U.S. Department of Health and Human Services
Public Health Emergency Medical Countermeasures Enterprise
Biomedical Advanced Research And Development Authority (BARDA)

DRAFT BARDA STRATEGIC PLAN for Medical Countermeasure Research, Development, and Procurement

INTRODUCTION

On December 19, 2006, President George W. Bush signed into law the Pandemic and All-Hazards Preparedness Act (Public Law 109-417), referred to as PAHPA.[1] Title IV of PAHPA established the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) to facilitate the research, development, and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases, including pandemic influenza.[2] BARDA establishes systems that encourage and facilitate the development and acquisition of medical countermeasures such as vaccines, therapeutics, and diagnostics, as well as innovative approaches to meet the threat of CBRN agents and emerging infectious diseases, including pandemic influenza, in support of the mission and priorities of the HHS Public Health Emergency Medical Countermeasures Enterprise[3] (HHS PHEMCE).

BARDA has worked with HHS partners to create this *Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement* (*Draft BARDA Strategic Plan*) to guide and facilitate research, development, innovation, and procurement of medical countermeasures, in fulfillment of Section 401(b) of PAHPA. ASPR is in the midst of a search process for a BARDA Director. This *Draft BARDA Strategic Plan* represents current thinking within BARDA. A *Final BARDA Strategic Plan* will be updated, finalized, and made public after the appointment of the BARDA Director.

[1] Available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ417.109.pdf

[2] Medical countermeasures for which this document discusses BARDA's strategy for promoting development include those drugs, biological products, and devices that meet the definitions of *qualified countermeasure* and *qualified pandemic or epidemic product* found in sections 319F-1 and 391F-3 of the Public Health Service Act. See 42 USC § 247d-7e.

[3] *Federal Register*, Vol. 71, No. 129, Thursday, July 6, 2006, Notices. The HHS Public Health Emergency Medical Countermeasures Enterprise leads the mission to develop and acquire medical countermeasures that will improve public health emergency preparedness as well as prevent and mitigate the adverse health consequences associated with chemical, biological, radiological, and nuclear threats and emerging infectious diseases, including pandemic influenza. HHS PHEMCE is a coordinated, intra-agency effort led by the Assistant Secretary for Preparedness and Response and includes three HHS internal agencies: the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health. Additionally, HHS PHEMCE collaborates with its *ex officio* members: the Department of Defense, the Department of Homeland Security, the Department of Veterans Affairs, and other interagency stakeholders as appropriate.

In April 2007, HHS announced intentions to establish BARDA under the Office of the Assistant Secretary for Preparedness and Response (ASPR) to encourage, facilitate, and streamline the development and acquisition of medical countermeasures.[4] The BARDA office is intended to incorporate all of the programs, mission responsibilities, and organizational functions previously managed by the HHS Office of Public Health Emergency Medical Countermeasures (OPHEMC), primary of which is the coordination, support, and execution of the goals and objectives of the HHS PHEMCE and the medical countermeasure goals of the *HHS Pandemic Influenza Plan*[5]. BARDA will work with other Federal Departments and agencies in the preparation and implementation of plans to manage and transport medical countermeasures and associated materials to and from manufacturers to designated sites, including the Strategic National Stockpile (SNS) and States, as appropriate, to support delivery platforms for the efficient deployment and utilization of medical countermeasures.

ASPR leads the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. Acting under the leadership of the ASPR, BARDA is the focal point for the advanced development and acquisition of medical countermeasures for CBRN threats and emerging infectious diseases, including pandemic influenza, for the U.S. civilian population. BARDA will work with industry, academia, public health organizations, other government agencies, and stakeholders to foster innovation and promote strategic initiatives, such as the development of rapid diagnostics, broad spectrum antimicrobials, and next-generation vaccine manufacturing technologies. Using its advanced research and development authority, BARDA will strengthen HHS efforts to bridge the *valley of death*[6] funding gap that exists between the early stages of product development and the acquisition of approved or approvable medical countermeasures for the SNS.[7] As a result, BARDA aims to enhance the availability of medical countermeasures to address public health emergencies arising from CBRN threats or pandemic and epidemic diseases.

STRATEGIC GOALS

The *Draft BARDA Strategic Plan* is built upon the framework established in national strategies for CBRN and pandemic influenza medical countermeasures, specifically the *National Strategy for Pandemic Influenza*[8] and the National Strategy for *Medical Countermeasures against Weapons of Mass Destruction* (Homeland Security Presidential Directive-18)[9]. BARDA has four specific goals:

Goal 1. BARDA will align with and coordinate the execution of the medical countermeasure goals articulated in the *HHS Pandemic Influenza Plan*.

[4] Announcement available at www.hhs.gov/news/press/2007pres/04/pr20070426d.html
[5] Available at www.hhs.gov/pandemicflu/plan/
[6] HHS testimony before the House Homeland Security Committee, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, April 18, 2007.
[7] For purposes of this document, the term *approval* includes approval or clearance under sections 505, 510(k), and 515 of the Federal Food, Drug, and Cosmetic Act and licensure under section 351 of the Public Health Service Act.
[8] Available at www.whitehouse.gov/homeland/pandemic-influenza.html
[9] Available at www.whitehouse.gov/news/releases/2007/02/20070207-2.html

Goal 2. BARDA will align with and coordinate the execution of the medical countermeasure goals articulated in the *HHS Public Health Emergency Medical Countermeasures Enterprise Strategy for Chemical, Biological, Radiological and Nuclear Threats* (*HHS PHEMCE Strategy for CBRN Threats*).[10]

Goal 3. BARDA, in concert with federal partners, will create a road map for execution of the *HHS Public Health Emergency Medical Countermeasures Enterprise Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats* (*HHS PHEMCE Implementation Plan*).[11]

Goal 4. BARDA, in concert with federal partners, will establish programs that promote innovation in medical countermeasure development.

As described specifically in the *HHS PHEMCE Implementation Plan* and the *HHS Pandemic Influenza Plan*, the United States Government (USG) has prioritized medical countermeasure research, development, and procurement programs. Such prioritization is critical because the development and acquisition of medical countermeasures for all potential threats to the U.S. civilian population would far exceed available resources. The overall goal is to provide the USG with an increased level of public health emergency preparedness to respond to a wide range of potential challenges, including traditional as well as novel agents that are highly communicable, associated with a high rate of morbidity or mortality, and/or without known medical countermeasure.

To implement this *Draft BARDA Strategic Plan*, BARDA will employ proven and successful approaches for the advanced development of medical countermeasures, an example of which is the HHS Pandemic Influenza Medical Countermeasures Program that supports the advanced development of multiple medical countermeasure candidates in order to reduce risk, maximize the odds of success, and inform sound acquisition decisions. Specifically, the HHS Pandemic Influenza Medical Countermeasures Program utilizes milestone-driven contracts and incremental funding to support multiple medical countermeasure candidates in the advanced stages of product development. As products near Food and Drug Administration (FDA) approval, increased consideration for their inclusion into national pandemic stockpiles stimulates competitive pricing and further development of new and better pandemic products by these and other manufacturers. Funding incentives for influenza vaccine manufacturing facility design, construction, and validation also stimulate product development and serve to expand domestic vaccine manufacturing surge capacity. BARDA awards contracts and provides technical guidance to manufacturers on the development of pandemic influenza medical countermeasures. The HHS Pandemic Influenza Medical Countermeasures Program's multi-pronged portfolio approach stimulates competitive product development, enables flexible and sound product acquisition decisions, and mitigates risk.

[10] Available at www.hhs.gov/aspr/ophemc/enterprise/strategy/strategy.html
[11] Available at www.hhs.gov/aspr/ophemc/enterprise/strategy/phemceimplementationplan.pdf

ENHANCING MEDICAL COUNTERMEASURE PRODUCTION

BARDA was established to provide funding and coordination to address challenges in medical countermeasure development. For CBRN threats, for example, the medical countermeasures required to address the highest priority threats are generally not supported by a commercial market. Large pharmaceutical firms and small biotechnology companies, whose product development strategies are driven by market forces, are reluctant to develop medical countermeasures for which there is no clearly-defined, robust, sustainable, commercial market. In many cases, the anticipated rate of return on development of a new medical countermeasure for a specific threat may not justify the required resource allocations. BARDA was created to enhance incentives - in conjunction with Project BioShield Act[12] authorities - to industry by providing greater government transparency. Furthermore, BARDA was created to increase funding for advanced research and development and to better coordinate the USG medical countermeasure development and acquisition process.

In addition to supporting novel product development, BARDA also may support evaluation and licensure of existing medical countermeasures that were developed originally by the private sector for commercial indications. These medical countermeasures also may have utility for addressing other CBRN threats and emerging infectious diseases. One such example is ciprofloxacin, which is available commercially for the treatment of clinical bacterial infections, and which is now also a significant component of the USG arsenal for treating anthrax.

BARDA will facilitate and support the advanced development of new or modernized medical countermeasures for pandemic influenza as well as the FDA review of the products for potential approval. Such pandemic influenza countermeasures may be produced by existing commercial industry. Further, BARDA will support the expansion of the domestic vaccine manufacturing infrastructure to support new seasonal influenza vaccines, national pre-pandemic influenza vaccine stockpiles, and pandemic influenza vaccines, where an expansion of domestic manufacturing surge capacity is desired to provide sufficient quantities of products in a timely manner to ameliorate the morbidity and mortality associated with worst case scenarios of an influenza pandemic.

THE MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT PATH: TECHNOLOGY READINESS LEVELS AND FUNDING SOURCES

The development path for biomedical products begins with a comprehensive and robust basic research effort that discovers and characterizes scientific concepts. These concepts can be exploited by trial and error as the basis for medical intervention. While there are several conventions for characterizing the various stages of the product development pathway once a candidate product has been identified, the path can be described as including four generic stages:[13]

[12] Project BioShield Act of 2004 (Public Law 108-276) available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf

[13] The specific activities described under each stage of development are most representative of the development of pharmaceuticals. Development activities may differ for devices, including diagnostics.

- **Early-Stage Product Development**
  Optimization; pre-clinical evaluation; animal model development; Phase 1 clinical trial (safety and pharmacology); manufacturing process development; formulation; and stability.

- **Mid-Stage Product Development**
  Advanced non-clinical toxicology; manufacturing process scale-up; advanced formulation and stability programs; animal model testing; and Phase 2 clinical trial (dose range and expanded safety, efficacy).

- **Late-Stage Product Development**
  Validation of the manufacturing process (e.g., consistency lot manufacturing) and all assays; Phase 3 clinical human safety studies; and Phase 3 clinical human efficacy studies that may be replaced by animal efficacy studies, provided applicable regulatory criteria are met.[14]

- **Licensure and Commercialization**
  Regulatory review and approval; marketing; post-marketing surveillance; and Phase 4 clinical evaluation.

As demonstrated in Figure 1, these generic stages overlap. Progress from one stage to the next is usually not represented by a sharp demarcation; rather, multiple activities occur in parallel. Attrition of products as they progress through evaluation and development is high; and maintaining a viable pipeline requires numerous candidate products entering early-stage development. The absolute number of products expected to reach late-stage development is small, whereas the costs of late-stage development are high. According to the FDA, the costs of bringing a new medicine to market have been estimated to be $800 million to $1.7 billion.[15]

To communicate and coordinate effectively and to increase transparency for stakeholders about medical countermeasure development activities, BARDA will promote and employ a detailed, rigorous, criteria-based nomenclature to identify stages of product development and the potential USG funding sources that are available at various stages. Through an interagency process, the HHS PHEMCE is developing Technology Readiness Level (TRL) criteria to describe the progression of medical countermeasures through the research and development pipeline as well as to delineate the milestones that are well-recognized by regulatory agencies and industry.[16] Each TRL level encompasses a diverse set of activities, from efficacy studies to manufacturing and regulatory milestones, which often occur in parallel and in coordination with multiple

[14] Food and Drug Administration. *Approval of Biological Products when Human Efficacy Studies are not Ethical or Feasible* (21 CFR 601 Subpart H and 21 CFR 314 Subpart I for New Drugs). This rule, known simply as the *Animal Rule*, was designed to permit approval or licensing of drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions caused by exposure to biological, chemical, radiological, or nuclear substances. This rule amends the new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products only when human efficacy studies are not ethical and field trials are not feasible. Available at www.fda.gov/cber/rules/humeffic.htm

[15] Food and Drug Administration. *Challenge and Opportunity on the Critical Path to New Medical Products*, March 2004. Available at www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

[16] The preliminary Technology Readiness Level criteria are available at www.hhs.gov/aspr/ophemc/barda/trl.html

stakeholders. As shown in Figure 1, the earliest TRL stages include basic research activities; subsequent levels progress through advanced development to the approval of safe and effective medical countermeasures.

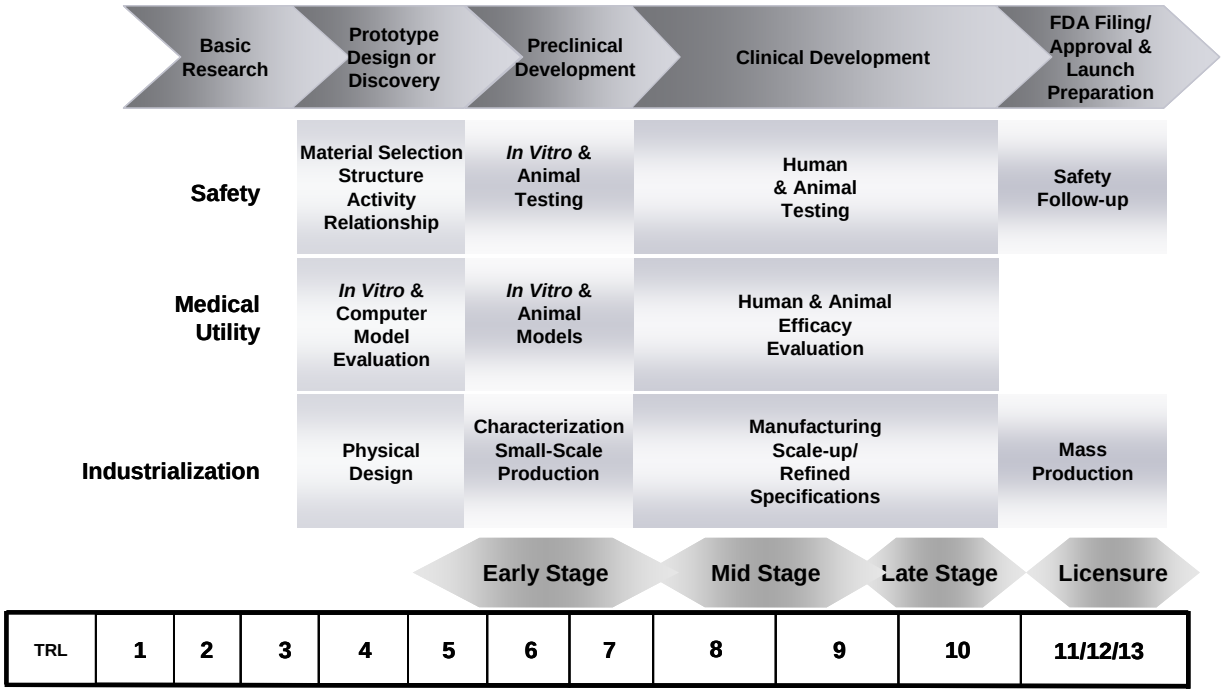

Figure 1. Product Development Path for Medical Countermeasures. This figure demonstrates the approximate juxtapositions of various conventions used to describe the product development pathway. BARDA will use the Technology Readiness Level (TRL) system. Figure adapted from *Challenge and Opportunity on the Critical Path to New Medical Products.*[17]

The current TRLs are in draft form; and four preliminary sets of TRLs have been released – one each for chemical, biological, and radiological/nuclear medical countermeasures (primarily focused on pharmaceuticals) and one for diagnostic devices. A TRL for medical countermeasure product development tools (PDTs) is under development. The HHS PHEMCE will continue to revise these TRLs and consider whether additional TRLs may be needed to accurately describe the development cycle for the diverse products that may be eligible for BARDA funding.

A candidate medical countermeasure's progression through the stages of development will include milestone decision reviews. Developers must successfully achieve milestones before moving to the next decision review. BARDA, working through the HHS PHEMCE, will use TRLs to identify the development pipeline milestones at which products are eligible to be transitioned to new funding mechanisms. The approximate correlations among TRLs and

[17] Food and Drug Administration. *Challenge and Opportunity on the Critical Path to New Medical Products,* March 2004. Available at www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

potential funding sources are displayed in Figure 2. The funding mechanism utilized at each TRL is determined on a case-by-case basis, due in part to significant investment differentials across the CBRN threat spectrum. If sufficient resources are available, BARDA will fund top priority medical countermeasure development programs where funding from other sources is unavailable or insufficient.

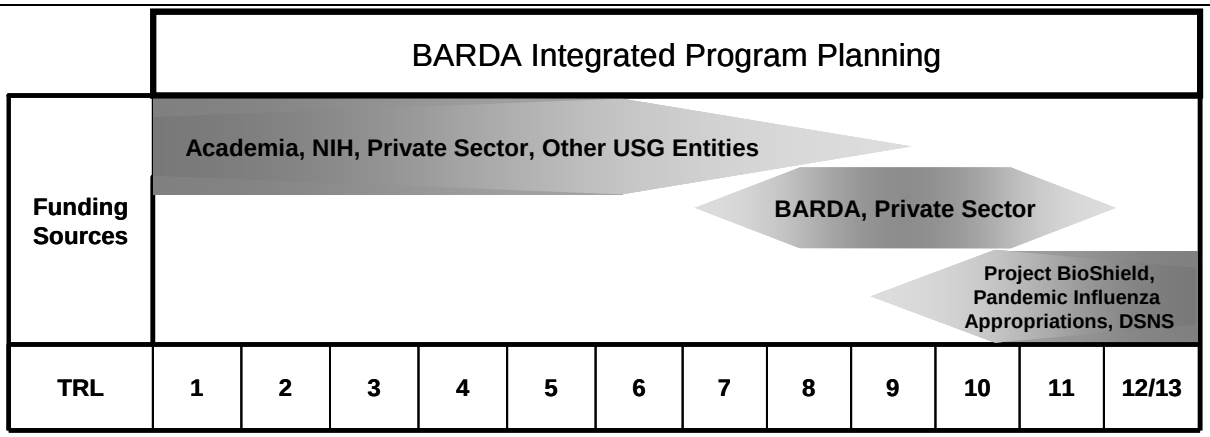

Figure 2. Potential Funding Sources for Medical Countermeasure Product Development (for the U.S. civilian population) at Various Technology Readiness Levels (TRL). Once the HHS PHEMCE recognizes the need to acquire a particular medical countermeasure for the U.S. civilian population, BARDA supports integrated planning across the product development pipeline for top priority medical countermeasures in partnership with USG and private sector stakeholders, as appropriate. Medical countermeasure products of potential utility in civilian public health preparedness may also be developed elsewhere for other demands. Whenever feasible and appropriate, BARDA will procure these medical countermeasures for addition to the Strategic National Stockpile.
Notes: *NIH* is the acronym for the National Institutes of Health. *DSNS* is the acronym for the Centers for Disease Control and Prevention Division of Strategic National Stockpile.

Basic Research and Development[18] *(Approximately TRL 1 through TRL 8)*

The development of medical countermeasures begins with a comprehensive and robust basic research effort that characterizes the course of disease following exposure to a particular threat agent, along with the evaluation of candidate medical countermeasures using *in vitro* and *in vivo* assays. These initial efforts lead to the identification of products or platforms that could be used to address specific medical and public health needs. Within the USG, research and development activities at these levels are funded largely through initiatives at the National Institutes of Health (NIH) and the Department of Defense (DOD). Once potential candidate medical countermeasures have been identified from basic research and development activities, they must proceed through the early stages of product development, which may include pre-clinical evaluation, Phase 1 clinical safety trials, manufacturing process development, and optimization of formulation and product stability. Promising candidates may be eligible for transitioning from NIH or other basic research and development programs to advanced product development activities supported by BARDA.

[18] The approximate TRL ranges correspond to the existing preliminary TRLs for medical countermeasures and may differ for diagnostics or in future TRLs. Relevant consideration for funding is based on whether the particular product has progressed to the stage of advanced development, as judged for that type of product.

Advanced Development *(Approximately TRL 7 through TRL 11)*

➡ Eligibility generally begins for BARDA support ⬅

As defined in PAHPA [Public Law 109-417, Title IV, Section 401(a)(6)], BARDA will seek to provide support for medical countermeasure programs between basic research and development activities and product acquisition by specifically supporting advanced research and development. Under this framework, BARDA links initial product development activities (e.g., advanced, non-clinical, toxicology studies; manufacturing process scale-up; advanced formulation and stability programs; and Phase 2 clinical trials) with later product development activities (e.g., validation of the manufacturing process, such as consistency lot manufacturing and all assays; commercial scale manufacturing facility validation; consistency lot manufacturing; and Phase 3 clinical human safety and efficacy studies). BARDA will work in close collaboration with other federal agencies, private sector developers, and academic collaborators to select and transition medical countermeasures that may be considered for acquisition to meet HHS requirements for public health emergency preparedness.

Attrition of products as they proceed through advanced development activities is high. To achieve programmatic success, it is therefore essential for BARDA to support a robust pipeline of numerous candidate products entering these levels. BARDA will have to support multiple products for each top priority medical countermeasure program to increase the likelihood of procuring at least one successful medical countermeasure for each priority program. Based on typical pharmaceutical industry rates of success, very few candidate products are expected to successfully proceed from TRL 1 to TRL 10 and advance to FDA licensure, approval, or clearance. According to the FDA, a new medicinal compound entering Phase 1 testing, often representing the culmination of approximately a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching the commercial market.[19]

In concert with the changing national need for medical countermeasures to address CBRN and emerging infectious disease threats, BARDA will continually monitor the medical countermeasure pipeline for candidate countermeasures for top priority public health threats, and will assess whether products or technologies are sufficiently robust to be transitioned to late-stage development. BARDA will establish clear and transparent principles for these selection criteria and for processes to support advanced product development and technology validation. Following these principles and making use of well-articulated medical countermeasure requirements, such as those delineated in the *HHS PHEMCE Implementation Plan*, the *HHS Pandemic Influenza Implementation Plan*, and ASPR-issued Requests for Proposals, BARDA will provide greater transparency and partnership between the USG and the private sector and will provide developers with clear targets for their product development activities.

BARDA will focus on those promising products that have entered clinical development (TRL 8) and that have relevant preliminary safety data. In this manner, BARDA will foster advanced development by overcoming the technical hurdles of commercial scale manufacturing and by providing assistance in meeting other regulatory requirements needed for eventual product approval. To maximize public health emergency preparedness, however, BARDA will maintain

[19] Food and Drug Administration. *Challenge and Opportunity on the Critical Path to New Medical Products*, March 2004. Available at www.fda.gov/oc/initiatives/criticalpath/whitepaper.html

sufficient flexibility to make specific funding decisions on a case-by-case basis. BARDA may support advanced research and development of a candidate medical countermeasure across a range of TRLs. For example, BARDA's support of an innovative product could begin at a stage before TRL 7 if the product is deemed to be truly innovative as a technology platform. As another example, BARDA may support early in the development pathway a novel technology that could be applied to improve existing products, resulting in advanced biomedical products that could be made more rapidly or less expensively, thereby increasing manufacturing surge capacity. Additionally, if sufficient resources are available, BARDA will fund top priority medical countermeasure development programs where funding from other sources is unavailable or insufficient.

Transition to Acquisition *(Approximately TRL 9 through TRL 12 or 13)*

BARDA will support medical countermeasure development as an integrated, end-to-end process, including the most risky and expensive later stages of product development. Products that successfully emerge from advanced development will have obtained, at a minimum, the information and data needed by the FDA to consider use of the unapproved product or unapproved use in a declared emergency under Emergency Use Authorization (EUA). Such products would be eligible for placement in the SNS under a Project BioShield Special Reserve Fund acquisition, or in other national stockpiles. Additionally, medical countermeasures at this point may be supported through FDA licensure, approval, or clearance by the Project BioShield Special Reserve Fund, the HHS Pandemic Influenza Medical Countermeasures Program, or other, non-governmental, funding mechanisms. These final stages of product development include regulatory review and approval, post-marketing surveillance, and Phase 4 clinical evaluation.

BARDA will allow products to advance further along the development pipeline before acquisition. Moreover, BARDA will ensure that acquisition funds are optimally utilized in stockpiling medical countermeasures that are the most appropriate products for use in a public health emergency. Other USG funding sources, such as CDC Division of Strategic National Stockpile (DSNS) funds and Pandemic Influenza Preparedness appropriations, also could be used to procure qualified medical countermeasures.

BARDA will encourage stakeholders to obtain advice from the FDA on regulatory requirements for approval, licensure, or clearance of medical countermeasures. One of the key elements of the BARDA contracts for advanced development of medical countermeasures for pandemic influenza preparedness and response is the requirement to obtain FDA licensure of these medical countermeasures. The FDA will continue to meet with interested persons and publish material to provide regulatory and product development guidance on qualified countermeasures and qualified pandemic or epidemic products.

ACQUISITION MANAGEMENT

HHS will build into BARDA a robust acquisition management system to maximize control, transparency, and accountability in all acquisition decisions and in the evaluation of contractor performance. This framework will ensure sound stewardship of public dollars through defined

processes and decision-points to guide procurement decisions and performance management for advanced research and development programs. With its acquisition management system, BARDA will move from managing component procurement projects to managing a systems acquisition program. This evolution will require extensive training in systems acquisition for contracting and project management staff. BARDA will systematically identify, analyze, and apply lessons learned to support the development of its acquisition management system.

The BARDA systems acquisition approach will incorporate the following well-established concepts for the management of complex development programs:

- Life cycle aspects of acquisition
- Analysis tools and techniques
- Test and evaluation
- Analysis of alternatives
- Cost, benefit, and performance metrics
- Defined milestones and Milestone Decision Authority for appropriate development stages
- Defined plans for test and evaluation, systems engineering, and acquisition support.

INNOVATIVE TECHNOLOGIES

As identified in the FDA's *Challenge and Opportunity on the Critical Path to New Medical Products*, innovative technologies will drive advances in medical countermeasure development.[20] Identifying those areas where investing in innovation will have the highest impact is a great challenge. An important partner for BARDA in fostering innovative technologies for medical countermeasures is DOD, through the Transformational Medical Technologies Initiative and the Defense Sciences Office of the Defense Advanced Research Projects Agency (DARPA). To the extent that these DOD candidate products or technologies address public health emergency preparedness priorities, BARDA may incorporate them into its medical countermeasure programs and initiatives for the U.S. civilian population.

BARDA will engage the medical product technology community (public and private sectors) to identify, encourage, and support the development of innovative *broad spectrum* approaches. While the early proof of concept is likely to be performed by other agencies or private industry, BARDA will select technologies to move forward for qualification. A key element for evaluating these technologies will be their potential to offer enhanced capabilities with regard to existing threats as well as to future and unknown threats. These innovative, flexible, broad spectrum products and technologies include:

[20] Ibid.

- **Broad Spectrum Medical Countermeasures**
  These products have broad spectrum activity against a range of threat agents and are desirable because they have the potential to be active against engineered and emerging threats. New classes of broad spectrum antimicrobials or antitoxins likely will target novel, but common, pathogen gene products or virulence factors. Broad spectrum products also may modulate host responses. Additionally, a small number of broad spectrum medical countermeasures (e.g., a universal influenza therapy or vaccine) potentially could provide the same coverage as dozens of pathogen-specific products, thereby reducing the number of products that are required in the SNS.

- **Broad Spectrum Technologies**
  This type of medical countermeasure may include technologies that are broadly applicable to improved product performance, such as adjuvants; temperature stabilization technologies; formulations that improve bioavailability or that allow for co-formulation of multi-valent drugs; and immuno-modulators as adjunct treatment to traditional anti-infective therapy.

- **Broad Spectrum Platforms**
  The application of proven platform technologies to the development of new medical countermeasures has the potential to reduce significantly the time and cost required to bring products to market. Technologies may include platform screening systems, universal expression modules, alternative fermentation, and chemical synthesis designs. The potential to rapidly apply such platform technologies to new threats will shorten and streamline the process of drug discovery and development.

TECHWATCH AND STAKEHOLDER OUTREACH

BARDA will maintain a contemporary understanding of public and private sector medical countermeasure development and acquisition activities through an endeavor known as TechWatch. Areas of TechWatch focus include private sector research and development activities and related USG initiatives. TechWatch is an interactive process that provides stakeholders the opportunity to directly communicate information on candidate medical countermeasures to BARDA through a dedicated portal, to make presentations to BARDA, and to respond to Requests for Information and Sources Sought Notices.

BARDA and the HHS PHEMCE remain committed to reaching out and engaging interested parties seeking to develop and manufacture medical countermeasures that meet HHS requirements. This outreach enables effective collaboration with public and private sector persons in the domestic and international medical product development communities, including academia, industry, and federal, state, and local governments. These efforts serve as an opportunity to maximize the transparency of HHS priorities, to solicit feedback, and to discuss implementation of future medical countermeasure advanced development and acquisition programs.

Four specific BARDA outreach efforts are:

- **HHS PHEMC Enterprise Stakeholders Workshop**
  Annually, the BARDA office will convene a meeting with interested persons to communicate HHS priorities for medical countermeasure development and acquisition and to receive feedback that can be appropriately incorporated into future efforts.[21]

- **BARDA Industry Day**
  Annually, the BARDA office will provide an opportunity for industry representatives and other interested parties to demonstrate in an open meeting the operation of biodefense technologies relevant to vaccines, diagnostics, therapeutics, and non-pharmaceutical medical countermeasures.[22]

- **Stakeholders Portal**
  BARDA will provide ongoing outreach to product developers through the stakeholders portal at *www.MedicalCountermeasures.gov*. With this portal, BARDA will centrally manage stakeholder requests for meetings with the USG to discuss possible development or acquisition targets and to present medical countermeasure product information. The portal will also provide interested persons with information on government-sponsored opportunities and events related to medical countermeasures. BARDA anticipates that *www.MedicalCountermeasures.gov* will be available for use in Summer 2007.

- **BARDA Dialogues**
  BARDA staff will continue their ongoing efforts to engage with stakeholders regarding the implementation of the BARDA legislation. In March 2007, for example, ASPR and BARDA leadership participated in a roundtable discussion with the Center for Biosecurity of the University of Pittsburgh Medical Center.[23]

CONCLUSION

The Pandemic and All-Hazards Preparedness Act established BARDA to promote innovation, to increase the potential for success for both medical countermeasure developers and the USG, and to invest in medical countermeasure development that will carry products through the crucial phases of advanced development to the acquisition of final products. BARDA is the focal point within HHS to accelerate, facilitate, and support the development of medical countermeasures for the public against the highest priority manmade and natural public health threats facing the Nation. Through the leadership of ASPR and the guidance of the HHS PHEMCE, BARDA will

[21] Additional information is available at www.hhs.gov/aspr/ophemc/enterprise/bioshield/2007workshop.html
[22] Additional information is available at www.hhs.gov/aspr/ophemc/barda/index.html
[23] Grovall GK, *et al*. Meeting Report: Biomedical Advanced Research and Development Authority (BARDA) Roundtable. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*. 2007. 5(2):1-6.

communicate and coordinate with stakeholders regarding medical countermeasure and technology development priorities and activities.

With NIH basic research and development programs, the newly established BARDA advanced development funding mechanism, the acquisition support available through the Project BioShield Special Reserve Fund, DSNS assets, and appropriations for pandemic influenza medical countermeasures, HHS now has a comprehensive, end-to-end capability to facilitate the successful advanced development, procurement, and availability of medical countermeasures to increase public health preparedness for responding to chemical, biological, radiological, and nuclear threats and emerging infectious diseases, including pandemic influenza. BARDA will select the most promising products and technologies in the pipeline; transition those products and technologies to advanced development and qualification; and fund their support to a stage at which the products and technologies are appropriate for acquisition. The scope of BARDA's advanced development activities will depend on future funding levels.