BIPARTISAN POLICY CENTER

Budgeting for Medical Countermeasures: An Ongoing Need for Preparedness

FEBRUARY 2018

AUTHORS

Tom Daschle
Former U.S. Senator

Judd Gregg
Former U.S. Senator

STAFF

G. William Hoagland
Senior Vice President

Anand Parekh, M.D.
Chief Medical Advisor

ACKNOWLEDGMENTS

BPC is grateful to the many experts who shared their perspectives with us as we developed this paper. BPC also acknowledges the feedback of Ashley Ridlon.

DISCLAIMER

This report does not necessarily represent the views or opinions of the Bipartisan Policy Center, its founders, or its board of directors.

Background

While the September 11, 2001 attacks on the World Trade Center and Pentagon ushered in the era of terrorism as the nation's primary security threat in the post-Cold War era, it was the October 2001 mailing of envelopes containing *Bacillus anthracis* spores to several locations in the U.S. that raised the specter of the use of biological weapons to kill civilians on a large scale. Many countries named by the U.S. State Department as sponsors of terrorism are believed either to possess or to be actively pursuing biological weapons.[1] Most recently, it has been reported that North Korea is moving steadily to acquire the essential machinery and scientific expertise that could potentially be used for an advanced bioweapons program.[2]

Thought leaders such as Bill Gates have warned that a pandemic, whether caused by a terrorist or nature itself, is one of the biggest threats our nation faces.[3] And importantly, the American public has expressed concern as well. The Alliance for Biosecurity, the Blue Ribbon Study Panel on Biodefense, and Trust for America's Health found in a survey that eight out of 10 Americans are concerned that naturally-occurring diseases like Ebola and Zika pose a threat to the U.S., and about nine out of 10 people are concerned that terrorists might use chemical or biological weapons against the U.S. Importantly, the survey found that most Americans support increasing the federal budget for preventive measures for biological threats.[4]

Preparedness against a chemical, biological, radiological, or nuclear (CBRN) threat requires a sustained and multi-pronged approach by both the public and private sectors. An essential component of this strategy is the development, procurement, and stockpiling of diagnostic tests, drugs, and vaccines in response to a potential event, as well as the ability to distribute these products where needed. To address this critical need, Congress passed the Project BioShield Act in 2004 to encourage the development of CBRN medical countermeasures by private manufacturers. Project BioShield created a government-market guarantee by providing a 10-year appropriation permitting the secretary of Health and Human Services (HHS) to obligate funds to develop and purchase medical countermeasures for stockpiling by the government. These products are added to the Strategic National Stockpile (SNS), managed by the Centers for Disease Control and Prevention (CDC). The act also establishes a process for the HHS secretary to temporarily allow the emergency use of countermeasures that lack Food and Drug Administration (FDA) approval.[5]

Over the last 13 years, Project BioShield has facilitated the procurement of 27 medical countermeasures against Department of Homeland Security-identified national security threats, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events. Of these, six products have received FDA approval.[6] However, gaps in preparedness remain. In particular, the transition from multi-year to year-over-year appropriations has raised questions about the sustainability of the program. Meeting the continued threat will require a joint commitment from both the public and private sectors.

This white paper will summarize the progress to date in procuring medical countermeasures and prior congressional funding mechanisms for Project BioShield. It will also discuss ways to optimize funding for medical countermeasures so that the existing public-private partnership can continue to thrive: namely, by restoring the program's original multi-year funding structure.

Progress to Date

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by the HHS assistant secretary for preparedness and response (ASPR), coordinates the government-wide development, acquisition, stockpiling, and use of medical products that are needed to respond to a variety of high-consequence public health emergencies, whether naturally occurring or intentional. The PHEMCE addresses high-priority threats that the secretary of Homeland Security determines to pose a material threat and/or that PHEMCE leadership determines to have the potential to seriously threaten the national health security.[7] The high-priority threats are listed in Table 1.

Table 1 – PHEMCE High-Priority Threats

Biological Threats
Bacillus anthracis (anthrax) and multi-drug resistant *Bacillus anthracis* (MDR anthrax)
Burkholderia mallei (glanders) and *Burkholderia pseudomallei* (melioidosis)
Clostridium botulinum toxin (botulism)
Ebola virus (Ebola hemorrhagic fever)
Emerging infectious diseases
Francisella tularensis (tularemia)
Marburg virus (Marburg hemorrhagic fever)
Pandemic influenza
Rickettsia prowazekii (typhus)
Variola virus (smallpox)
Yersinia pestis (plague)
Chemical Threats
Acetylcholiesterase inhibitor nerve agents
Chlorine
Cyanide salts (potassium and sodium cyanide)
Hydrogen cyanide
Phosgene
Vesicants
Radiological and Nuclear Threats

Source: 2017-2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan. U.S. Department of Health and Human Services.

Of these threats, medical countermeasures supported under Project BioShield include those directed against anthrax, botulism, smallpox, nerve agents, radiological and nuclear agents, and most recently, viral hemorrhagic fevers like Ebola. Individual products and their uses to counter specific threats are listed in Table 2. While some of these products are still in late-stage development, others have been approved by the FDA or are under an FDA Emergency Use Authorization and are stockpiled in the SNS. Whenever possible, the government seeks to support multiple products to counter each threat, including products for both prophylaxis and treatment. In addition, efforts are made to ensure that countermeasures exist for special populations for whom primary products may be inadvisable, such as those who are immune-compromised.

Table 2 – Medical Countermeasures Supported Under Project BioShield

Product	Threat	Use
Raxibacumab	Anthrax	Treatment of inhalational anthrax
Anthrasil	Anthrax	Treatment of inhalational anthrax
ANTHIM	Anthrax	Treatment of inhalational anthrax
Biothrax vaccine	Anthrax	Postexposure prophylaxis
Nuthrax vaccine	Anthrax	Postexposure prophylaxis
HBAT	Botulism	Treatment of symptomatic botulism
IMVAMUNE	Smallpox	Prevention of smallpox
Tecovirimat	Smallpox	Treatment of smallpox infection
Versed	Nerve Agents	Treatment of nerve-agent induced seizures
Neupogen	Radiation	Treatment of bone marrow suppression
Leukine	Radiation	Treatment of bone marrow suppression
Neulasta	Radiation	Treatment of bone marrow suppression
ThyroShield	Radiation	Thyroid blocking agent
Ca-DTPA	Radiation	Chelating agent
Zn-DTPA	Radiation	Chelating agent
Silverlon	Radiation burns	Antimicrobial wound dressing
Nexobrid	Radiation burns	Enzymatic debridement of wounds
Recell	Radiation burns	Donor graft sparing technology
Stratagraft	Radiation burns	Artificial skin substitute
REDI-Dx	Rad/Nuc agent	Detect/quantify level of radiation exposure
Arad	Rad/Nuc agent	Detect/quantify level of radiation exposure
Asell biodosimetry test	Rad/Nuc agent	Detect/quantify level of radiation exposure
200A	Rad/Nuc agent	Detect/quantify level of radiation exposure
V920 vaccine	Ebola	Prophylaxis
AdVac & MVA-BN vaccine	Ebola	Prophylaxis
ZMapp	Ebola	Treatment of Ebola
REGN3470-3471-3479	Ebola	Treatment of Ebola

Sources: Adapted from: Joseph C. Larsen and Gary L. Disbrow, "Project BioShield and the Biomedical Advanced Research Development Authority: A 10-Year Progress Report on Meeting US Preparedness Objectives for Threat Agents," *Clinical Infectious Diseases* (2017):64; 1430-4.; "HHS accelerates development of first Ebola vaccines and drugs," U.S. Department of Health and Human Services, https://www.hhs.gov/about/news/2017/09/29/hhs-accelerates-development-first-ebola-vaccines-and-drugs.html[8]; "HHS sponsors development of two tests for radiation exposure," U.S. Department of Health and Human Services, https://www.phe.gov/Preparedness/news/Pages/biodosimetry.aspx.[9]

While the vast majority of Project BioShield's initial investments were directed towards anthrax, smallpox, and botulism, more recently the program has diversified its portfolio to counter additional threats such as radiation and nuclear agents and viral hemorrhagic fever. As noted above, BioShield is used only for countermeasures to prevent or protect against "material threats" as identified by the Department of Homeland Security and intelligence community. The procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases falls largely outside the auspices of Project BioShield.

Despite substantial progress made since the passage of Project BioShield, significant preparedness gaps remain. These gaps include countermeasures for threats not yet addressed; next-generation countermeasures that are more effective than currently procured products; and insufficient quantities of procured products. To meet these gaps, PHEMCE has created a prioritization framework to guide research, development, manufacturing, procurement, and operational planning.[10] Based on the framework, additional procurements from Project BioShield's Special Reserve Fund (SRF) are projected through fiscal year 2020 for anthrax, botulism, nerve agents, nuclear agents, radiological agents, smallpox, and viral hemorrhagic fevers. Procurements of broad-spectrum antimicrobials for treatment of multiple biothreats and diagnostics for biological threats and radiological/nuclear threats are also planned.[11,12]

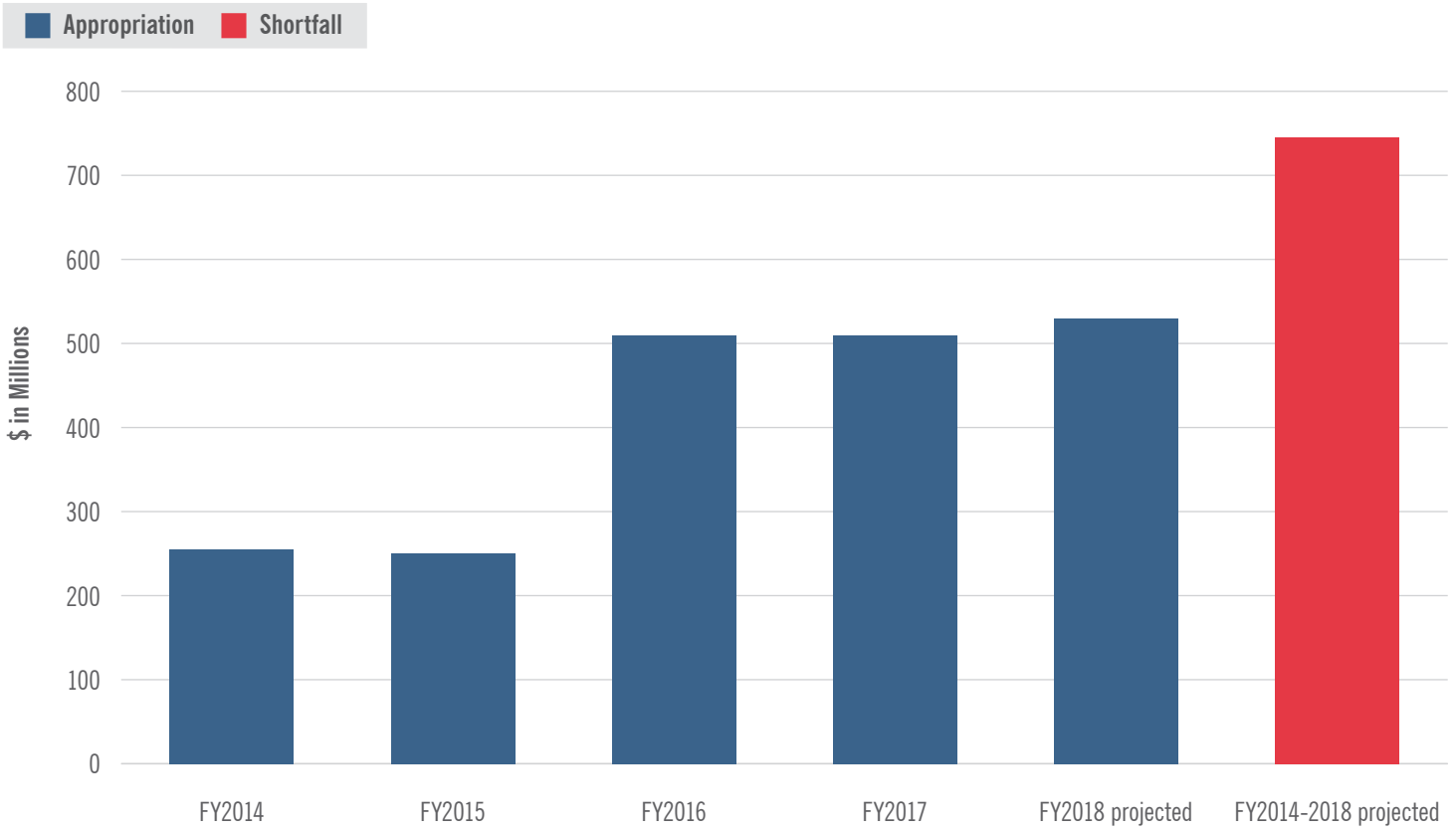
Although it is not the primary responsibility of Project BioShield's SRF, additional procurements will be necessary to replace countermeasures in the SNS whose shelf-life has expired. In the past, HHS has used funding from both the SNS's annual appropriations as well as Project BioShield's appropriations to replenish expiring countermeasures.[13]

Project BioShield Funding History

With the passage of the Project BioShield Act in 2004, the 108th Congress provided an appropriation of $5.593 billion to develop and acquire countermeasures for fiscal years 2004 through 2013. Of this amount, Congress transferred a portion of the advance appropriation to the Biomedical Advanced Research Development Authority (BARDA) and the National Institutes of Health for countermeasure development and influenza preparedness.[14]

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPA) extended the Project BioShield procurement program through FY2018 and authorized appropriations of up to $2.8 billion for fiscal years 2014 through 2018.[15] However, no advance appropriation was provided. As seen in Figure 1, Congress has appropriated $1.525 billion over the first four years.[16] For fiscal year 2018, $510 million was proposed in the president's budget, and $530 million was included in the House Labor, Health and Human Services and Education Appropriations bill.[17] If the House spending level is eventually approved by Congress as-is, it would result in a shortfall of approximately $750 million from the five-year authorized level. As of this writing, Congress has not yet approved final appropriations for FY2018, and Project BioShield is functioning under a continuing resolution, annualized at the FY2017 level of $510 million.

Figure 1 – Project BioShield Funding, Fiscal Years 2014-2018



In light of the public-private partnership necessary to sustain the medical countermeasures enterprise, the dependence on annual appropriations creates uncertainties in the private sector. Developing a new commercial vaccine or drug may take more than 10 years and cost more than $1 billion. Unlike with other therapeutic products, in the case of medical countermeasures, the U.S. government is typically the sole purchaser. As such, companies must take into account not only the technical and financial risks but also the opportunity costs. An authorization subject to annual

appropriations can cause companies to question whether the government is a reliable customer committed to a long-term contractual relationship.[18] This is particularly true in an environment where the federal government has increasingly relied on short-term continuing resolutions to fund the government rather than the traditional appropriations process. Similarly, some manufacturers have stated that an advance appropriation makes it easier to obtain capital from investors.[19]

Specifically, the dollar value and scope of Project BioShield awards to manufacturers have changed significantly since Congress switched from the initial 10-year appropriation to the subsequent annual appropriation. Projects funded under the 10-year appropriation were much larger and funded all late-stage development activities necessary to support potential FDA approval of the countermeasures as well as procurements. For projects funded since Project BioShield has been subject to annual appropriations, BARDA has typically only been able to provide funding for a portion of late-stage development. Additional support has been dependent on future appropriations and subject to availability. This has created uncertainties for companies, which have also seen significantly smaller award sizes.[20]

In 2018, PAHPA will once again require reauthorization, and thus a discussion of the most appropriate funding mechanisms for Project BioShield is urgently needed.

Options for Optimizing Project BioShield Funding

Policymakers could consider different budgeting strategies to stabilize the medical countermeasures ecosystem. Some of these strategies would require adjustments to statutory processes and congressional procedures put in place since enactment of the Project BioShield Act in 2004. For example:

- The most significant restriction is the spending limit (cap) on discretionary budget authority, with automatic enforcement procedures, which were established in the Budget Control Act of 2011 and remain in effect through 2021.
- Beginning as early as 2001, several congressional budget resolutions have imposed various limits on advance appropriations. These limits were codified in statute for FY2014 and FY2015 but have since been adopted procedurally through annual budget resolutions. Most recently, in October 2017, H. Con. Res. 71, the Concurrent Budget Resolution for FY2018, reestablished budget enforcement procedures in the U.S. Senate when considering any measure that would provide an advance appropriation for any discretionary spending account. These limitations are enforceable through a budget point-of-order that can be waived or suspended only by an affirmative three-fifths (60) of the Senate.
- Finally, multi-year funding would need to be supported in the underlying reauthorization of PAHPA, since making funds available for a delayed period of availability may violate House and Senate rules governing unauthorized appropriations.

Congress has, however, recognized the "vital" importance of the medical countermeasures enterprise and endorsed advance funding for this effort, as reflected in the FY2018 House Budget Committee resolution report:

> *Defend Against Bioterrorism. The Constitution requires the Federal Government to provide for the common defense—a function that has implications for health care in a global environment fraught with chemical, biological, radiological, and nuclear [CBRN] weapons. In following this commitment, the budget supports funding to guard against bioterrorism, such as the countermeasure procurement and development activities of the Secretary of Health and Human Services.*
>
> *The Federal Government operates a pathway for medical countermeasures [MCM] to bioterrorism events. When the Department of Homeland Security, in collaboration with the U.S. intelligence community, identifies a CBRN threat, it begins the MCM development and stockpiling process. The linchpin of the process is Project BioShield. Project BioShield uses the Special Reserve Fund to procure and stockpile MCMs that are approved only for emergency use, following their research and development by NIH and the Biomedical Advanced Research and Development Authority [BARDA]. Upon approval by the Food and Drug Administration [FDA], MCMs are shifted to the CDC-managed Strategic National Stockpile. This budget recognizes the collaborative effort in developing MCMs is vital to safeguarding Americans against a bioterrorism attack. As such, it supports adequate, consistent, and advance funding for these activities.*

Beyond congressional appropriations, the Blue Ribbon Study Panel on Biodefense has recommended that BARDA and Congress consider additional incentives to attract industry participation, such as success-based milestone payments and monetary prizes; minimum procurements or advanced market commitments; guaranteed pricing; patent extension; orphan-drug status expansions; wild-card exclusivity; transferable data exclusivity extensions; and priority review vouchers for pathogens that have been determined to be high-priority threats (which were enacted in 2016 as part of the 21st Century Cures Act).[21]

Given the shortcomings of the current annual appropriations structure, options for optimizing Project BioShield funding include:

OPTION 1: FORWARD FUNDING

Forward funding requires the annual appropriations process to make funds available late in the budget year that would be carried forward and remain available in the following year or years. This funding procedure is used in a very limited way today. For example, for programs operated by the Departments of Education and Labor that require program funding prior to the beginning of the federal fiscal year (e.g., school-based programs in which the school year may begin earlier than October), annual appropriations will often forward funds to become available at an interval that starts

on July 1 and are available during at least two fiscal years.

Notably, for congressional enforcement and scorekeeping purposes, forward funding is scored against the budget year in which it is enacted. This means that, absent a waiver, the full amount of forward funding of the BioShield program would be counted against the restrictive annual spending caps. Thus, absent such a waiver, this option is an uncertain and only partial solution to the problem of annual appropriations.

OPTION 2: EMERGENCY FUNDING

Should a CBRN attack occur on United States soil, it would inevitably be followed by a presidential and congressional declaration of a national emergency, followed by appropriated emergency funds. However, providing funding for medical countermeasures after an attack would significantly delay the response. Other mechanisms may be preferable to provide a preventive and more immediate response to an attack.

One option is to use a new mechanism of automatic emergency appropriations. Funds designated as emergency are not subject to the budgetary restraints imposed by the current spending caps. Using emergency funds, the administration and congressional authorizing and appropriations committees would coordinate to ensure adoption of the PHEMCE multiyear budget procurement levels (which would need to be updated for this purpose). Following PAHPA reauthorization and the passage of each subsequent appropriation bill for the duration of the reauthorization, if the appropriated funding did not support the PHEMCE's prioritization and replenishment requirements, expenditures over the appropriation levels necessary to close the gaps would be automatically appropriated and defined as emergency appropriations. A base level of regular appropriations for BioShield would be required in all instances.

The drawbacks of this approach include congressional reluctance to designate funds as "emergency" and not subject to current spending caps. Additionally, the complexity of this model could lead to difficulties in execution.

OPTION 3: ADVANCE APPROPRIATIONS

Project BioShield's initial 10-year funding mechanism was based on advanced funding. As discussed, advanced funding provided for larger, more complete federal investments and greater certainty for private-sector developers of medical countermeasures. However, as outlined above, the budget environment and procedural hurdles are more restrictive today than they were at the time of the original law's enactment, and statutory and procedural adjustments would be needed to restore this mechanism. This option would involve four steps:

- First, budget enforcement procedures addressing advance appropriations would need to be revised as part of a congressional budget resolution (or other legislation, in the absence of a budget resolution). The current FY2018 resolution carries over language from prior resolutions and establishes an aggregate spending limit on advance appropriations ($28.9 billion) for a specific set of accounts identified in the resolution for FY2019 and FY2020. In addition to the aggregate advance appropriations available for these identified accounts, the budget resolution exempts a subset of accounts from any restriction on advance appropriations.[a]

---

[a] The FY2018 budget resolution sets an aggregate amount of $28.9 billion allowed annually for advance appropriations. This aggregate amount has remained unchanged since the FY2010 resolution and the accounts it allows to be advanced funded have remained unchanged since FY2002. They are: Labor, HHS – Employment and Training Administration; Labor, HHS – Job Corps; Labor, HHS – Education for the Disadvantaged; Labor, HHS – School Improvement; Labor, HHS – Head Start; Labor, HHS – Career, Technical, and Adult Education; Financial Services and General Government – Postal Service; and Transportation/HUD – Tenant-based Rental Assistance.

Second, the FY2018 budget resolution completely exempts certain accounts from any limitation on advance appropriations, including The Corporation for Public Broadcasting and certain programs of the Department of Veterans Affairs (Medical Services, Medical Support and Compliance; Veterans Medical Community Care; and the Medical Facilities accounts of Veterans Health Administration).

Project BioShield would need to be exempt from any limitation on advance appropriations, as has been done with select other accounts (namely the Corporation for Public Broadcasting and certain programs of the Department of Veterans Affairs). Alternatively, the budget resolution (or other legislation, in the absence of a budget resolution) could add Project BioShield to the list of advance appropriation accounts, with an adjustment to the aggregate $28.9 billion annual advanced level of funding reflecting the advanced request for Project BioShield.

- Second, adjustments could be made as part of any legislation to increase the budget caps put in place by the Budget Control Act of 2011. Unlike the forward funding set out in Option 1, advance appropriations scorekeeping counts the expenditure against the year in which it becomes available for obligation. As a consequence, with restrictive spending caps established through FY2021, some policymakers may worry that any increase in advance appropriations will reduce flexibility in future budgetary decisions.

  As such, the advanced BioShield appropriation could be exempt from being scored against the spending caps, or the spending caps could be adjusted upward to account for the advanced funding included in the congressional budget resolution. This would reduce the uncertainties surrounding funding in the current BioShield program as well as the concern that this advance funding would count against other federal spending in future years.

- Third, legislative or report language from the authorizing committees could help to make it clear that advance appropriations are authorized.

- Fourth and finally, the BioShield program would need its authorized funds to be appropriated.

This four-step option would restore the original funding mechanism that made Project BioShield so successful.

Future Considerations

In today's global security environment, CBRN threats are omnipresent and growing, and preparedness requires a sustained commitment from both the federal government and private sector partners. To ensure the sustainability of the medical countermeasures enterprise, the federal government needs to demonstrate that developing and procuring medical countermeasures will be a long-term priority for the United States. Advance appropriations offer the greatest stability for the private sector to invest in a high-risk area in which the government is the sole purchaser. Advance appropriations also allow the federal government to better plan for procurement over a longer period of time.

Advance appropriations offer the greatest stability for the private sector to invest in a high-risk area in which the government is the sole purchaser. Advance appropriations also allow the federal government to better plan for procurement over a longer period of time.

Beyond these points, there are additional considerations that deserve attention.

First, it is important that the administration continue to champion Project BioShield. In its recently released National Security Strategy, the White House discussed the importance of combating biothreats and pandemics, but did not mention the need to reinvigorate the medical countermeasures enterprise.[22] As part of the National Defense Authorization Act for FY2017, Congress mandated the creation of a comprehensive National Biodefense Strategy.[23] That effort, currently being led by the National Security Council, will be important in reinforcing support for the procurement of medical countermeasures.

Second, it is important in the future that Project BioShield's Special Reserve Fund not be diverted for other uses given the potential negative signal this may send to private sector partners.

Third, it is incumbent upon the administration to present Congress with their best estimates of how much money will be necessary to procure medical countermeasures over the course of the next few years. As opposed to relying on previous estimates, Congress should utilize a new detailed medical countermeasure procurement budget projection.

Ultimately, sustainable progress in America's medical countermeasures ecosystem depends on leadership, collaboration, and robust communications between the legislative branch, executive branch, and the private sector. Few issues today have greater implications for our national security and public health.

Endnotes

1 Donald A. Henderson, Thomas V. Inglesby, and Tara O'Toole, *Bioterrorism: Guidelines for Medical and Public Health Management*, 1-5, Chicago: AMA Press, 2002.

2 Joby Warrick, "Microbes by the ton: Officials see weapons threat as North Korea gains biotech expertise," *The Washington Post*, December 10, 2017. Available at: https://www.washingtonpost.com/world/national-security/microbes-by-the-ton-officials-see-weapons-threat-as-north-korea-gains-biotech-expertise/2017/12/10/9b9d5f9e-d5f0-11e7-95bf-df7c19270879_story.html?utm_term=.40ae6a84fb72.

3 Bill Gates, "A new kind of terrorism could wipe out 30 million people in less than a year – and we are not prepared," *Business Insider*, February 18, 2017. Available at: http://www.businessinsider.com/bill-gates-op-ed-bio-terrorism-epidemic-world-threat-2017-2.

4 Alliance for Biosecurity, "American Perceptions of Biosecurity Preparedness." Available at: https://www.allianceforbiosecurity.com/biosecurity-public-opinion-poll.

5 Frank Gottron, "The Project BioShield Act: Issues for the 113th Congress," Congressional Research Service, June 18, 2014, 2.

6 Joseph C. Larsen and Gary L. Disbrow, "Project BioShield and the Biomedical Advanced Research Development Authority: A 10-Year Progress Report on Meeting US Preparedness Objectives for Threat Agents," *Clinical Infectious Diseases* 64 (2017): 1430-4.

7 "2017-2018 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan," U.S. Department of Health and Human Services. Available at: https://www.phe.gov/Preparedness/mcm/phemce/Documents/2017-phemce-sip.pdf.

8 "HHS accelerates development of first Ebola vaccines and drugs," U.S. Department of Health and Human Services. Available at: https://www.hhs.gov/about/news/2017/09/29/hhs-accelerates-development-first-ebola-vaccines-and-drugshtml; https://www.phe.gov/Preparedness/news/Pages/smallpox-specialpops-28Sept2017.aspx.

9 "HHS sponsors development of two tests for radiation exposure," U.S. Department of Health and Human Services. Available at: https://www.phe.gov/Preparedness/news/Pages/biodosimetry.aspx.

10 "2016 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan," U.S. Department of Health and Human Services. Available at: https://www.phe.gov/Preparedness/mcm/phemce/Documents/2016-phemce-sip.pdf.

11 Ibid.

12 "Public Health Emergency Medical Countermeasures Enterprises Multiyear Budget – Fiscal Years 2016-2020," U.S. Department of Health and Human Services. Available at: https://www.phe.gov/Preparedness/mcm/phemce/Documents/2017-myb.pdf.

13 Frank Gottron, "The Project BioShield Act: Issues for the 113th Congress," Congressional Research Service, June 18, 2014, 17.

14 Ibid., 7.

15 Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113–5 (2013). Available at: https://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf

16 FY2017 Labor-HHS-Education Appropriations Bill, S. 3040, 114th Cong. (2016). Available at: https://www.appropriations.senate.gov/imo/media/doc/FY2017%20Labor,%20Health%20and%20Human%20Services,%20and%20Education%20Appropriations%20Bill%20-%20S3040.pdf

17 "Appropriations Committee Releases the Fiscal Year 2018 Labor, Health and Human Services, Education Funding Bill," U.S. House of Representatives Committee on Appropriations, (2017). Available at: https://appropriations.house.gov/news/documentsingle.aspx?DocumentID=394995.

18 Robert Kadlec, "Renewing the Project BioShield Act – What Has It Bought and Wrought?" Center for a New American Security, January 2013, 4.

19 Frank Gottron, "The Project BioShield Act: Issues for the 113th Congress," Congressional Research Service, June 18, 2014, 16.

20 Communication with Dr. Gary Disbrow, Acting Deputy Director, BARDA, ASPR, HHS, January 23, 2018.

21 Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, October 2015, 55. Available at: https://s3.amazonaws.com/media.hudson.org/20151028ANATIONALBLUEPRINTFORBIODEFENSE.pdf

22 The White House, *National Security Strategy of the United States*. December 2017, 9. Available at: https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf.

23 National Defense Authorization Act for Fiscal Year 2017, Public Law 114–328 (2016). Available at: https://www.congress.gov/114/plaws/publ328/PLAW-114publ328.pdf

BIPARTISAN POLICY CENTER

The Bipartisan Policy Center is a non-profit organization that combines the best ideas from both parties to promote health, security, and opportunity for all Americans. BPC drives principled and politically viable policy solutions through the power of rigorous analysis, painstaking negotiation, and aggressive advocacy.

bipartisanpolicy.org | 202-204-2400
1225 Eye Street NW, Suite 1000
Washington, D.C. 20005

@BPC_Bipartisan
facebook.com/BipartisanPolicyCenter
instagram.com/BPC_Bipartisan

BPC POLICY AREAS

Economy

Energy

Finance

Governance

Health

Housing

Immigration

Infrastructure

National Security

BIPARTISAN POLICY CENTER

1225 Eye Street NW, Suite 1000
Washington, D.C. 20005
202-204-2400 | bipartisanpolicy.org