

SUMMARY

OF

BLUE RIBBON STUDY PANEL ON BIODEFENSE WORKSHOP

Building a Stronger Public Private Partnership

19 February 2015

OVERVIEW

At the request of the Blue Ribbon Study Panel on Biodefense (“the Panel”), the Alliance for Biosecurity convened a workshop on 19 February 2015 to generate recommendations from industry partners on policy changes that will strengthen national biodefense. Jim Greenwood, BIO President and CEO and a Blue Ribbon Study Panelist attended the Workshop and facilitated the dialogue.

The theme for the Workshop was “Building a Stronger Public-Private Partnership.” A robust and effective partnership among government and industry stakeholders is essential to success. A copy of the workshop agenda and pre-read document are included as appendices. Thirty-four representatives from 21 companies and organizations participated in the Workshop.

This report - prepared by the Alliance for Biosecurity and BIO - summarizes the discussions and recommendations from the Workshop. The recommendations are focused on the following core areas where policy changes could help strengthen the medical countermeasure (MCM) enterprise and sustain a viable development pipeline for critical drugs and vaccines:

- Ensuring adequate and sustained funding
- Increasing transparency
- Streamlining the contracting process
- Promoting consistent, clear and coordinated leadership and implementation
- Exploring novel and effective incentives for industry to develop MCMs
- Improving international efforts on preparedness

“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 economic cost could exceed \$1 trillion for each such incident.” President Obama’s National Strategy on Countering Biological Threats

The overarching context for the Workshop discussions was the significant threat that emerging diseases and bioterror agents present to our nation and the global community. We understood that the Panel was collecting information and testimony on threats during other sessions, so did not focus our discussions in this area. It is important to note, however, that the existing threat is a principal motivator for industry’s commitment to research and developing medical countermeasures. The recent Ebola outbreak highlights the need for MCMs to be on hand to prevent and mitigate disease impact and human suffering, minimize economic effects, and speed our national recovery. Availability of MCMs for Ebola would have reduced deaths in the US and Africa and significantly lessened the economic impact of this outbreak.

The Department of Homeland Security (DHS) has identified 13 chemical, biological, radiological, and nuclear (CBRN) material threats. In the last decade, there have been seven pandemic flu or other serious disease outbreaks. Within the decade of Project BioShield funding (\$5.6 billion), industry responded and, in partnership with Biomedical Advanced Research and Development Authority (BARDA), developed and delivered 12 new MCMs to the Strategic National Stockpile (SNS). Over 12 new MCMs are anticipated to be ready for the SNS by 2018. There are also more than 160 products in the pipeline. Even with these advances there are no medical countermeasures in the SNS for many of the identified material threats. Industry's participation in this mission has been and is essential – industry has the talent, resources, expertise, and commitment needed to work in this unique partnership.

UNDERSTANDING INDUSTRY AS A PARTNER

Creating effective policy measures and incentives to tap the innovative potential of biopharmaceutical companies requires an in-depth understanding of the industry and the realities of business planning. The first Roundtable discussion of the Workshop reviewed the key aspects of business planning. The following points and observations were highlighted:

- In order to survive and thrive, biopharmaceutical companies must make rational business decisions and invest their limited resources wisely. Companies and investors analyze costs, risks, and expected return on investment. An important element of this analysis is identifying and understanding unmet medical needs.
- The shareholders, Boards, and executives of biopharmaceutical companies must see a financially attractive market to gain support for investment in the development of drugs and vaccines with limited or no commercial market. Otherwise the opportunity cost of pursuing MCMs is too high when compared to other commercial products.
- Drug development occurs over a lengthy time horizon (8-12 years) and the risk of failure is a natural, invariable part of the process.
- In the MCM space, development cost can be off-set by government funds that serve as non-diluted capital. But at the end of the development process, things are far less certain—MCM companies need transparency into what the government plans to procure and stockpile. More importantly, the government must maintain these commitments.
- A study from the Tufts Center of Drug Development recently found that the cost of bringing a new drug to market has doubled in the past 11 years to

approximately \$2.5 billion, primarily due to the high failure rate of novel science.¹

- Venture capital and other investors are frequently reluctant to invest in MCMs in light of perceived risks and uncertainties, particularly in terms of the government's commitment to purchase products. Some investors have gone as far as devaluing companies that work with the government on MCM development.
- The shift in 2013 from the initial Project BioShield model (10 years of appropriated funds representing a market guarantee) to essentially an annual appropriations process raises significant questions and increases uncertainty for companies and investors.

SUSTAINING PROGRESS AND INVESTING FOR THE FUTURE

Dedicated commitment and sustained government investment in MCMs is critically important. It is a matter of national security and we must remain vigilant in developing preemptive measures. There is generally no market outside of government procurement for medical countermeasures (MCM). Therefore, industry's involvement in MCM development is predicated on adequate government funding to support not only long, risky development programs but, importantly, the purchase of MCM products. Companies need to be certain that if they develop new MCMs successfully, there will be a robust market through government purchase.

As the Ebola outbreak has demonstrated, emergency supplemental requests at the time of crisis are inadequate to the challenge and vastly more costly than the funds that would have been needed for preparedness. The resources invested in public health and preparedness will pale in comparison to those that are needed if we fail to adequately invest. Drawing parallels to the defense industry sector may be instructive. For decades, the United States has sustained enormous investment to promote defense capabilities and military readiness. As Jeremy Farrar, Director of the Wellcome Trust, aptly commented during a recent meeting on MCMs: "We don't ask for a cheap battleship."²

Unfortunately, a guaranteed marketplace ceased to exist at the end of Fiscal Year (FY) 2013 when the BioShield Special Reserve Fund (SRF) expired and the supplemental pandemic influenza balances were exhausted. Both programs became subject to annual appropriations in FY 2014 and experienced a dramatic decrease in funding. As illustrated in the Attachment *Project BioShield Funding Shortfall*, the amount

¹ http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

² *Enabling Rapid Response and Sustained Capability with Medical Countermeasures to Mitigate Risk of Emerging Infectious Diseases: An Institute of Medicine Workshop*, 26-27 March 2015 in Washington, DC.

appropriated in FY 2014 and FY 2015 for Project BioShield, \$255 million, does not reflect the authorization level passed by Congress in the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), which is \$2.8 billion over a five-year period. Congress should fund the SRF with robust, advanced multi-year funding to give BARDA the necessary flexibility to procure products to improve the predictability and ensure the availability of consistent, robust funding for the development of MCMs.

Pandemic influenza preparedness has also been woefully underfunded by Congress since the expiration of emergency supplemental funding, with \$115 million in FY 2014 and \$72 million in FY 2015. To sustain the current level of preparedness that has been achieved, pandemic influenza must have authorizing language and be appropriately funded at \$400 million annually in order to: (1) advance research and development of next generation influenza technologies, (2) regularly test and evaluate preparedness and rapid response capabilities for known and new pandemic threats, and (3) ensure the testing and replenishment of stockpiles to manage the lifecycle of influenza vaccines, bulk antigen and adjuvant material. Lastly, investment is needed against this high priority national security threat to adequately support the National Strategy for Pandemic Influenza, the HHS U.S. Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Review, and the HHS Pandemic Influenza Plan.

Recommendation: Congress must adequately fund the MCM enterprise in 2016 and beyond. Adequate funding includes:

- \$763M for the BioShield Special Reserve Fund to purchase MCMs, consistent with the \$2.8B authorized over 5 years
- \$400M for Pan Flu preparedness for development & procurement
- \$571M for SNS replenishment at Centers for Disease Control and Prevention (CDC) as requested by the President
- \$522M for Advanced Development at BARDA as requested by the President

Additional funding will be needed in future years for procurement of new MCMs and replenishment of the SNS. Implementing multi-year flexible funding like the original Project BioShield would enhance and energize innovative efforts and strengthen the public-private partnership while allowing the US Government the flexibility to respond to unknown infectious disease threats.

INCREASING TRANSPARENCY

To be an effective partner, industry must understand the priority threats to which the government wishes to be able to respond, and how they intend to respond. Providing enhanced information about national security priorities, preferred delivery methods,

quantities, and procurement commitments will spur focused, effective research and development efforts.

Who Owns the Threat List

Currently, the U.S. Department of Homeland Security (DHS) owns the unmet medical need calculation and threat determinations. Information about what agents are on the material threats list is available, but prioritization of these threats—determined by intelligence information and other means—is classified. This hampers industry’s ability to make decisions about where to invest resources to match the needs of the government. Greater transparency on HHS’ and DoD’s prioritization of threats would increase understanding and likely result in more streamlined preparedness efforts.

Clarity on Product Requirements

Another factor negatively impacting industry’s ability to efficiently contribute to the nation’s preparedness is a lack of clear and detailed requirements for medical products under development. Whether the government prefers a vaccine or a therapeutic, the form such a drug or vaccine may take, and the volume of doses required, are all factors that could contribute to moving products more quickly through development to a point where manufacture and deployment is possible in a short time frame. A target product profile – with some flexibility to cope with scientific uncertainty – would help focus industry’s efforts to match the government’s needs.

Government as Sole Purchaser

Lessening the uncertainty that currently exists on the procurement side of the equation will ensure that needed medical products are available in an emergency. Many biopharmaceutical companies that develop and produce products with exclusively national security or public health preparedness applications—such as anthrax and smallpox vaccines—are small to mid-size operations with a limited number of products and they operate exclusively in the biodefense space. These companies, as well as large companies with a broader portfolio, need more clarity on when and how much of their products will be purchased by their sole customer—the U.S. government. The government must also maintain commitments and contractual obligations related to procurements. Finally, advanced market commitments should not drive prices below market value. It would be unsustainable for any company to remain in the biodefense space if the ultimate return on investment is negative or reduced compared to commercial products.

PREP Act

The Public Readiness and Emergency Preparedness Act (PREP) Act (P.L. 109-148) authorizes the HHS Secretary to issue a declaration that provides immunity from tort liability for claims of loss caused by countermeasures (e.g., vaccines, drugs, products) against diseases or other threats of public health emergencies. The PREP Act provides important protections for manufacturers which make investing and working in this space more attractive. A number of declarations under the PREP Act are set to expire in 2015. The HHS Secretary should extend the PREP Act designations for anthrax, smallpox and other public health threats to encourage rapid production of vaccines and therapeutics to protect American citizens.

Recommendation: HHS and DoD should provide greater clarity on MCM requirements and priorities, including projected quantities and target product characteristics.

Recommendation: HHS should submit to Congress and make public a transparent, updated five year MCM plan and budget for development and procurement on an annual basis.

Recommendation: Extend the PREP Act designations for anthrax, smallpox, and other public health threats to encourage rapid production of vaccines and therapeutics.

STREAMLINING THE CONTRACTING PROCESS

Progress of U.S. government-funded projects is often slowed unnecessarily due to unpredictable funding, a lack of clear communication to industry partners, and a lengthy, confusing contracting process. Drug development entails constant change, and the contracts process should be more nimble to handle changes quickly and effectively.

Flexibility in Contracting

Given the long timeframes associated with the development of a new drug or vaccine, contracts between industry and government agencies need to be imbued with a certain amount of flexibility to allow for changes informed by new information gained within the development process. Allowing companies to shift resources between different potential products throughout the development process will create efficiencies and decrease the likelihood of a company moving down a path that ultimately does not result in a successful product because they were locked into a too-limited contract.

HHS used its “other transactional authority” (OTA) for the first time in a contract with GlaxoSmithKline (GSK) in 2013. This structure can offer increased flexibility and be less onerous than traditional contracting under the FAR. Under an OTA contract, companies

have the ability to move assets in and out of the development process more easily and it can enhance and increase the interaction between a company and BARDA. The OTA structure also results in shared risk between companies and agencies, and could encourage a more cooperative relationship. It is important to recognize however, that OTA is not a panacea for contracting concerns. It could be difficult for a small company to implement, due to lack of resources and breadth of portfolio. Including more flexibility in contracts through the existing structure is not only possible, but practical and necessary, in particular for smaller companies for which OTA may not be a viable path.

Contracting Authority and Review

Timelines for medical product development are already very long—as mentioned above, it can cost \$2 billion and take 10 years or longer to develop a single drug or vaccine. Adding unnecessary bureaucratic steps to an already long process should be avoided. Currently, authority over all BARDA contracts is controlled by the Office of Acquisitions Management, Contracts and Grants (AMCG) in the Office of the Assistant Secretary for Preparedness and Response (ASPR). The existing cumbersome arrangement has created confusion, unnecessary delays, and uncertainty regarding time sensitive countermeasure contracts. Contracting authority should reside within BARDA, the agency that best understands the biopharmaceutical industry.

Additionally, Office of Management and Budget (OMB) review of BioShield procurement contracts is unnecessary and burdensome. When BioShield was created in 2004, the funding was derived from DHS while the program was administered by HHS. At the time, it was necessary for all BioShield procurement contracts to be reviewed independently by OMB. However, now that all BioShield funds are housed at HHS, it is unnecessary and unwise for OMB to review all contracts already approved by HHS and funded by HHS. This extra layer of bureaucracy has slowed critical MCM procurement contracts and made it harder for manufacturers to partner with the USG on countermeasure development.

Recommendation: HHS should get input from industry to make the contracting process more transparent, predictable, and flexible to better meet the changing needs and priorities of MCM drug development programs.

Recommendation: Cost-Plus R&D contracts should include a management reserve to cover unforeseen costs and program changes.

Recommendation: HHS should deploy OTA more frequently, where appropriate.

Recommendation: HHS should return contracting authority from ASPR to BARDA.

Recommendation: OMB review of BioShield procurement contracts should not be required.

**PROMOTING CONSISTENT, CLEAR, AND COORDINATED
LEADERSHIP AND IMPLEMENTATION**

In conjunction with improved transparency and contracting, there is also a need for better coordination among federal departments and agencies involved in the U.S. Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). Health security is a shared responsibility between the federal government; state, local, tribal, and territorial governments; and the private sector. Within the federal government there are many players and partners and Congressional oversight is fractured across multiple Committees.

The existing U.S. government infrastructure responsible for developing and stockpiling the vaccines and drugs essential to any effective preparedness and response plan encompasses numerous government stakeholders. Responsible agencies include ASPR, BARDA, National Institutes of Health (NIH), CDC, Food and Drug Administration (FDA), DoD, DHS, and the White House National Security Council (NSC). These departments and agencies have greatly aided programs in key biosecurity areas, but they must coordinate effectively and eliminate any barriers that may slow or complicate development and distribution of vaccines and drugs.

Speed and efficiency of regulatory interactions between MCM developers and the US government is integral to success. The pathway for appeal when companies hit roadblocks with BARDA, FDA, DoD or other agencies - or when there is a lack of consensus among the agency partners - is not always clear. Some agencies provide poor feedback or rationale for their decisions. This can make it difficult for a company to understand the problem and companies can be afraid to appeal for fear of reprisal. Some companies have experienced a lack of coordination as a product moves into the SNS.

FDA plays a critical role in the regulatory review process. MCM products often face unique regulatory challenges associated with relying on animal models for establishing efficacy, in addition to safety. Ensuring that the FDA's Animal Rule is finalized and applied consistently among Divisions and based on sound regulatory science is critical. Varying and shifting application of the Animal Rule and associated guidance creates risk for industry.

Leadership

Strong leadership within each of the relevant agencies is critical for advancing the MCM pipeline and our level of preparedness and ensuring effective coordination among US government partners. This is particularly important as it relates to the position of the ASPR. A recent report by the National Preparedness and Response Science Board found that the ASPR must better use its statutory authority and responsibility to provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and emergency medical preparedness. ASPR should be far more bold, visible, and effective when carrying out this leadership role provided by statute. Empowered leadership is critical to ensuring the nation's capability to respond to public health crises.³

In addition to strong leaders across the PHEMCE, the reestablishment of the position of Special Assistant to the President for Biodefense (an alternative title may be Special Assistant to the President for Health Security) at the White House would provide cross-governmental leadership, coordination, and continuity. This position previously existed under both President Bill Clinton and President George W. Bush. While the ASPR oversees PHEMCE activities across HHS agencies, there currently is no single entity or person who has a view of all activities occurring across the federal government – HHS, DHS, DoD, USDA, and VA.

Improved Coordination

The U.S. response to the West African Ebola outbreak highlighted issues related to interagency coordination. Companies had been contracting with both DoD and HHS on Ebola MCMs prior to the outbreak. During the response in recent months, BARDA has focused on the development of vaccines while DoD had focused on therapeutics.

In recent years, namely since the passage of the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), the BARDA-FDA relationship has improved. Now that the enterprise has matured, FDA has grown into its role and knows its function in relation to other PHEMCE partners.

One area that still needs attention is transition planning. The lack of CDC guidance for clinicians and state and local health leaders for MCMs entering the SNS and activities related to shelf life extensions are concerning. As initial SNS procurements reach expiration and need replenishment and new products reach procurement stage, additional funds will be needed, but CDC will also need to communicate with BARDA and manufacturers regarding requirements. CDC is also responsible for developing

³ <http://www.phe.gov/Preparedness/legal/boards/nprsb/meetings/Documents/aspr-fswg-report03162015.pdf> (page i)

clinical utilization guidelines, which give health care providers and state/local public health officials guidance on how to use products in the SNS. There are examples where it took four years from the time a product was delivered to the SNS to finalize the products utilization guidelines.

BARDA's Scope

While it was the original intent of BARDA's drafters that, if successful, the agency's scope could be expanded to other areas of work, it should be examined whether BARDA is properly structured and resourced. A holistic examination of the ASPR structure by the Congressional Research Service (CRS) or the Government Accountability Office (GAO) would be useful in determining whether moving BARDA to an operating division under the HHS Secretary would help with contracting and funding issues previously discussed. This review could also assess the proper extent of the role of BARDA in addressing both bio-threat and more classic public health threats. It is vital that this review examine the resources and personnel capabilities that would be needed to achieve an expanded mission within BARDA.

Recommendation: HHS should finalize the guidance on the Animal Rule and apply it consistently.

Recommendation: The White House should establish a senior position responsible for maintaining consistency, coordinating budgeting, and accountability for the MCM enterprise.

Recommendation: ASPR and CDC should work closely to establish utilization guidelines for products entering the SNS.

Recommendation: Congress should commission a study of the BARDA mission, structure, and scope to best define the resources necessary to adequately prepare and respond to known and unknown public health threats.

EXPLORING NOVEL INCENTIVES

As noted above, industry makes investment decisions based on cost, risk, and return. As with all product decisions, companies must weigh the opportunity costs of such work, particularly since there is little to no commercial market for many MCMs. In the biodefense space, there is limited return on investment, which companies must balance with competition for limited internal resources. Lack of a commercial market and unclear government commitments to purchasing makes investment in biodefense extremely difficult and unattractive. BARDA must take on some of the risk and operate

within a framework that accounts for the reality that late-stage MCM candidates may fail.

Project BioShield created a guaranteed market, but with the shift to annual appropriations, that guarantee is diminished and other incentives are needed. These incentives must provide more flexibility in reallocating money within contracts and the implementation of contracts.

A number of incentives were discussed at the Blue Ribbon Panel workshop on medical countermeasures; additional exploration of these incentives to identify the most effective would be beneficial. BIO and the Alliance for Biosecurity will work with leaders at BARDA and other economic and investor thought leaders to convene a group to review and assess potential industry incentives. The goal would be to recommend a basket of incentives that could be leveraged by BARDA and other agencies in working with biopharmaceutical companies of various sizes.

Monetary Prizes

Monetary prizes for the approval or licensure of a MCM could help with pricing predictability for MCMs. Investors could see monetary prizes as a signal of the viability of the value of the marketplace.

BARDA already has the authority to offer such prizes. For example, BARDA and NIH are offering a \$20 million prize for the development of novel diagnostics for antimicrobial-resistant pathogens. In this model, companies must foot the bill for R&D, but it does encourage innovation and represent a market, despite the fact there is still risk for the company.

A monetary prize could be formatted in a number of ways, either as a winner take all lump sum prize for the first company to reach approval; prizes for the first, second, and third products in a given threat area; or the prize as a percentage of a company's investment.

A review of where prizes have been used before (e.g., space exploration) and how they have worked could inform the structure and viability of the use of prizes in the biodefense space.

Minimum Procurements/Advanced Market Commitments

In the area of public health vaccines, GAVI has provided a market for vaccine purchases for the developing world by committing to purchasing a specified number of vaccines. Such an advanced market commitment rewards innovator companies with a

guaranteed market at competitive prices. BARDA and DoD could apply these principles to purchases for MCMs in order to provide companies with some certainty that their investment will pay off once the procurement stage is reached.

Priority Review Vouchers (PRVs) for Pathogens on the Material Threat List

Congress recently amended the Tropical Disease Voucher Program to include Ebola/Filovirus, providing the same incentive for the 13 pathogens identified by DHS as a material threat could incent additional MCM development. A priority review voucher provides a shorter review period for an FDA application, accelerating deployment to market. The voucher can also be sold thereby providing direct financial benefit. The structure of current voucher programs would limit the number of countermeasures eligible because products with commercially approved indications would not qualify.

Other Incentives

Other incentives that were noted during the Workshop:

- Patent extensions
- Orphan drug status
- Wild-card exclusivity

Recommendation: Convene a workshop during 2015 (co-hosted by BARDA, BIO, the Alliance for Biosecurity, and other experts) to actively discuss and prioritize additional industry incentives.

**IMPROVING GLOBAL THREAT AWARENESS AND INCREASING
GLOBAL EFFORTS ON MCMs**

The United States has been the global leader in medical countermeasure development and stockpiling. Indeed, there is little MCM preparedness or stockpiling activity occurring outside the United States, causing other countries to rely on the US SNS. In the effort to protect the world from CBRN and pandemic events, a hegemonic approach will not be adequate. Having a market outside the United States would be very helpful for MCM developers, as a larger market would provide companies and investors with additional market reassurance.

While the United States has made progress against a number of threat agents and pathogens to date, the United States does not have the capacity to protect our own population, much less serve as the world's MCM reserve. In an increasingly globalized world, CBRN threats, pandemic influenza, or emerging infectious disease can spread

rapidly and without warning. CBRN and other disease threats are global in nature. The United States could play an important role in promoting an international market and, where possible, facilitating regulatory harmonization for MCMs through the Global Health Security Agenda (GHSA) and other means.

The recent Ebola outbreak in West Africa has demonstrated the need for greater global focus and efforts on preparedness for CBRN and infectious disease threats. When Ebola reemerged in December 2014, there were no vaccines or therapeutics available in the United States or elsewhere. The outbreak also demonstrated how countries can successfully cooperate in response; however, efforts to build capacity and systems and not just respond to specific pathogens as they emerge must be sustained between outbreaks in order to more effectively prevent, detect, and respond to global threats.

Canada, the United Kingdom, and Israel have also been doing some work in this space, but not nearly to the scale of the United States. In addition, the US DoD does have agreements with other countries (e.g., Canada) for the co-funding of some development programs. These agreements may be a good starting point for discussions of greater global activity. Additionally, Japan has plans to replicate the U.S. PHEMCE model.

Currently, there are three specific challenges for international markets for MCMs:

- The US government's Emergency Use Authorization (EUA) processes to enable the purchase of unlicensed drugs prior to an event are limited and are not replicable in other countries. In other countries, there are regulatory mechanisms for the use of unapproved products. However, it is often difficult to purchase large amounts of products that are meant for use by a specific patient population, as prescribed by a provider (e.g., special access in Canada, temporary use authorizations (ATU) in France).
- The markets in other countries are very small and the international market is limited. Outside the United States, the market tends to be for militaries only.
- The threat level varies by country. The UK's top ten threat list looks very different from France's even though they are neighbors. There is a lack of regional discussion of threats and joint procurements (regional stockpile markets). It would be helpful for the US government to facilitate these regional dialogues.

The World Health Organization (WHO) International Health Regulations (IHR) rely on self-assessments by member countries and recently only 30 percent of countries reported "being prepared" according to IHR standards. The goal of the GHSA, a collaboration among countries, international organizations, and civil society that was introduced in February 2014, is to strengthen health security infrastructure around the

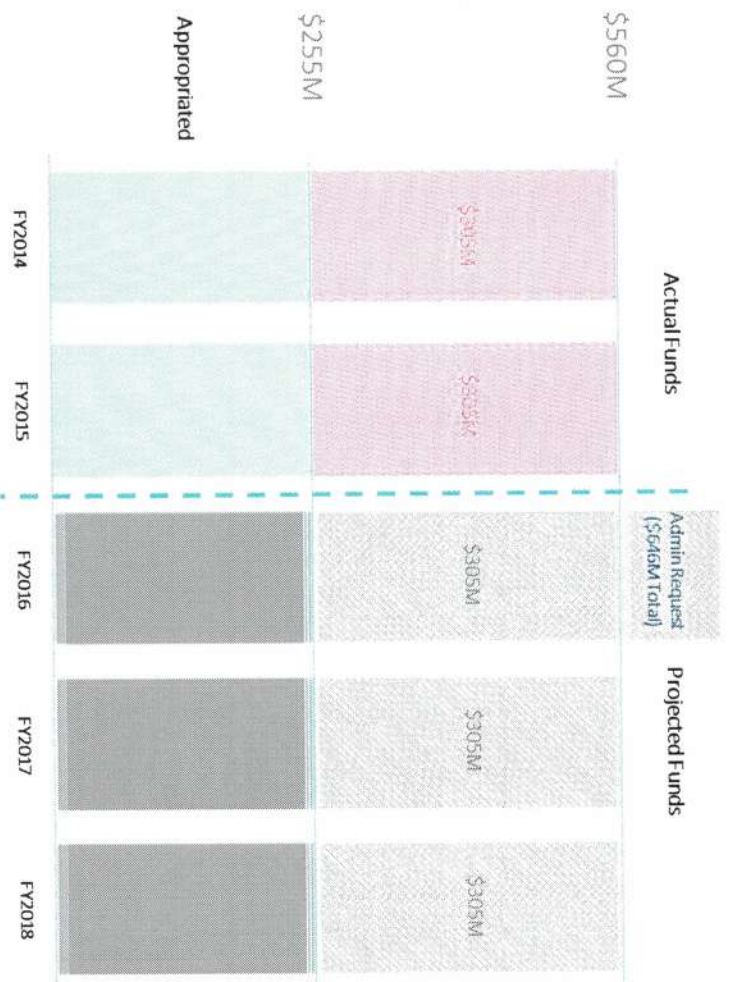
world and increase the ability of the international community to prevent, detect, and respond to infectious disease threats, thereby spurring progress toward full implementation of the IHR. The GHSA sets five year targets for national frameworks in 12 areas, including biosafety and biosecurity, immunization, national laboratory systems, real-time surveillance, public health workforce development, and MCM and personnel deployment.

The WHO could facilitate regional threat assessments and regional stockpiles. In response to the worldwide fear following the Ebola outbreak, WHO will be convening a meeting in 2015 regarding the creation of a global market for MCMs; industry should be involved in this meeting in order to ensure policy recommendations from the meeting do not disadvantage manufacturers.

Recommendation: The USG should build international threat awareness and consensus on priorities via international collaboration (for example, the Global Health Security Agenda and the ASPR International Health office).

Recommendation: The USG should encourage international stockpiling by helping facilitate regulatory pathways and joint purchasing for international procurement of MCMs.

Project BioShield Funding Shortfall



Funding Shortfall

\$1.53B

- \$2.8 billion authorized by Congress over 5 years
- On track to appropriate less than 50% of authorized level
- Will result in numerous national security MCMs lost or cancelled

MCMs lost:

- Smallpox vaccine
- Anthrax vaccine
- Ebola vaccine
- ARS therapy
- Rad nuke treatment
- Antimicrobials