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Renewing the Project BioShield Act
What Has It Bought and Wrought?

POLICY BRIEF

By Robert Kadlec

In the next several months, the president and members of Congress will decide whether to continue the funding and authorities associated with Project BioShield, which seeks to expand the U.S. stockpile of medical countermeasures for potential chemical, biological, radiological and nuclear (CBRN) attacks. Congress established Project BioShield in 2004 and provided it with 10 years of guaranteed funding. Two years later, it created the Biomedical Advanced Research and Development Authority (BARDA) to oversee BioShield's advanced development and procurement efforts. To date, BioShield has developed and procured more than 50 million doses of vaccines and drugs against several CBRN threats, and its investments have provided ancillary benefits as well. Renewing Project BioShield funding and authorities would enable continued research, development and procurement of many promising treatments, which could prove critical if the United States were ever attacked with CBRN weapons.

Introduction

When President George W. Bush signed the Project BioShield Act on July 2, 2004, he declared that it would "help America purchase, develop and deploy cutting-edge defenses against catastrophic attack."[1] The act authorized the secretary of Health and Human Services (HHS) to conduct and support research, development and procurement activities for medical countermeasures (MCMs) "to treat, identify, or prevent harm from any biological, chemical, radiological or nuclear (CBRN) agent that may cause a public health emergency affecting national security."[2] It provided an advance appropriation of $5.593 billion over 10 years, from Fiscal Year (FY) 2004 to FY 2013, in order to create a guaranteed market incentive for pharmaceutical companies to produce CBRN MCMs for which there is no commercial demand.[3]

To date, eight MCMs against anthrax, smallpox, botulinum toxin and radiological threats have been procured. Eighty other candidate MCMs are undergoing advanced development. Unless Congress acts, the authorities and funds contained in the Project BioShield Act will expire at the end of FY 2013. The legislative experiment of BioShield is now subject to evaluation and reconsideration in the House and the Senate, which have both passed versions of reauthorization legislation.[4]

In order to help inform this decision, this policy brief examines the history of Project BioShield. It starts by highlighting the CBRN risks that motivate the U.S. government's preparedness efforts, providing a historical context for America's CBRN MCM efforts and highlighting congressional legislation that has complemented or facilitated Project BioShield implementation. The brief also describes the types of MCMs that HHS has invested in and purchased for the Strategic National Stockpile (SNS) and highlights other significant benefits of BioShield funding.

The Evolving Risk of CBRN Attacks

The perceived risk of CBRN attacks has evolved significantly over the past two decades. Following the 1990 invasion of Kuwait, the Department of Defense was "ill prepared" for the threat posed by Iraqi chemical and biological weapons.[5] Specifically, DOD "had limited stockpiles of drugs and vaccines for biological defense before and during Operations Desert Shield and Desert Storm. The industrial base could not supply all the items needed. Long production lead times, and the legal and medical problems related to the use of these drugs, delayed their fielding."[6] Following that conflict, DOD recognized the growing risk of proliferation and increased its efforts to address the risk of CBRN attacks on military forces. In 1994, Congress mandated a consolidation of the separate Army, Navy and Air Force programs under a single DOD authority and increased investments in CBRN environmental detection, physical protection and MCM development.[7]

After the terrorist attacks of September 11, 2001, and subsequent anthrax letter attacks, congressional investigations and intelligence assessments highlighted a growing risk of CBRN attacks. Several terrorist groups actively sought CBRN weapons of one kind or another. In particular, the Japanese cult Aum Shinrikyo, al Qaeda and al Qaeda's associates – notably the Egyptian Islamic Jihad, Jemaah Islamiya and Lashkar al Tayyib – demonstrated intent or efforts to acquire and use such weapons.[8]

Even though bin Laden is dead and al Qaeda is severely weakened, the risk of CBRN terrorism persists.

Osama bin Laden's 1998 fatwa proclaimed al Qaeda's commitment to acquiring weapons of mass destruction, particularly nuclear and strategic biological weapons for high-consequence attacks on the United States.[9] Documents discovered after the U.S. invasion of Afghanistan showed that bin Laden's deputy, Ayman Zawahiri, organized al Qaeda's efforts to acquire and produce anthrax for mass-casualty attacks against the United States and had built a dedicated laboratory in Kandahar, Afghanistan.[10] Al Qaeda was also interested in other pathogens, such as plague, cholera and tularemia,[11] and its biological weapons program was further along than previously believed.[12] In April 2012, the Department of Homeland Security (DHS) emphasized that anthrax remained the principal biological weapon concern, given past terrorist interest, its ubiquity in nature and its relative ease of production and dissemination.[13]

Even though bin Laden is dead and al Qaeda is severely weakened, the risk of CBRN terrorism persists. Zawahiri, the organizer of al Qaeda's anthrax program, replaced bin Laden as al Qaeda's leader. An al Qaeda-affiliated franchise, al Qaeda in the Arabian Peninsula, publicly stated its intent to use "poisons or chemical and biological weapons against [U.S.] population centers."[14] Senior U.S. intelligence officials have warned that the group is committed to obtaining chemical and biological agents and is focused on inspiring homegrown

American militants to launch attacks from within the United States.[15] Director of National Intelligence James Clapper's 2012 congressional testimony noted that "given the compartmented nature of [terrorist] CBRN programs, the spread of technological information and the minimal infrastructure needed for some CBRN efforts, the intelligence community remains alert to the CBRN threat."[16] The current conflict in Syria heightens concerns about the security and possible use of its chemical and biological weapons, as well as the risk of terrorist acquisition of such weapons.[17]

As the United States continues to press its global counterterrorism offensive and promote adherence to international agreements prohibiting the development and use of biological weapons,[18] a robust defense is still needed in case a vigorous offense and active diplomacy fail. President Barack Obama's "National Strategy on Countering Biological Threats" succinctly describes the stakes: "The effective dissemination of a lethal biological agent within an unprotected population could place at risk the lives of hundreds of thousands of people. The unmitigated consequences of such an event could overwhelm our public health capabilities, potentially causing an untold number of deaths. The economic cost could exceed one trillion dollars for each such incident. In addition, there could be significant societal and political consequences that would derive from the incident's direct impact on our way of life and the public's trust in government."[19]

Complicating the CBRN risk landscape is the emerging discipline of synthetic biology. Increasingly, tools are becoming available to potentially recreate eradicated agents like smallpox and to create entirely new pathogens. The prospect of a "Bio Una-bomber" adds further uncertainty to the future security landscape and the effectiveness of prevention-based strategies.[20] The difficulty in attributing such attacks, as shown by the 2001 anthrax investigation and the lingering controversy around the technical forensics of the case, highlights the challenges of deterrence and retribution policies.

Past U.S. Responses to CBRN Threats

The first U.S. government efforts to develop CBRN MCMs began in World War II, when President Franklin D. Roosevelt directed the development of offensive biological weapons to retaliate against the potential use of such weapons by either Germany or Japan.[21] In order to permit offensive research into pathogenic organisms and toxins, medical defenses were essential to protect the researchers, as well as troops at risk of attack.[22] During the war, the U.S. government successfully developed vaccines for influenza and botulinum toxin.[23] After President Richard Nixon terminated the U.S. offensive biological warfare program in 1969, however, U.S. efforts to develop defensive MCM efforts slowed. Nixon's decision shifted most medical defense efforts from DOD to the Department of Health, Education and Welfare,[24] but that department never received the necessary congressional mandates or funds. DOD's remaining modest medical defense research was unsuccessful in producing CBRN MCMs that could be licensed by the Food and Drug Administration (FDA).[25]

Although the 1990 Iraq war energized DOD efforts, civilian biodefense efforts lagged. In 1998, Congress took initial steps in civilian CBRN preparedness with the Public Health Improvement Act (PL 106-505). Among several initiatives to increase preparedness, funds were appropriated to create the National Pharmaceutical Stockpile at the Centers for Disease Control and Prevention. DOD and HHS were directed to "coordinate the development, maintenance and procedures for the release of strategic reserves of vaccines, drugs and medical

supplies which may be needed rapidly after a bioterrorist attack upon the civilian population."[26]

Following the 2001 anthrax letter attacks, Congress passed the comprehensive Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 108-276). HHS was required to develop and "maintain a stockpile [later renamed the Strategic National Stockpile] of drugs, vaccines, biological products, medical devices and other supplies … to provide for the emergency health security" of the United States and to ensure that a sufficient amount of vaccine against smallpox is available to meet the health security needs of the United States.[27] The FDA was required to issue a substitute animal-testing rule for human testing as part of the CBRN MCM regulatory review process.[28] The National Institutes of Health (NIH) were granted further authorities to accelerate basic CBRN research, and NIH's annual appropriation was increased to $1.6 billion.[29]

As a consequence of this legislation, 56 academic research centers and public health agencies, organized into eight regional biodefense centers, began researching new CBRN MCM candidates.[30] Whereas research centers discover new candidate vaccines and drugs, pharmaceutical companies turn concepts into licensed products. The series of laws passed prior to BioShield addressed the early phases of MCM development, but they did little to address the issues that kept the pharmaceutical industry away from the effort.

Commercial Pharmaceutical Development: Long, Expensive and Risky

Developing a new commercial vaccine or drug may take over 10 years and cost more than $1 billion.[31] The two greatest factors contributing to the cost are time and risk. The risks of failure are significant, and the likelihood of failure is linked directly to safety, efficacy and commercial concerns.[32] For the 50 largest pharmaceutical companies, the probability that a candidate will prove both safe and effective through the three phases of clinical trials necessary to achieve FDA licensure is 1 in 6.[33] Failures often result during testing because the product is unsafe (30 percent) or ineffective (30 percent). Forty-three percent of product failures occur in late stages of testing (Phase III), and another 23 percent occur after the product has completed all clinical trials and the application for licensure is submitted to the FDA.[34] Late-stage failures are especially expensive because of extensive testing and opportunity costs.

Large pharmaceutical companies mitigate the risk of failure by developing multiple candidate products that cover a range of clinical uses. However, small biotechnology companies may not have such a diversity of candidate products or the financial resources to support multiple candidates. Thus, the success or failure of each product is linked to the firm's commercial viability. The U.S. government therefore needs to mitigate the risks of developing CBRN MCMs by identifying a sufficient number of candidate products to achieve a specific goal (e.g., an ebola vaccine).

In evaluating new candidates for the MCM marketplace, companies conduct an extensive set of analyses. Firms must assess not only the direct financial and technical risks involved but also the unique opportunity costs of working with the government on complex products with limited or no direct commercial value. Because the U.S. government is the sole customer, companies considering this market need to know several things:

- How much will the government buy?
- What is the company's expected profit?
- What can companies expect given federal acquisition rules that are perceived as slow and onerous?
- Will the government be a reliable

customer, committed to a long-term contractual relationship?

- What are the company's liability risks for adverse reactions associated with these MCMs?[35]
- Will Congress reliably appropriate funds for procurement?
- How will the FDA regulatory process evaluate human effectiveness of CBRN MCMs, given that these products will only be tested in animals?[36]

A lack of clear answers only raises companies' perceptions of the risks of an already risky endeavor. The government must address these concerns in order to develop a sustainable public-private partnership. The pharmaceutical industry wants a reliable partner, with a certain, transparent process backed by a predictable market. Project BioShield was designed to help answer such questions.

Project BioShield: Incentivizing the Pharmaceutical Industry to Support National Security

President Bush proposed the Project BioShield concept during his 2003 State of the Union address and provided a more detailed description in public remarks given at NIH on February 3, 2003.[37] It was designed to motivate U.S. pharmaceutical companies to enter the CBRN MCM market by providing a substantial guaranteed market, expediting governmental contracting practices and clarifying FDA regulatory requirements for products used in a public health emergency. When the president proposed the concept, he asked for $6 billion for a Strategic Reserve Fund (SRF) "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, ebola and plague."[38] Although the final legislation guaranteed $5.593 billion for procurement, it did not clarify the type or size of the procurement the government would make.

In order to determine the potential size of the CBRN MCM procurement, Congress outlined a mechanism to constrain MCM purchases to those that had no commercial market and were actually needed to address the CBRN threat. The legislation explicitly required the newly established DHS to identify potential CBRN agents that are "material threats" to national security.[39] To date, DHS has determined 15 agents to be material threats, including examples of all four types of CBRN weapons.

Once DHS identifies a given agent as a threat, the HHS secretary must determine that a MCM is necessary to protect public health and must assess the availability and appropriateness of a MCM to address the material threat. HHS and DHS then jointly submit a proposal to the president (now delegated to the director of the Office of Management and Budget) identifying the required MCMs and allowing the government to enter into contracts to procure MCMs while they are still in development, up to eight years before product licensure is expected.[40] The government guarantees that it will buy a certain quantity at a predetermined price once the MCM meets specific requirements or milestones. The government pays the agreed-upon amount only after these requirements are met and the product is delivered to the SNS but has the option to provide up to 50 percent of the total award in advance payments.[41] If the MCM does not meet the requirements within the specified time frame, the contract can be cancelled without any payment to the contractor. Thus, Project BioShield reduces the developer's market risk but not the technical development risk.

HHS was also given expedited procurement authorities, including simplified procedures allowing other than fully open competition in certain circumstances as well as expediting peer review and the contracting of specialized personnel.[42] According to the Congressional Research Service, "The act relaxes procedures under the Federal Acquisition Regulation for procuring property or services used

in performing, administering or supporting CBRN countermeasure research and development. These expedited procedures decrease … the amount of paperwork required for these expenditures" and potentially increase the speed of the procurement process, allowing the government to hire the necessary technical expertise to work with industry.[43]

BioShield successfully created a guaranteed market. It did not, however, eliminate the technical development risks, the lack of requisite technical expertise in the company or the need for sufficient development funding to license a product.

Finally, BioShield granted the FDA authority to permit the use of unapproved CBRN MCMs if the secretaries of DHS and HHS agree that there is significant risk of an actual or potential CBRN attack and public health emergency. In such cases, the FDA can approve use of a CBRN MCM without completing all safety and efficacy testing and formal licensure, as long as it determines the level of safety and efficacy based on all data available at the time.

The Guaranteed Market Meets Technical Risk Four months after the law was enacted, the first BioShield procurement contract was awarded. A small California-based company called VaxGen received $877.5 million to provide 75 million doses of a second-generation anthrax vaccine,[44] even though it had not licensed a vaccine with the FDA before. There was great excitement and expectation, but at the outset, there were also lingering concerns. As described by *The Washington Post* in November 2004, "The new anthrax vaccine is a centerpiece of BioShield, but many questions remain about its effectiveness and how long it can be stored."[45] Yet two years later, in December 2006, VaxGen had failed to meet the development and production milestones, and HHS terminated its contract. Under the terms of the BioShield contract, HHS only paid VaxGen $1.5 million of the $877 million initially awarded. A Government Accountability Office investigation of VaxGen's efforts identified three major problems with the contact. First, HHS awarded the procurement contract while the company was still in the early stages of developing the vaccine and had not addressed many critical and technical manufacturing risks. The contract required VaxGen to deliver 25 million doses of the vaccine in two years, which would have been unrealistic even for a larger manufacturer. Second, VaxGen took unrealistic risks because of the aggressive delivery timeline, lacked in-house technical expertise (this was exacerbated by the attrition of key company staff) and had limited options for securing any additional funding needed. Third, important FDA requirements regarding the testing required for the vaccine to be eligible for use in an emergency were not known at the outset of the procurement contract. Much of the expensive testing VaxGen performed did not produce the data needed to address FDA questions or concerns.[46]

BioShield successfully created a guaranteed market. It did not, however, eliminate the technical development risks, the lack of requisite technical expertise in the company or the need for sufficient development funding to license a product. Among the problems cited by the Government Accountability Office at that time was that interested companies found it difficult to secure additional funding for the testing required to advance a candidate MCM through the development cycle and regulatory review process. The later stages of product development, often called the "valley of death," involve

the greatest requirements for financial support and technical assistance, and the greatest risks of technical failure. Companies that are not well capitalized can falter or fail when facing these challenges.[47] Therefore, Congress provided another incremental refinement to address this liability.

The 2006 Pandemic and All-Hazards Preparedness Act (PL 109-217) granted HHS further authority to facilitate BioShield implementation. This legislation established BARDA within HHS to coordinate and fund the acceleration of MCM advanced research and development.[48] BARDA works with companies to develop and commercialize countermeasures that are not yet mature enough for a BioShield contract and promotes innovation to reduce the time and cost of MCM development.[49] BARDA also manages and executes all Project BioShield acquisitions.[50] Congress established a separate additional fund, the BARDA Biodefense Medical Countermeasure Development Fund, to pay for advanced development contracts. Unlike the SRF's 10-year guaranteed appropriation, BARDA's fund is subject to annual congressional appropriations. In 2009, SRF funds started being used to support BARDA's development efforts. With the creation of BARDA, Congress consolidated central elements of HHS's advanced development and acquisition of CBRN MCMs, but it did not address oversight or funding of NIH's basic research on CBRN MCMs or management of the SNS by the Centers for Disease Control and Prevention.

Project BioShield: The Results to Date

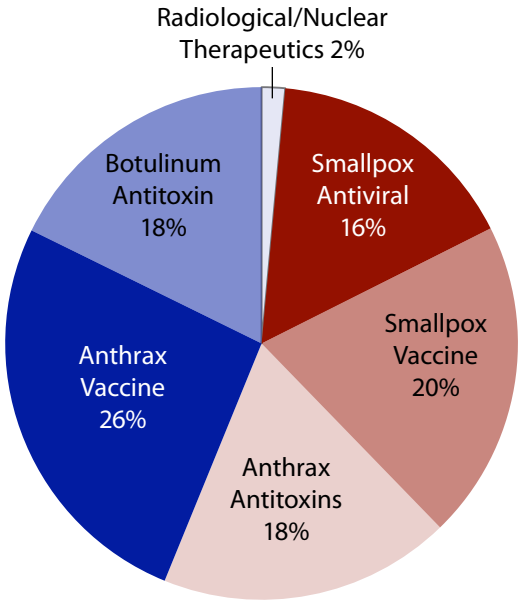
In the past eight years, HHS has awarded a total of 11 BioShield procurement contracts totaling $2.686 billion to seven pharmaceutical companies. Through these contracts, HHS has purchased eight MCMs for the SNS, which address four of the material threats identified by DHS (anthrax, radiological/nuclear, botulinum and smallpox). Five of these MCMs are licensed for use by the FDA, including an anthrax antitoxin that was just licensed in December.[51] Three other BioShield MCMs are undergoing regulatory review, with the expectation that they will receive FDA licensure by 2016.[52]

By the end of FY 2013, BARDA anticipates awarding three additional BioShield procurement contracts and exercising options on existing contracts for additional quantities of smallpox vaccine, anthrax antitoxins, radiological/nuclear therapeutics and chemical agent treatments for the SNS at a projected cost of $1.236 billion.[53] The projected 10-year BioShield CBRN MCM procurement is estimated to be approximately $3.75 billion of the $5.593 billion (67 percent) originally appropriated.[54]

Congress originally intended to use the entire $5.593 billion for MCM procurement. Beginning in FY 2009, however, Congress permitted the transfer of $1.823 billion, approximately one-third of the SRF, for non-acquisition purposes. $1.382 billion was transferred into BARDA's Biodefense Medical Countermeasure Development Fund. Approximately $1.237 billion of that was used to support advanced development of CBRN MCM candidates that are too early in development for BioShield acquisition. The remainder, $145 million, was used for BioShield and BARDA management and administration costs.

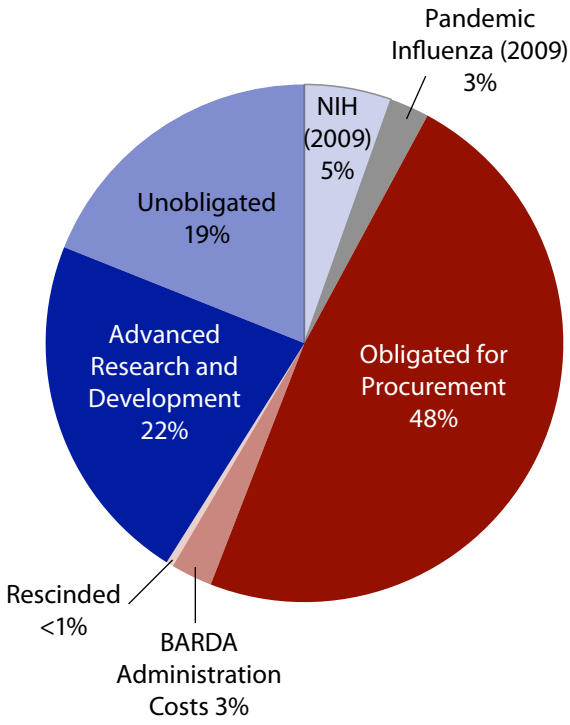
Additionally, Congress transferred $137 million and $304 million from the SRF in FY 2009 to respond to the H1N1 influenza pandemic and to support NIH basic science research activities, respectively.[55] This $441 million transfer was directed by Congress and not requested by the administration or HHS. Congress also removed $25 million from the SRF account through rescissions enacted in the Consolidated Appropriations Act of 2004 (PL 108-199) and the Consolidated Appropriations Act of 2005 (PL 108-447).[56]

FIGURE 1: PROJECT BIOSHIELD PROCUREMENTS BY TYPE AND PERCENTAGES FOR FISCAL YEARS 2004-2012



Source: Interview at Biomedical Advanced Research and Development Agency, November 2012

FIGURE 2: PROJECT BIOSHIELD TRANSFERS AND OBLIGATIONS BY PERCENTAGES FISCAL YEARS 2004-2012



Source: Interview at Biomedical Advanced Research and Development Agency, November 2012

BARDA and its predecessor office have sponsored the advanced development of 80 candidate CBRN products since 2004, worth a total of $1.6 billion.[57] These products represent over 90 companies, academic institutions, nonprofits and U.S. government agencies. The candidates can be grouped by type of threat:

- 24 candidates to counter material biological threats – such as anthrax (seven vaccines and seven antitoxins), smallpox (three vaccines and two antiviral drugs) and botulism (one antitoxin) – including broad-spectrum antibiotics for multidrug-resistant anthrax, tularemia and plague (four compounds);
- 53 candidates to prevent and treat radiological injuries and the effects of a nuclear detonation, including acute radiation syndrome drugs (33), decorporation agents (6), thermal burn therapies (2) and biodosimetry devices (11); and
- Four candidates to treat the effects of exposure to chemical nerve agents and cyanide poisoning.

Nineteen advanced development contracts were terminated either because the companies failed to meet predetermined milestones or because the candidate product failed to meet clinical testing endpoints, such as efficacy standards.

The proportion of BARDA funding dedicated to different product types – such as vaccines, therapeutics and antitoxins – was initially limited to two threats: smallpox and anthrax. Congress

BioShield in Action: A Safer Smallpox Vaccine

Smallpox is a virus that is transmitted from person to person. Historically, it killed one-third of those infected and left survivors badly scarred. In the 20th century, over 200 million people died from smallpox. The World Health Organization declared smallpox eradicated in 1980 after a successful global vaccination campaign.

After the 2001 terrorist attacks, concerns arose about possible smallpox attacks. Intelligence suggested that Iraq, Russia and North Korea possessed smallpox for biological weapon purposes.[58] In 2002, Congress directed HHS to ensure that it had sufficient smallpox vaccine for all Americans, and President Bush announced a National Smallpox Vaccination Policy that resumed military vaccinations and made the vaccine available voluntarily to medical and public-health first responders.[59]

However, the standard smallpox vaccine used by the World Health Organization to eradicate the disease had serious side effects. For every million people vaccinated, one to two died, between 15 and 50 had life-threatening complications and up to 900 had serious but non-life-threatening effects. Since this vaccine was widely used in the 1960s and 1970s, a greater number of Americans have immune deficiencies that would predispose them to greater likelihood of these complications.[60]

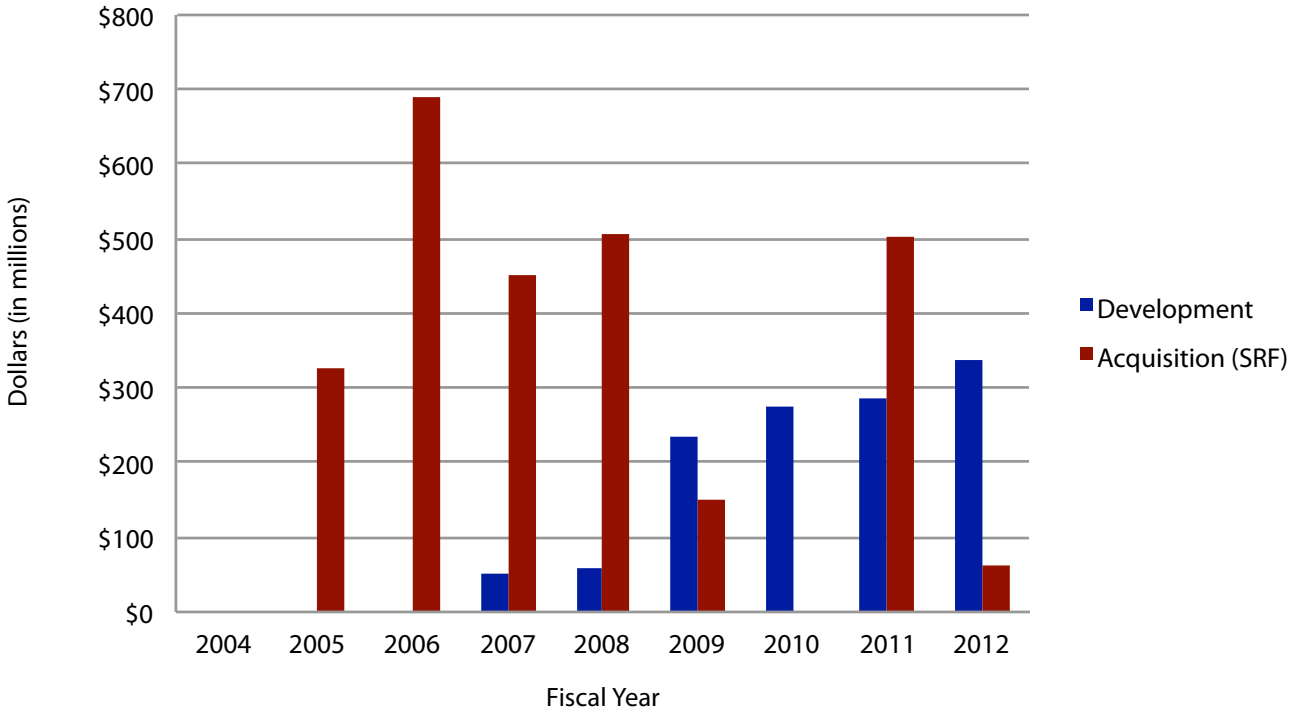
In early 2003, HHS awarded contracts to two companies to research a safer smallpox vaccine. By 2004, NIH announced that an experimental smallpox vaccine, modified vaccinia Ankara (MVA), protected animals as well the standard vaccine did. Significantly, MVA could be used in people with health conditions that would prevent the use of the standard vaccine.[61] In June 2007, HHS awarded a $500 million BioShield contract to deliver 20 million doses of MVA vaccine to the SNS, with the first delivery completed by July 2010. BARDA has subsequently awarded a BioShield-related advanced development contract to improve and prolong the shelf-life of the MVA vaccine. NIH has awarded grants to evaluate whether the MVA vaccine can be used against other potential bioterror threats such as Marburg virus, a viral hemorrhagic fever.

mandated a MCM for smallpox in the 2002 "Public Health Security and Bioterrorism Preparedness and Response Act," based on intelligence assessments at the time. Meanwhile, DHS determined that anthrax was the most likely bioterrorism threat agent. In its 2011-2016 strategic plan, BARDA outlined a strategic goal of identifying and supporting the development of broad-spectrum antimicrobials, which will provide greater utility and cost efficiency than vaccine development.[62] This shift is evident in the growing proportion of candidate products classified as broad-spectrum antimicrobials for bacterial and rickettsial material threats (e.g., tularemia, glanders, meliodosis plague and typhus). Furthermore, as vaccines, antitoxins and therapeutics for smallpox and anthrax are procured, developmental efforts are transitioning to other material threats, such as chemical, radiological and nuclear agents.

Taken as a whole, BioShield's procurements and advanced development contracts demonstrate a robust set of CBRN MCM-related activities and indicate an effort consistent with the strategic intent of Project BioShield and the Pandemic and All Hazards Preparedness Acts (Figure 3).

The initial expenditures were largely focused on procurement of MCMs that were mature enough for a BioShield contract. The shift in expenditures to development demonstrates the shift to identifying

FIGURE 3: BIOSHIELD-FUNDED PROCUREMENT AND BARDA-FUNDED ADVANCED DEVELOPMENT FISCAL YEARS 2004-2012



Source: Interview at Biomedical Advanced Research and Development Agency, November 2012

potential MCM candidates that, if advanced, could be subject to later BioShield procurement. Based on BARDA projections, another 12 CBRN MCMs could be subject to BioShield procurement consideration.[63]

The accomplishments of Project BioShield go beyond the quantities of CBRN MCMs stockpiled or the number of advanced development contracts awarded. The ancillary benefits appear substantial. BARDA has funded innovation in vaccine development, diagnostics and medical devices.[64] Although innovation investments account for a relatively small dollar amount since its inception (approximately $100 million, or 1.7 percent), the investment has already yielded a new FDA-approved diagnostic device that improves the rapid diagnosis of infectious disease, including biological terrorism and pandemic threats, as well as a next-generation portable patient ventilator. BARDA has used innovation funding to develop animal models that are essential for validating and supporting FDA regulatory review of MCMs against anthrax, glanders, meliodosis, smallpox, tularemia, and radiological and nuclear threats.

The cumulative effects of the procurement and advanced development activities have also created a growing consortium of CBRN MCM producers that includes approximately 47 participating companies. Arguably, BioShield has not yet attracted many large pharamecuetical companies to the CBRN MCM market. However, large firms have received advanced development contracts for broad-spectrum antibiotics, and one of the producers of anthrax antitoxin was recently acquired by a large

pharamaceutical company.[65] Furthermore, BARDA has tried to capitalize on signficant investments for pandemic influenza that are transferrable to the CBRN MCM effort by subsidizing domestic vaccine manufacturing capacity and establishing three centers of excellence to provide companies with technical assistance for advanced development and surge manufacturing in the event of a public health or national security emergency.[66]

The benefits have extended beyond what the drafters may have originally intended. This additonal contribution will enable the future development of CBRN MCMs and facilitate future procurement for the SNS. In the end, however, the success of BioShield will be measured on whether it has produced the kinds and quantities of CBRN MCMs needed in the case of an event, whether deliberate or accidental.

The Future of Project BioShield and BARDA

Because BARDA will likely expend the remainder of the SRF funds by the end of FY 2013, the future of Project BioShield is uncertain. In light of the fiscal realities that the nation faces, it is not clear whether the administration and Congress have the political will to reappropriate funds at the previous levels. If they do, the issue will be whether the amount requested, authorized and appropriated will be sufficient to continue the guaranteed market incentive. The funds expended so far demonstrate a robust advanced development pipeline of prospective candidate products that include vaccines, therapeutics, and diagnostic and medical devices. Furthermore, policymakers have to consider the risk of future CBRN attacks. Despite recent successes such as the elimination of Osama bin Laden and the degradation of al Qaeda, the intelligence community warns that "the compartmented nature of [terrorist] CBRN programs, the spread of technological information and the minimal infrastructure needed for some CBRN efforts" demands vigilance and continued preparedness for possible CBRN attacks.[67]

Project BioShield: Comparison with Commercial Pharmaceutical Success Rates

Antibodies are one class of medical countermeasures developed by HHS. They are naturally produced by the body as part of the immune response to infection. For more than a century, they have also been used as medical countermeasures to prevent and treat infectious diseases. They represent an important adjunct to other types of therapies.

Commercial pharmaceutical companies have taken advantage of improvements in antibody discovery, development and production to use them for an increasing array of diseases, including cancer, autoimmune disorders and infectious diseases. The current FDA approval rate of antibody treatments is consistently in the range of 18 percent to 29 percent, which is at least 10 percent higher than that of other drug classes.

BARDA has funded several candidate antibody treatments for anthrax and botulinum toxin. Two have been procured for the Strategic National Stockpile, and several other preparations are undergoing development and testing. The FDA licensed one of the anthrax antibody treatments in December 2012, which means that the FDA has approved approximately 17 percent of Project BioShield antibodies.

The legislation that passed both the Senate and House of Representatives in the 112th congressional session authorizes $2.8 billion over five years (FY 2014 to FY 2018) for the SRF for the advanced development and procurement of CBRN MCMs. This is roughly equivalent to the funds provided by the original act. The bills also authorize an additional $415 million annually for BARDA's advanced development fund. These bills require similar commitment and affirmation by the relevant appropriation committees. If the president submits a

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comparable annual budget request, Project BioShield and BARDA should receive continued funding at a level that has historically demonstrated an ability to develop and procure MCMs that can mitigate CBRN attacks and potentially save hundreds of thousands of lives and trillions of dollars.

As part of its five-year strategic plan, BARDA envisions uninterrupted funding for both advanced development and BioShield-related procurement.[68] BARDA analyses and projections anticipate the procurement of up to 12 additional CBRN MCMs in the next 10 years.[69] These projections reflect candidate products currently being supported in the BARDA advanced development program that can be reasonably expected to become eligible for BioShield procurement. They do not, however, factor in additional procurement dollars that may be needed to exercise options on exisiting procurement contracts. BARDA's strategic thinking, however, is evolving to consider more generic approaches to address the need for leveraging common technology platforms that may offer greater efficiency and sustainability.[70] This approach offers potential opportunities to mitigate the inherent technical risks associated with pharmaceutical development, increasing the likelihood of successful MCM development and offering potential cost savings.

Conclusion

Project BioShield was conceived over a decade ago in the aftermath of the 9/11 terrorist and anthrax letter attacks, when the perceived risks of CBRN attacks on the homeland loomed large. It was viewed an essential element step in acquiring "effective vaccines and treatments against agents like anthrax, botulinum toxin, ebola and plague"[71] by creating a guaranteed market for such products that otherwise lacked a commercial market. Since BioShield became law, enabled by additional legislative authorities, the U.S. government has demonstrated a commitment and ability to discover, develop and procure MCMs for a variety of CBRN threats. In the eight years of BioShield funding, MCMs against four threats have been procured, and advanced development investments are projected to yield MCMs addressing several others. The handful of companies initially involved has grown to over 70 companies and institutions that have received procurement awards or advanced development contracts. Less tangible, but potentially more significant, is the public-private partnership that BioShield created by promoting and fostering a CBRN MCM industry that simply did not exist before.

The capacity and capability of this national security partnership is a strategic hedge against an uncertain future created by the increasing availability of the technologies that would permit potential perpetrators to develop CBRN weapons. Before Project BioShield's funding and authorities expire next year, the president and Congress should affirm its value as an indispensible insurance policy against the risk of CBRN attacks. BioShield has achieved the strategic objectives initially envisioned and merits continued support and funding.

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ENDNOTES

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