



United States Government Accountability Office
Washington, DC 20548

February 22, 2012

The Honorable Joseph I. Lieberman
Chairman
The Honorable Susan M. Collins
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

Subject: *National Preparedness: Countermeasures for Thermal Burns*

A failed car bomb attempt in New York City in spring 2010 underscored the nation's vulnerability to intentional terrorist threats from explosive devices, such as conventional explosives, radiological "dirty bombs," and nuclear weapons.¹ The blast and subsequent fires from such weapons could inflict serious thermal burns; in the case of a nuclear detonation, these injuries could affect hundreds to thousands of people.² In such an attack, stabilizing individuals with burns and other injuries would be an immediate priority. Medical care for thermal burns in a mass casualty incident would require the ready availability of large quantities of medical countermeasures, such as pain medications, wound dressings, and intravenous fluids, both on-site and in emergency treatment facilities.

The Department of Health and Human Services (HHS)³ is the federal agency primarily responsible for identifying and supporting the development and acquisition of the medical countermeasures needed to prevent or mitigate potential health effects from exposure to chemical, biological, radiological, and nuclear (CBRN) agents and other terrorist threats.⁴ In addition to identifying these countermeasures, including those for thermal burns, HHS also has responsibility for engaging with industry to research and develop them and, ultimately, for acquiring them for the

¹A dirty bomb, or radiological dispersal device, is a mix of explosives, such as dynamite, with radioactive material. When the dynamite or other explosives are set off, the blast carries radioactive material into the surrounding area.

²Thermal burns, as distinguished from chemical and electrical burns or injury to the skin from radioactive isotopes, are caused by intense light and heat.

³For a full list of abbreviations, see enc. I.

⁴For a list of previous GAO products relevant to this topic, see Related GAO Products at the end of this report.

U.S. Strategic National Stockpile (SNS), if appropriate.⁵ The Project BioShield Act of 2004 authorized the establishment of a procurement fund for these countermeasures. Specifically, the act authorized the appropriation of about \$5.6 billion over the 10-year period from fiscal year 2004 through fiscal year 2013 for the Project BioShield Special Reserve Fund to acquire certain medical countermeasures for the SNS.⁶

Multiple organizations have raised concerns about HHS's ability to work with industry to successfully develop and acquire medical countermeasures to respond to CBRN incidents and other terrorist threats, and since 2004 congressional committees have held several hearings to assess HHS's medical countermeasure development and acquisition efforts.⁷ You requested that we examine whether HHS has developed and acquired medical countermeasures that address thermal burn injuries that would result from conventional explosives or radiological or nuclear devices. Our review addresses (1) the medical countermeasures in the SNS that would address thermal burns, (2) the steps HHS has taken to obtain information about and inform industry of its interest in additional countermeasures for thermal burns, and (3) the medical countermeasures in the pipeline for development and acquisition into the SNS that could serve to address thermal burns.

To identify the medical countermeasures in the SNS that would address thermal burns, we reviewed relevant HHS documents, such as risk assessments, requirements papers, documentation of the contents of the SNS and related gap analyses, and other HHS information about the types of medical countermeasures needed and the department's prioritization of countermeasures for thermal burns. We interviewed HHS officials from the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) to obtain information on the types and status of medical countermeasures in the SNS that are available to treat thermal burns. We also interviewed burn experts, such as officials from the American Burn Association and the Department of Defense, to gain a better understanding of thermal burns and the care and treatment of these injuries. Finally, we interviewed state and local

⁵The SNS is a national repository of medications, medical supplies, and equipment for use in a public health emergency. SNS items may be stored in dedicated warehouses, preplaced in local or state jurisdictions, or managed by pharmaceutical and medical device manufacturers if needed for use in a public health emergency. In addition, HHS may have agreements in place with hospitals or other facilities to make use of certain products in the event of a public health emergency.

⁶The Project BioShield Act of 2004 authorized the appropriation of funds for the Special Reserve Fund for the acquisition of certain medical countermeasures using the authorities granted under that law. 6 U.S.C. § 321j. Prior to enactment of this law, the Department of Homeland Security appropriations act for fiscal year 2004 appropriated the amount of the Special Reserve Fund. Pub. L. No. 108-90, 117 Stat. 1137, 1148 (2003).

⁷For example, see Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Defending Against Public Health Threats*, 111th Cong., 2nd sess., 2010; Senate Committee on Homeland Security and Governmental Affairs, *Six Years after Anthrax: Are We Better Prepared to Respond to Bioterrorism?* 110th Cong., 1st sess., 2007; and House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, *Can BioShield Effectively Procure Medical Countermeasures That Safeguard the Nation?* 110th Cong., 1st sess., 2007.

government disaster management officials to obtain a better understanding of the issues related to deployment of thermal burn countermeasures.

To identify the steps HHS has taken to obtain information about and inform industry of its interest in additional countermeasures for thermal burns, we reviewed HHS's medical and public health consequence assessments and countermeasure requirements, and documentation and reviews of the contents of the SNS. We also reviewed HHS's requests for information, notices, and any other information HHS made publicly available from 2010 through 2011 to determine how HHS communicated its thermal burn countermeasure needs to industry and other partners. We chose this period because it reflects HHS's most recent activities for countermeasure development and acquisition. We interviewed HHS officials to obtain information on how the department determined the need for thermal burn countermeasures and the extent to which HHS has provided information to industry about its thermal burn countermeasure needs. We also contacted experts knowledgeable about HHS's medical countermeasure activities, including officials at the Institute of Medicine and officials from five pharmaceutical and medical device companies varying in size and product mix that have experience working with HHS on countermeasure development or acquisition, to obtain their perspectives on the extent to which HHS has provided information to industry and other relevant stakeholders about its thermal burn countermeasure needs.

To identify the medical countermeasures in the pipeline for development and acquisition into the SNS that could serve to address thermal burns, we reviewed BARDA and NIH data on medical countermeasure investments for CBRN and related incidents. This review helped us to determine which investments could serve to address needs for thermal burn countermeasures and to analyze NIH data on countermeasures currently in the pipeline that could address thermal burns. We interviewed HHS officials to obtain information on how they identify candidate products in the pipeline that have the potential for use as countermeasures for thermal burns.

We conducted this performance audit from October 2011 to January 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

The SNS contains supportive care items for thermal burns, such as bandages, pain medications, intravenous fluids, and topical antimicrobial cream needed for the immediate treatment of burn injuries to reduce the risk of infection and stabilize injured individuals. HHS officials told us that the goal of the SNS is to supplement state and local supplies used for immediate care in the initial response—identified as within 72 hours of sustaining injury. CDC compiled supplies needed for the immediate treatment of burn injuries into kits in 2002 and 2003, based on information provided at that time by burn experts about needed items. Because most

medical countermeasures for thermal burns can be found in local hospitals, countermeasures in the SNS would be used to supplement local supplies and inventories, with kits deployed within 24 to 48 hours of notification. The SNS does not contain other countermeasures that may be available for both the immediate care and the longer-term treatment of burn injuries. However, HHS is currently considering whether to acquire some additional countermeasures, including those for longer-term treatment of burn injuries.

HHS has taken several steps since 2010 to obtain information about thermal burn countermeasures, such as conducting interviews and site visits with burn experts, clinicians, and industry officials, which also signaled to industry HHS's interest in these products. HHS has issued two formal notices to solicit information from industry about the types of countermeasures that may be available specifically to treat thermal burns in a mass casualty incident. For example, these notices solicit information about products for immediate care of thermal burns, such as bandages with antimicrobial barriers that could be used for several days without needing to be changed, and products for longer-term burn care, such as temporary skin substitutes. HHS officials stated that in response to these notices and consistent with the Federal Acquisition Regulation (FAR), HHS has also had e-mail, telephone, and in-person discussions with interested companies. In addition, HHS has discussed with industry the department's interest in these additional countermeasures at regional meetings held in 2011.

NIH has some medical countermeasures that are currently in the development and acquisition pipeline that could serve to address thermal burns. The National Institute of Allergy and Infectious Diseases (NIAID), the NIH institute tasked with developing a research program to identify and develop new medical countermeasures for use in radiological and nuclear incidents, is funding research on candidate countermeasures, such as topical creams and antibiotics. NIAID is also funding basic research on the effects of burns and radiation injuries to skin and other tissue. NIH's National Institute of General Medical Sciences is currently funding research on potential or improved burn care treatment. According to HHS officials, NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases is also funding research on such treatment.

Background

Care of Thermal Burns Following a Mass Casualty Incident

Thermal burns from fires, conventional explosives, or radiological and nuclear weapons are treated similarly in the first days and weeks of injury.⁸ Immediate treatment of thermal burns may require medical countermeasures such as intravenous pain medications and fluids, wound dressings, and intubation if an airway is obstructed by swelling resulting from the burns. In addition, individuals with thermal burns sustained in a mass casualty incident may require topical

⁸For burns sustained from radiological or nuclear detonations, once initial burn care has begun, affected individuals would be monitored for radiation exposure and short- and long-term health effects of such exposure in the weeks and months after an incident.

antimicrobial cream or antimicrobial barrier bandages and dressings to prevent or mitigate infection and stabilize patients. Antimicrobial barrier bandages and dressings may include those that are impregnated with silver as the antimicrobial agent and do not need frequent changing for patients who may not be able to be cared for immediately or may need to be transferred to specialized burn centers.

Longer-term treatment for serious burns may require surgical removal of damaged skin and grafting of temporary skin or skin substitutes until permanent skin grafting using the patient's own skin can be performed. Typical products used for temporary coverage include cadaver or pig skin. For prolonged periods of time beyond the acute or initial phase of the medical response, care for serious thermal burns also requires additional specialized staff, resources, and equipment. These additional needs make the overall response to a mass casualty incident complicated. For example, the number of health care providers with significant burn care expertise may be in short supply locally, and care for severely burned individuals beyond the initial response requires complex, expensive, resource-intensive care, such as skin grafts. There are approximately 1,850 burn beds in 126 burn units across the United States. The American Burn Association estimates that 700 to 800 of these beds may be occupied at any given time. To respond to a mass casualty incident such as a nuclear detonation—in which HHS estimates the number of individuals requiring specialized burn care could be over 10,000—burn patients would need to be transferred to specialized burn centers throughout the country because there may be relatively few dedicated burn beds available in the region. In addition, patients may need to be treated in other care sites, such as trauma centers, if specialized burn centers are filled to capacity.

Federal Roles and Responsibilities Related to Medical Countermeasures

In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a federal interagency body responsible for providing recommendations to the Secretary of HHS on medical countermeasure priorities, development and acquisition activities, and strategies for distributing and using medical countermeasures held in the SNS.⁹ PHEMCE's working groups and senior council serve as the primary means of communication between HHS and participating federal departments on medical countermeasure issues. As required by the Pandemic and All-Hazards Preparedness Act of 2006, PHEMCE also conducts annual reviews of the contents of the SNS.¹⁰

Within HHS, several agencies and offices have specific responsibilities for medical countermeasure development and acquisition.

⁹PHEMCE is composed of officials from several HHS offices and agencies that have specific responsibilities for countermeasure development and acquisition. PHEMCE also includes officials from other federal departments and offices, including officials from the Departments of Agriculture, Defense, Homeland Security, and Veterans Affairs. See GAO, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*, [GAO-12-121](#) (Washington, D.C.: Oct. 26, 2011).

¹⁰PHEMCE conducts these reviews on behalf of the HHS Secretary. 42 U.S.C. § 247d-6b(a)(1).

- ASPR leads PHEMCE and the medical and public health response to potential mass casualty incidents, including strategic planning, medical countermeasure prioritization, and support for developing and acquiring medical countermeasures.
- Within ASPR, BARDA—established by the Pandemic and All-Hazards Preparedness Act—oversees advanced development and acquisition of some medical countermeasures into the SNS.¹¹
- NIH’s NIAID leads the agency’s CBRN countermeasure programs and, as such, conducts and funds basic and applied research needed to develop new or enhanced medical countermeasures and related medical tools to protect the nation against threats posed by CBRN agents.
- CDC maintains the SNS and supports state and local public health departments’ efforts to detect and respond to public health emergencies, including providing guidance and recommendations for the mass distribution and use of medical countermeasures from the SNS.
- FDA assesses the safety and effectiveness of medical countermeasures and regulates their development, approval or licensure, and postmarket surveillance as part of its overall role to assess the safety and effectiveness of medical products.¹² FDA also provides technical support for the creation of tools to support medical countermeasure development and may authorize the emergency use of medical products that have not yet been approved or licensed or were approved or licensed only for other uses.

Medical Countermeasure Research, Development, Acquisition, and Support

HHS’s and PHEMCE’s medical countermeasure acquisition strategy is based on a multistep process that includes assessing the threat and public health consequences of CBRN agents, determining the type and quantity of needed medical countermeasures, evaluating the public health response capability, and developing and acquiring countermeasures for the SNS. The Project BioShield Act requires HHS to assess the public health consequences of exposure to CBRN agents that the Department of Homeland Security (DHS) determines are material threats to the nation¹³ and to determine for which of these agents medical countermeasures are

¹¹42 U.S.C. § 247d-7e(c). The act also gave BARDA the authority to make advance and milestone-based payments to vendors prior to product delivery to the SNS. 42 U.S.C. § 247d-7e(c)(5)(C), (D).

¹²Under federal law and FDA regulations, vaccines and other biologics are “licensed,” drugs are “approved,” and devices may either be “approved” or “cleared.” See 42 U.S.C. § 262, 21 U.S.C. § 355, 21 U.S.C. §§ 360e, 360(k).

¹³As part of its responsibilities under the Project BioShield Act, DHS develops material threat assessments to assess the threat posed by given CBRN agents or classes of agents and the potential number of human exposures in plausible, high-consequence scenarios. DHS uses the material threat assessments to determine which CBRN agents pose a material threat sufficient to affect national security. See GAO, *National Preparedness: DHS and HHS Can Further Strengthen Coordination for Chemical, Biological, Radiological, and Nuclear Risk Assessments*, [GAO-11-606](#) (Washington, D.C.: June 21, 2011).

necessary to protect the public's health.¹⁴ HHS's public health consequence modeling reports use the exposure information from DHS's material threat assessments to calculate the number of individuals who may become ill, be hospitalized, or die based on a specific scenario or set of scenarios. HHS then evaluates the public health response capability based in part on the availability of desired medical countermeasures. Because desired medical countermeasures may not be developed to a point where they are available for acquisition, NIH and BARDA oversee and support countermeasure research and development, which is conducted in several stages: (1) basic research, (2) applied research, (3) early development,¹⁵ and (4) advanced development.¹⁶ (See fig. 1.) NIH and NIAID typically provide federal funding for basic and applied research and early development. BARDA typically funds advanced development of medical countermeasures. If a medical countermeasure is not FDA approved or licensed,¹⁷ its acquisition into the SNS is typically funded by the Project BioShield Special Reserve Fund.¹⁸ If a countermeasure is FDA approved or licensed, CDC may purchase the countermeasure for the SNS.

¹⁴42 U.S.C. § 247d-6b(c)(2)(B).

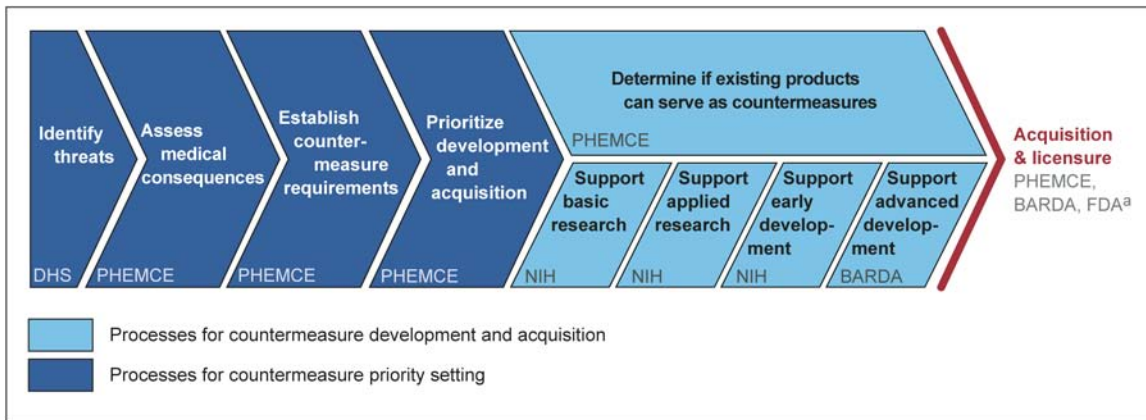
¹⁵This early, or basic, research seeks to better understand the effects of illness and injury sustained from CBRN incidents and the response of the host organism to illness and injury through the study of the cellular and molecular biology and physiologic processes. Applied, or translational, research builds on basic research by validating and testing concepts in practical settings to identify potential products. Successful concepts move from the applied research stage into the early development stage, in order to demonstrate basic safety, reproducibility, and ability to be used in humans.

¹⁶In the advanced development stage, potential medical countermeasures are further evaluated to demonstrate safety and effectiveness for preventing, diagnosing, or treating disease. Successful products are then available for development and acquisition. In addition, BARDA determines whether manufacturing, scale-up production, and licensing of countermeasures can be achieved in a timely and reliable manner.

¹⁷In addition to approving or licensing medical countermeasures, FDA works with researchers throughout the development stages to review safety and effectiveness test results and provide technical assistance to help ensure that research meets FDA's regulatory requirements.

¹⁸The Project BioShield Act provides that the Special Reserve Fund may be used to acquire countermeasures for which the HHS Secretary determines the scientific research supports a reasonable conclusion that the product will qualify for FDA approval or licensing within 8 years. 42 U.S.C. § 247d-6b(c)(1)(B)(i)(III)(bb).

Figure 1: Processes for Medical Countermeasure Development and Acquisition



Source: GAO analysis of HHS information.

³In addition to approving or licensing medical countermeasures, FDA works with researchers throughout the development stages to review safety and effectiveness test results and provide technical assistance to help ensure that research meets FDA's regulatory requirements.

The SNS Contains Supportive Care Items for the Immediate Treatment of Thermal Burns, Such as Bandages and Pain Medications

The thermal burn countermeasures in the SNS include supportive care items for thermal burns compiled in kits that include sterile bandages and dressings, pain medications, intravenous fluids, and topical antimicrobial cream needed for the immediate treatment of burn injuries to reduce the risk of infection and stabilize injured individuals. According to HHS officials, the goal of the SNS is to supplement state and local supplies used for immediate care in the initial response—within 72 hours of sustaining injury. In addition to the items needed specifically for burns, CDC officials told us that the SNS contains certain multiuse products that could be helpful for treating patients with thermal burns. For example, the SNS contains airway management supplies such as ventilators and intubation supplies, as well as ancillary supplies for this equipment, which would be needed for individuals with compromised airways.¹⁹ Most of the thermal burn countermeasures in the SNS were initially acquired in 2002 and 2003. HHS officials told us that CDC acquired the supplies for the burn kits after consulting with burn clinicians about needed products. For example, officials from burn centers as well as the American Burn Association provided CDC with a list of recommended products for the immediate treatment of burns, which included topical antimicrobial creams and other supplies to prevent infection and stabilize individuals. CDC officials told us that most medical countermeasures for immediate treatment of thermal burns can typically be found in local hospitals and community medical care sites. Therefore, in an incident requiring thermal burn care, countermeasures in the SNS could be used to supplement local supplies and inventories. According to CDC officials, the thermal burn countermeasure kits can be deployed to an affected area within 24 to 48 hours of notification.

¹⁹According to CDC officials, the thermal burn countermeasures are for treating heat-related injuries regardless of heat source and may be of some use in treating radiation or chemical injuries. Airway management and ancillary supplies may also be used in treating the health effects of exposure to other CBRN agents and infectious diseases, such as pandemic influenza, and in treating injuries other than burns.

The SNS does not contain other countermeasures that may be available for thermal burns, but HHS is currently considering whether to acquire additional countermeasures for immediate and longer-term burn care. In September 2010, HHS established the PHEMCE Thermal Burns Product Coordination Team, which is specifically responsible for assessing available medical countermeasures for the treatment of thermal burns that might be sustained during a nuclear detonation. According to HHS officials, this coordination team has discussed the possibility of acquiring additional products and supplies for both the immediate care and the longer-term treatment of burn injuries. As part of this process, in October 2011, HHS completed an analysis of the number and types of thermal burns that would potentially be sustained in a nuclear detonation and the resources and capabilities needed to care for injured individuals. HHS officials told us that this analysis provided HHS and PHEMCE with an estimate of the demand for thermal burn products and helped identify what may currently be available in the market to close any gaps in available supplies. The analysis also included HHS's requirements for needed types and quantities of additional thermal burn countermeasures. Although HHS has not yet made any decisions about whether to add specific products to the SNS, burn clinicians and burn experts told us that countermeasures that ideally should be in the SNS for immediate care of burns within the 72-hour window after injury include supplies such as silver-impregnated antimicrobial barrier bandages and dressings, topical antimicrobial creams, intravenous fluids, and pain medications. Some burn clinicians and experts indicated that silver-impregnated antimicrobial barrier bandages and dressings, which are not currently in the SNS, could be useful for stabilizing patients until they could be transported to a burn center, where specialized personnel could care for them. Clinicians and experts told us that these products, which are available from several different manufacturers, may be beneficial since the dressings may not need to be changed for several days, can be stored at room temperature, and require less specialized skill to apply than topical antimicrobial creams. This could be helpful in a mass casualty incident in which immediate access to burn clinicians may be limited. Local and state government disaster management officials agreed that countermeasures needed in the SNS for the immediate care of thermal burn injuries would include topical antimicrobial creams, silver-impregnated antimicrobial barrier dressings, and other supplies that would allow first responders to conduct burn first aid and stabilize patients until they could be treated in a burn center.

The SNS also does not contain, and HHS is not currently stockpiling, countermeasures for longer-term care, such as artificial skin and other skin therapies. Burn clinicians and experts we spoke with were uncertain about the benefit of stockpiling products for longer-term care in the SNS for several reasons. First, burn clinicians and experts emphasized that even if there were existing stockpiles of skin products and available burn beds, the availability of clinicians with the appropriate expertise to administer these therapies would be the limiting factor, because artificial skin or skin substitutes require application by skilled burn surgeons. Second, burn clinicians and CDC officials told us that biological products such as artificial skin have very short shelf lives. For example, some artificial skin products have a shelf life of 18 to 24 months. CDC officials pointed out that if HHS stockpiles more of these products than are used in the United States on a routine basis, HHS may need to dispose of expired and unused excess quantities. Third,

burn clinicians and experts also told us that products for longer-term care, such as artificial skin and skin therapy products, must be kept refrigerated at very low temperatures. This storage need may also complicate the transport of these products to care sites.

HHS Met with Experts and Industry Representatives and Issued Notices of Interest to Solicit Information about Thermal Burn Countermeasures

HHS has taken several steps to obtain information about thermal burn countermeasures, which also signaled to industry its interest in these products. To obtain information about existing and needed countermeasures for thermal burns, HHS and the PHEMCE thermal burns coordination team that was established in September 2010 conducted outreach to potential end users of these products, including physicians, burn experts, and first responders. For example, HHS officials conducted interviews with representatives from the American Burn Association, clinicians at local and regional burn centers, and Department of Defense burn researchers and experts. HHS and PHEMCE participants visited burn centers and attended meetings with burn experts. HHS also conducted interviews with industry representatives to obtain information about potential products in development.

HHS has issued several notices to solicit information from industry about thermal burn countermeasures,²⁰ which also informed industry about HHS's interest in additional thermal burn countermeasures.

- In December 2010, BARDA issued a request for information (RFI) for thermal burn countermeasures to solicit information from manufacturers about the types of products that may be in development or available to treat thermal burns resulting from a mass casualty nuclear detonation.²¹ The RFI also sought information on the degree to which potential products would require specialized expertise or specialized resources, the capability of manufacturers to “surge” production—or increase their usual rates of production and supply—and alternate strategies for stockpiling potential products.
- In August 2011, BARDA issued a “sources sought” notice for information on thermal burn countermeasures for a mass casualty nuclear detonation incident.²² The sources sought notice expanded on the previous RFI to solicit additional

²⁰In addition to the notices specifically for thermal burn countermeasures, in March 2011, HHS also renewed its 2009 Broad Agency Announcement soliciting advanced research and development for the range of medical countermeasures for CBRN agents that PHEMCE is interested in acquiring. According to HHS, proposals for the development of thermal burn countermeasures are within the scope of the Broad Agency Announcement.

²¹An RFI may be issued when an agency requires technical, scientific, or business information, or a combination of these, and input from the marketplace for project planning purposes regarding the availability of existing or potential solutions. The notice and the information received are not to be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. 48 C.F.R. § 315.201.

²²The primary purpose of a sources sought notice is to identify all potential sources, regardless of organizational type and size classification, and determine their capabilities to fulfill a potential government requirement. Like an RFI, the notice and the information received are not to be used to determine how well respondents can perform a requirement, which can only be evaluated in response to a solicitation. 48 C.F.R. § 305.205.

detail about products that could be used by first responders in the field for immediate care and for products that could be used by clinicians in medical settings for longer-term burn care. Desired products for immediate care include bandages with antimicrobial barriers that could be used for several days without needing to be changed and other bandages or dressings that would require minimal changing. Desired products for longer-term care include temporary skin substitutes and products that use an individual's own skin cells to form skin substitutes or replacements. HHS officials told us that because the department did not limit the notices to either immediate or long-term care products, it received information on a mix of products, some of which reflect advances in products since the burn kits in the SNS were assembled. For example, the SNS contains silver-based antimicrobial cream that must be applied to burns, covered with a bandage, and reapplied at least once every 24 hours; newer products include bandages impregnated with antimicrobial silver that only require applying the bandage and can be changed less frequently.

HHS officials told us that consistent with the FAR, HHS has also discussed its interest in thermal burn countermeasures through e-mail, telephone, and in-person discussions with industry representatives and at the department's regional medical countermeasure meetings. HHS officials told us that once the department posted the thermal burns RFI, HHS held a number of technology meetings and had telephone and e-mail conversations with industry representatives. In addition, in January, June, and October 2011, BARDA held regional "industry days" for countermeasure manufacturers during which HHS officials discussed the department's interest in thermal burn countermeasures. According to HHS officials, the technology meetings and regional meetings allowed HHS to obtain additional information from industry about potential thermal burn countermeasures in development.

Some Medical Countermeasures in Development Could Address Thermal Burns

NIH has some medical countermeasures in the development and acquisition pipeline that could address thermal burns. NIAID, the institute at NIH that coordinates CBRN countermeasure research and development for injuries caused by radiation exposure combined with other injuries such as thermal burns, informed us that the countermeasures for thermal burns in the pipeline include topical creams and antibiotics, such as a topical formula using amino acid peptides. In addition, NIAID is funding basic research to determine how burns and radiation-related injuries affect skin and other tissue on a molecular level.²³

Within NIAID, medical countermeasures that could address thermal burns are a secondary focus of most of its research, according to officials. NIAID's research primarily concentrates on radiation injury combined with burns and other injuries. In addition, NIAID officials told us that the research on these combined radiation and thermal burn injuries and potential countermeasure candidates is still in the early

²³According to NIH officials, as part of its CBRN countermeasure work, NIAID routinely works with NIH's National Cancer Institute to determine whether its countermeasure research may be applicable to radiation-induced injuries.

stages. Therefore, NIAID officials did not provide us with an estimate of how long it could take HHS to acquire any of these candidate countermeasures, if successful, for the SNS.²⁴

In addition to the research being funded by NIAID, other NIH institutes are also funding burn research. For example, NIH's National Institute of General Medical Sciences funds academic research centers and training programs in trauma, burn, and wound healing. This institute is currently funding research on potential burn care treatments, which may be helpful in developing future countermeasures for thermal burns. For example, one research study is examining the effects of certain white blood cells in burn healing, burn excision, and skin grafting for the purposes of potentially developing therapeutics for burn patients. According to HHS officials, NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases is also funding research on such treatment.

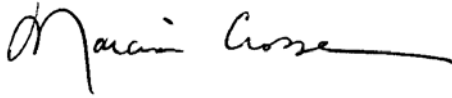
Agency Comments

We provided a draft of this report to HHS, and its comments are reprinted in enclosure II. In its comments, HHS stated that the report provides a fair and balanced presentation of HHS's efforts to prepare for a mass casualty incident that could result in a large number of individuals with thermal burns. HHS discussed its thermal burn countermeasure development and acquisition activities, including stockpiling supportive care products for the immediate treatment of thermal burns and exploring the development of new and improved products for longer-term burn care. HHS also described other BARDA and PHEMCE activities beyond countermeasure development and acquisition that could help the department respond to a mass casualty incident, such as the National Disaster Medical System's detailed roster of available personnel who could support state and local authorities' medical response efforts. In addition, HHS provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of HHS and interested congressional committees. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

²⁴The federal government faces a variety of challenges in developing and acquiring medical countermeasures. One scientific challenge is that as with other medical products, the failure rate for development of certain CBRN medical countermeasures can be higher than 80 percent for those drugs, vaccines, and diagnostic devices in the early development stage, with an increasing probability of success as the product moves further through development. In addition, HHS estimates that the period from scientific discovery to product licensure or approval of successful countermeasures can be as long as 20 years. See GAO, *Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents*, [GAO-11-567T](#) (Washington, D.C.: Apr. 13, 2011).

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in enclosure III.

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal flourish at the end.

Marcia Crosse
Director, Health Care

Enclosures – 3

Abbreviations

ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
RFI	request for information
SNS	Strategic National Stockpile

Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

JAN 24 2012

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft correspondence entitled, "NATIONAL PREPAREDNESS: Countermeasures for Thermal Burns" (GAO-12-304R).

The Department appreciates the opportunity to review this correspondence prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "NATIONAL PREPAREDNESS: COUNTERMEASURES FOR THERMAL BURNS" (GAO-12-304R)

The Department appreciates the opportunity to review and comment on this draft correspondence. We welcome GAO's balanced presentation of our efforts to prepare for mass casualty events that could result in a large number of patients with thermal burns. HHS has stockpiled a number of supportive care products for the immediate treatment of thermal burns and is exploring the development of new and improved products that would enhance the definitive care of burn patients in a mass casualty setting.

HHS takes its responsibility to prepare for rare but catastrophic events such as the detonation of an improvised nuclear device with the utmost seriousness. Tragic events such as the anthrax attacks of 2001 and the H1N1 influenza pandemic of 2009 underscore the reality that our nation remains vulnerable to deliberate chemical, biological, radiological, and nuclear (CBRN) threats as well as pandemic and other emerging infectious diseases. The Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 established the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services and designated the Secretary as the lead official responsible for all federal public health and medical response to public health emergencies and incidents covered by the National Response Framework, an authority that has been delegated to the Assistant Secretary. Within ASPR, the Biomedical Advanced Research and Development Authority (BARDA) manages Project BioShield, which supports the development and procurement of medical countermeasures against CBRN threat agents.

BARDA is committed to creating a robust and dynamic pipeline of medical countermeasures that address the threats we face and is currently supporting more than 100 candidate countermeasures across a variety of threats. Since March 2009, BARDA has had an open Broad Agency Announcement (BAA) seeking proposals from industry for the advanced development of potential candidates for medical countermeasures against CBRN threats. This mechanism provides the means through which BARDA would support companies proposing to develop improved thermal burn countermeasures. As detailed in GAO's correspondence report, BARDA has engaged in significant outreach activities to understand the current state of the art in burn care and needs of treating clinicians. Simultaneously, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has performed modeling and other analysis to develop Scenario-Based and Product Specific Requirements documents. BARDA program managers regard the extensive outreach and analysis performed to understand these needs and requirements as a new benchmark against which future efforts to define requirements should be measured.

Complex scientific, financial, and marketplace challenges characterize our efforts to develop and procure needed medical countermeasures for all threats, including thermal burns. To address these challenges, Secretary Sebelius requested a review of the medical countermeasures enterprise in December 2009. In August 2010, HHS released the *Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to meet Long-Range National Needs* (MCM Review). The MCM Review focused on "processes, policies, and infrastructure required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling" and made recommendations and proposed initiatives to reduce risk and

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accelerate this process. The PHEMCE is now in a period of transformation, and it is within this context that the evaluation of our thermal burn requirements has occurred.

Lastly, as mentioned in the GAO Correspondence report, federal agencies supplement State and local capabilities during public health incidents. During a public health emergency, HHS follows the authorities of "Emergency Support Function #8 – Public Health Services Annex" which "provides the mechanism for coordinated Federal assistance to supplement State, tribal, and local resources in response to a public health and medical disaster, potential or actual incidents requiring a coordinated Federal response, and/or during a developing potential health and medical emergency." It is important to underscore that if a public health emergency that resulted in a large number of thermal burn patients were to occur, a wide array of Federal assets would augment state and local capabilities as needed. Modest supplies of medical countermeasures for the immediate treatment of thermal burns are maintained at local hospitals and community medical care sites and it seems likely that the majority of burn casualties would present for care at such facilities, quickly overwhelming State and local capabilities. The National Disaster Medical System (NDMS) is a federally coordinated system that augments the Nation's medical response capability. The overall purpose of NDMS is to provide an integrated National medical response capability that can support State and local authorities dealing with the medical impacts of public health emergencies. NDMS maintains a detailed roster of available personnel, including burn care specialists, who can be called upon in emergencies and as circumstances warrant.

HHS has made significant investments in medical countermeasure research, development, acquisition, and procurement to better prepare the nation against a wide array of CBRN, pandemic and other emerging infectious disease threats. HHS is committed to ensuring the nation is prepared for these threats, and it is in the light of this commitment that we have investigated and will pursue the development of improved thermal burn countermeasures. We thank GAO for its interest in our thermal burns program and for the fair and balanced presentation of our efforts to date.

Enclosure III

GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, key contributors to this report were: Sheila K. Avruch, Assistant Director; Shana R. Deitch; Tracey King; Carolina M. Morgan; Roseanne Price; and Jessica C. Smith.

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