was initiated more than 20 years ago by the U.S. Bureau of Mines. The objective for the LTFE program is to obtain data to determine the expected performance characteristics of SCSRs used in the mining industry. LTFE program results based on scientific principles can provide useful information to monitor expected SCSR performance and assess possible degradation due to the physical stresses of in-mine use. Of utmost concern is the successful performance of any SCSR that passes its inspection

<sup>20</sup> On December 30, 2005, President George W. Bush signed into law the Public Readiness and Emergency Preparedness Act (PREP Act) as part of the 2006 Defense Appropriations Act.