PREPAREDNESS LEADERSHIP COUNCIL INTERNATIONAL

A changing global threat environment, coupled with increasingly interdependent societies and aging infrastructure, is a dangerous combination that must be addressed by today's preparedness leaders.

June 2019

Biodefense Roundtable

Implementation and Operationalization of The National Biodefense Strategy

Dana Saft

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Implementation and Operationalization of The National Biodefense Strategy

By Dana Saft

The Preparedness Leadership Council International

The Preparedness Leadership Council International (PLC), is a thought leadership group comprising insider practitioners and opinion leaders who offer advice and recommendations on topics relevant to emergency planners, responders, receivers, local-state-federal authorities, nongovernmental organizations, and the private sector. Focusing primarily on prevention, protection, response, recovery, and mitigation, the PLC is tasked with developing quantifiable and quantitative feedback from surveys and roundtable discussions that is gathered from and shared with a broad multidiscipline, multi-jurisdictional audience of operational professionals and policy advisors. Information shared via the publications: DomesticPreparedness.com (online and mobile), *DP Weekly Brief* (email newsletter), and the *DomPrep Journal* (PDF download).

Domestic Preparedness

DomPrep is an information service for the preparedness and resilience community. Created in 1998, offers content – provided by practitioners and subject matter experts – to tens of thousands of first responders, medical receivers, emergency planners, local-state-federal authorities, nongovernment organizations, and private-sector professionals.

Note: All comments provided in this report reflect the opinions of the individuals and do not necessarily represent the views of their agencies, departments, companies, or organizations. Quotes within the report without acknowledgement were made anonymously by survey responders.

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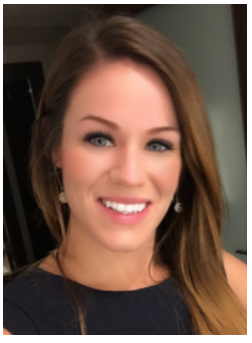

Dana Saft, an Associate at Booz Allen Hamilton, possesses 10 years of program management and technical experience supporting the multiple federal agencies and commercial industries. Currently, she provides contractor support to assist with managing the Department of Homeland Security's (DHS) University-led Centers of Excellence (COEs) that conduct next generation research in the areas of food security, agriculture defense, biodefense, and critical infrastructure resilience. Prior to supporting DHS, she provided program management support to large scale research and development programs. She has a Bachelor of Science in Chemistry Pre-Health from Radford University and a Master of Science in Biodefense from George Mason University. She is active in her Washington, D.C. community and is a member of the Junior League of Washington.

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ACKNOWLEDGMENTS

The Preparedness Leadership Council was truly honored to host a roundtable in October 2018 at the Booz Allen Hamilton Innovation Center, in Washington, DC. During that event, Dr. Robert Kadlec, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS), presented his overview on the President's National Biodefense Strategy. I am pleased to present the meeting readout as a report that will be distributed to preparedness and resilience professionals.

This report would not be possible without the support of many participants, most significantly the ASPR office, including Dr. Kadlec, Theresa Lawrence, Ph.D., CAPT, USPHS, Director, Division of Biosafety, Biosecurity, and Countering Biological Threats, Office of Policy and Planning, and Jack Herrmann, M.S.Ed., N.C.C., L.M.H.C., the Deputy Director of the Office of Policy and Planning. Also, my thanks to Marco Bourne, Joseph Nemmich, Dana Saft, and David Sulek at Booz Allen Hamilton for their sponsorship, support, and guidance assembling this roundtable and report. Additional appreciation goes to the 20 roundtable participants and more than 600 respondents to a nationwide survey from which key data points were extracted.

This is not the PLC nor DomPrep's first report in the biodefense space. In addition to many articles on biodefense, I published the following reports: Advancing Technology in Biological Surveillance and Detection in September 2012; BIODEFENSE. The Threat, the Cost & the Priority in June 2013; and Optimal Biothreat Preparedness: Impeded by Deficits in Funding, Training & Risk Communication in March 2015.

What is different today can be summed up in one word: leadership. This new biodefense strategy is a multi-departmental effort that brings seasoned practitioners together to develop and execute a multilayered plan. As Executive Director of the Preparedness Leadership Council and Publisher of DomesticPreparedness.com, I believe and hope that this is not another half-hearted attempt to address a critical problem, but one that truly comes to grip with this existential threat to our nation's security.

Martin D. Masiuk
Executive Director
Preparedness Leadership Council International

SUMMARY

The Preparedness Leadership Council (PLC) and Domestic Preparedness (DomPrep) hosted a roundtable to discuss the National Biodefense Strategy (released 18 September 2018), on 17 October 2018 in Washington, D.C. The goal of this meeting was to discuss the key operational challenges, integration, and resourcing (both financial and technical) needed for effective implementation.

The National Biodefense Strategy is directly aligned with the 2018 National Security Strategy. Explicitly, Pillar One of the 2018 National Security Strategy calls for protecting "the American people, the homeland, and the American way of life."[1] As noted in the National Biodefense Strategy, a component of this goal can be achieved by detecting and containing biothreats at their source, supporting and promoting the responsible conduct of biomedical innovation, and improving emergency response.

The National Biodefense Strategy highlights the president's commitment to protect the American people, "and establishes objectives to effectively counter threats from naturally occurring, accidental, and deliberate biological events."[2] This strategy is intended to guide innovation and collaboration beyond the federal government. The president is targeting this strategy for action by state, local, territorial, and tribal (SLTT) entities, practitioners, scientists, educators, and industry.

This report is a meeting readout. It relays the sentiments of the many experts who participated but is not an exhaustive analysis of the recommendations and how they should be implemented. It is meant to lay the groundwork for the next steps, which key leaders and policymakers should consider. The information relayed herein is generally reflective of the opinions voiced at the meeting as well as the survey respondents, though any given statement should not necessarily be viewed as consensus.

Key Challenges:

- Creating a sustainable market and infrastructure
- Advocating for sustainable funding
- Effectively utilizing and sharing data

[1] The Department of Defense. (2018). "Summary of the 2018 National Defense Strategy: Sharpening the American military's competitive edge." https://dod.defense.gov/Portals/1/Documents/pubs/2018-National-Defense-Strategy-Summary.pdf

[2] The President of the United States. (September 2018). "National Biodefense Strategy." https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf

STRATEGY OVERVIEW

President Donald J. Trump signed into effect the National Biodefense Strategy on 18 September 2018. This strategy includes five goals associated with, "strengthening the entire biodefense enterprise and establishing a layered risk management approach to countering biological threats and incidents."[3] The 2018 National Biodefense Strategy replaces Homeland Security Presidential Directive 10 (HSPD10): Biodefense of the 21st Century[4] and Presidential Policy Directive 2 (PPD2): The National Strategy for Countering Biological Threats.[5] This new strategy looks at deliberate, natural, and accidental events impacting humans, animals, plants, and the environment. Over the course of the past decade, threats have changed. This change in the threat landscape has created an explosion of biotechnology and science that can be used by a broader range of actors, including "do-it-yourself" biologists. The strategy is both comprehensive and focused, with a large number of objectives and sub-objectives coming together to form a truly national plan. The strategy's high-level goals are represented below:

> *"Whether you are a democrat or republican, a biological threat affects us all."*
>
> —DR. ROBERT KADLEC
> Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS)

- Goal 1: Enable risk awareness to inform decision-making across the biodefense enterprise.
- Goal 2: Ensure biodefense enterprise capabilities to prevent bioincidents.
- Goal 3: Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents.
- Goal 4: Rapidly respond to limit the impacts of bioincidents.
- Goal 5: Facilitate recovery to restore the community, the economy, and the environment after a bioincident.

[3] The President of the United States. (September 2018). "National Biodefense Strategy." https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf

[4] The White House. (28 April 2004). "Homeland Security Presidential Directive 10 (HSPD10): Biodefense of the 21st Century." https://fas.org/irp/offdocs/nspd/hspd-10.html

[5] Homeland Security Digital Library. (9 December 2009). "Presidential Policy Directive 2 (PPD2): The National Strategy for Countering Biological Threats." https://www.hsdl.org/?abstract&did=31404

This strategy is of great national security interest and economic importance. By making wise investments, the nation will improve its national security through addressing pandemics and other public health threats. The U.S. biodefense enterprise promotes risk awareness based on both intelligence and biosurveillence techniques. It looks at prevention beyond the use of treaties, with a heavy emphasis on a culture of responsibility: the assembly of beliefs, attitudes, and patterns of behavior that can support, complement, or enhance existing operating procedures, rules, and practices. In order to be prepared, the biodefense community must work together to understand current and emerging biothreats, whether they are natural or malicious. The government needs to come to agreement on priorities and begin longer-term and next generation projects immediately. Support for this should be promoted globally, with the United States being more forward leaning – perhaps by more heavily utilizing collaboration through the Biological Weapons Convention and scientific circles. To this end, there must be rapid and effective innovation in this space.

Figure 1: Do you believe there is a credible homeland security threat from a biological event – either naturally occurring or manmade – in the near future?

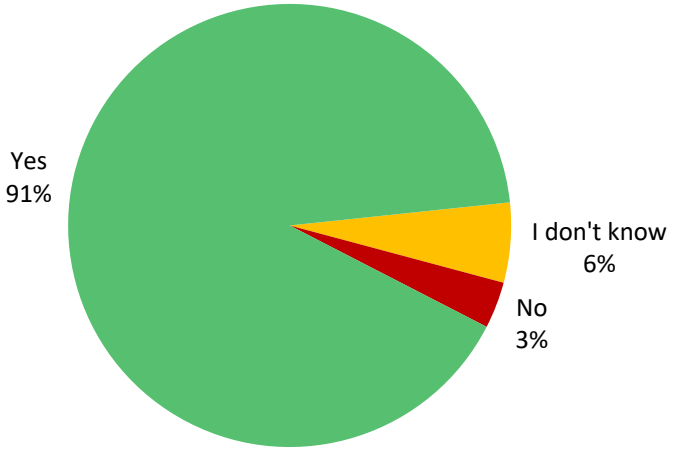
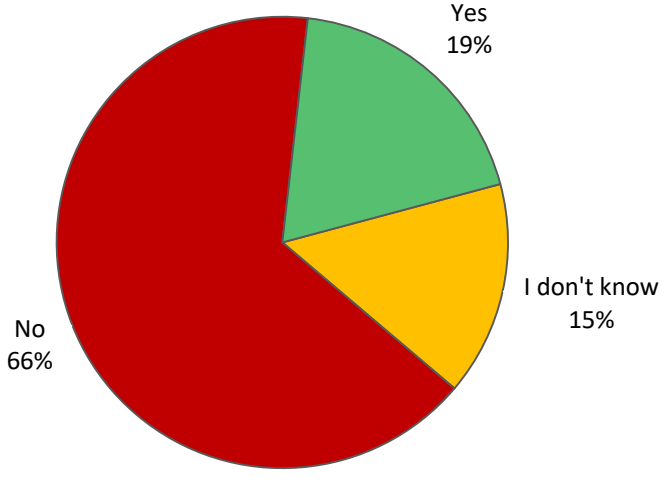


Figure 2: If you answered yes to Question 1, in your professional opinion, is your jurisdiction prepared for such an event?



IMPLEMENTATION OF STRATEGY RECOMMENDATIONS

As a result of releasing the strategy, all Departments and agencies with responsibilities pertaining to biodefense are being asked to identify programs, projects, and activities that contribute to biodefense. The information collected will lead to the identification of gap areas. The national security advisor serves as the lead for policy coordination and review, and will provide strategic input and facilitate policy integration for federal biodefense efforts. This collection of data is long overdue. Given the nature of biological threats, responsibilities and authorities relating to biodefense are scattered among several departments and agencies. An organized understanding of current efforts will help to enhance advocacy for funding as well as to streamline efforts.

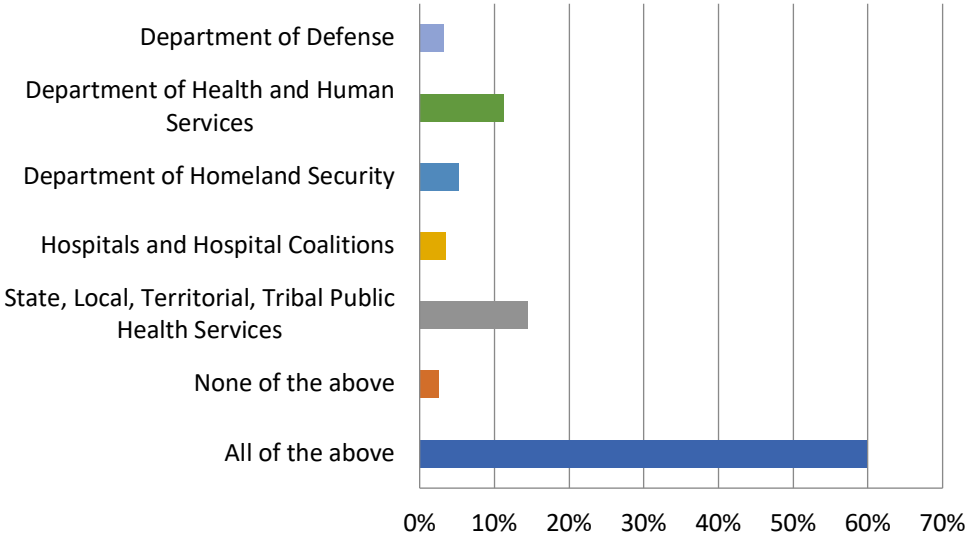
In an effort to better sync current and future projects, key stakeholders need to better understand the gaps and challenge areas. These may be obtained either through integrated product teams, directly received from front line responders in the field, acquired through means of intelligence or reasonable likelihood of a potential threat, or gathered through literature analysis such as the Quadrennial Homeland Security Review or documentation produced by the Blue Ribbon Panel.[6] By better understanding the challenges and threat landscape, requirements can be assigned to the appropriate departments or agencies and evaluated to determine if private industry or academia would be better positioned to address them.

[6] Blue Ribbon Study Panel on Biodefense. (2019). https://www.biodefensestudy.org/a-national-blueprint-for-biodefense

INTERAGENCY COLLABORATION

In science, collaboration is key. A diverse set of experts and non-experts taking a multitude of approaches can ultimately lead to breakthrough discoveries. This does not mean every approach should be new. Biodefense efforts can capitalize on current federal agency efforts such as those from the Department of Defense (DOD), Department of Homeland Security (DHS), Department of Health and Human Services (HHS, including the Centers for Disease Control [CDC] and the National Institutes of Health [NIH]), and United States Department of Agriculture (USDA). Leaders from each respective department should encourage collaboration among their counterparts. This will not only promote the exchange of ideas, but also assist in fostering relationships and advancing the workforce. It would be beneficial to understand what made specific programs successful or unsuccessful in order to make refinements based on the lessons learned.

Figure 3: Who would you look to for leadership should a biological event occur?

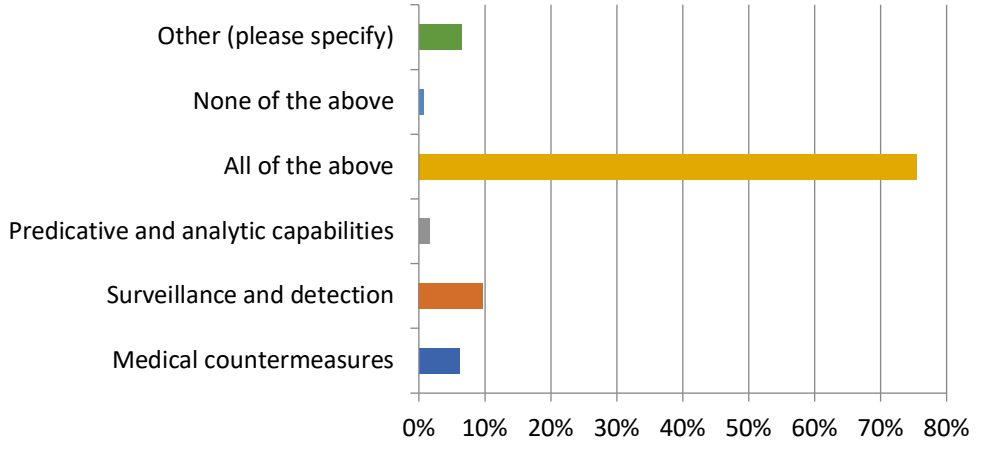


On a much smaller scale, the interagency is collaborating on public health issues such as the opioid crisis. Examples include efforts such as successful data sharing, expansive training among a diverse set of individuals, and resources successfully being allocated and shared

among many groups. The participants highlighted the successful collaboration and partnerships between the USDA's Agriculture Research Service (ARS), DOD's Defense Advanced Research Projects Agency (DARPA), HHS's Biomedical Advanced Research and Development Authority (BARDA), and the U.S. Food and Drug Administration (FDA), which have a vested interest in each other's efforts to advance product development and innovation. Members of the discussion noted that, although these efforts are on a smaller scale, they can serve as examples to address the entirety of the National Biodefense Strategy.

A whole of government approach involves collaboration within and among departments and agencies. A recommendation is for departments and agencies to assign personnel to a designated committee (detail-ees) and to continue to engage stakeholders to maintain engagement. This committee of engaged individuals (the Biodefense Coordination Team) should meet weekly or biweekly, as necessary. Engagement through the BCT will ensure accountability. It is critical for all agencies to have an awareness about the location of resources.

Figure 4: Where do you believe the federal government should focus its priorities?



Federal departments and agencies are reporting programs, projects, and activities, identifying resources allocated to biodefense, identifying gaps and challenges, and assessing the extent to which the goals and objectives of the strategy are being met. The BCT will take the information from each department and agency and synthesizes it into a Biodefense Assessment. The Biodefense Assessment will form the basis of Joint Policy Guidance, issued

by the National Security Council, to address federal biodefense priorities. Additionally, the Blue Ribbon Study Panel has recommended the Office of Management and Budget to be involved throughout the establishment of the process to collect information on the current biodefense efforts[7].

Survey respondents suggested that, along with the priority areas identified in survey Question 4, the government should also focus on training emergency responders as well as the average citizen, increase information dissemination (when appropriate), and make additional investment in the local public health infrastructure. HHS held a public meeting[8] on April 17 to learn about nonfederal biodefense priorities.

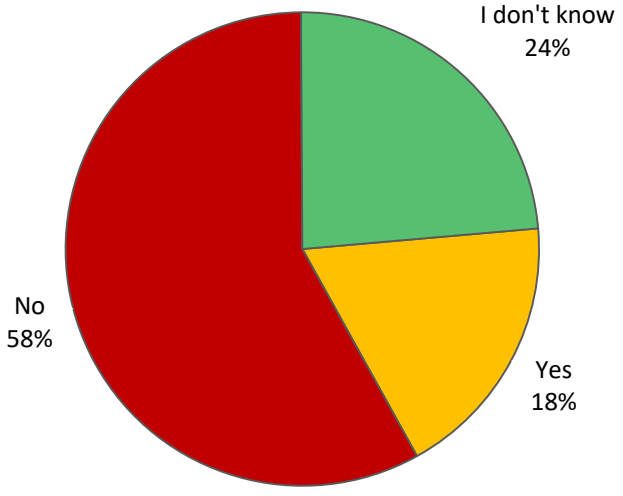
[7] Blue Ribbon Study Panel, Budget Reform for Biodefense (2018), https://www.biodefensestudy.org/Budget-Reform-for-Biodefense-Feb-2018.htm

[8] Biodefense Summit Implementation of the National Biodefense Strategy (2019) https://www.phe.gov/Preparedness/biodefense-strategy/Documents/summit-detailed-ag-508.pdf

FOSTERING PARTNERSHIPS WITH THE INDUSTRIAL BASE

Appreciating the talent and level of innovation that the private industry can bring to addressing biodefense challenges is crucially important. Even more critical is the government's ability to know *when* and *how* to leverage the capabilities of the private sector. As with other technological domains such as cybersecurity, innovation in the biotechnology domain is exponentially growing.

Figure 5: Do you believe the private sector, especially the medical industry, partners effectively with government agencies for research and development?

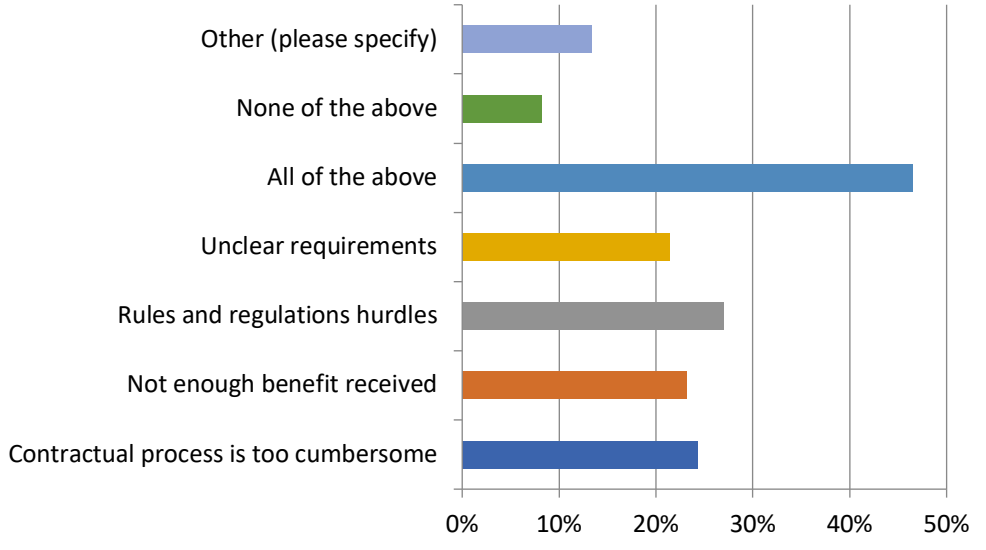


In instances where a market does not currently exist for specific technology – yet the government has requirements – the government must foster interaction with industry on multiple levels. This includes communicating industry requirements that are easily understood, declassifying them when appropriate, and establishing mutually beneficial relationships. Traditional means of advertising requests for information or requests for proposals should be revitalized. The use of other contractual vehicles should also be assessed. Many companies in the private sector are small to medium sized and are not used to conducting business with federal agencies. The traditional approach to contracting and incentivizing may not be as

appealing to these types of companies compared to those that are larger and have experience with government contracting.

A significant amount of survey respondents concluded that the private industry does not partner often with the federal government due to the "hype effect." When a public health concern or threat is highly publicized, this almost creates an instant market. However, the downside to this is that once the hype has subsided so does the interest from both parties. The government needs to determine how to be proactive prior to the "hype effect" as well as to sustain (if needed) the interest in the concern or threat area.

Figure 6: If you answered no to Question 5, which of the following applies? (Choose all that apply)

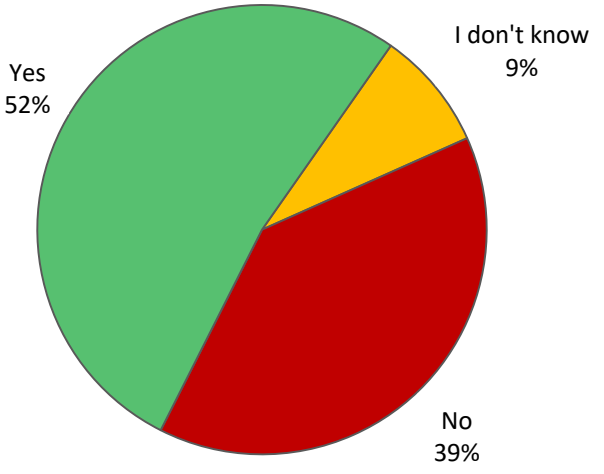


The Defense Production Act (DPA) of 1950 allows the president the authority to influence domestic industry in support of national defense. Since its inception, the DPA has been broadened to include activities beyond military preparedness, such as enhancing domestic preparedness, response, and recovery.[9] Considering the current DPA, participants at the biodefense roundtable suggested an analysis of the present and future states (of the authorities). An assessment of lessons learned from engaging with the private industry should also be considered. Furthermore, the National Defense Executive Reserve (NDER) was authorized

[9] Congressional Research Service. (20 November 2018). "The Defense Production Act of 1950: History, authorities, and considerations for Congress." https://fas.org/sgp/crs/natsec/R43767.pdf

under the DPA – and is administered and evaluated by the Federal Emergency Management Agency (FEMA) – for the purpose of providing a reserve of highly qualified individuals from industry to serve in civilian positions within the federal government during a national emergency.[10] The roundtable participants recommended the potential utilization of the NDER more regularly, not just in instances of emergency. If that is acceptable, the NDER could become agile, adaptable, and sustainable (with adequate funding and continuous training and engagement). Legacy investments have the potential to build momentum for innovation. A foundation that could fund this continuously – instead of only in times of national emergencies – has the potential to be more successful and have added value.

Figure 7: Has your organization trained and exercised for such an event?



Participants also agreed that the relationship with the private sector should increase. A plan should be developed on how to engage with industry as well as state and local governments and how to include them going forward. Participants agreed with the realization that the government does a poor job of engaging pre-event with industry and academia. Establishing an engagement plan that promotes continuous communication would help build partnerships and inform about problems ahead of an event.

[10] Federal Emergency Management Agency. (1 August 2007). "Interim guidance for the National Defense Executive Reserve (NDER) Program." https://www.fema.gov/media-library/assets/documents/15720

SPURRING INNOVATION

Capacity and infrastructure building is crucially important. The government must do this in areas that are not necessarily attractive to private industry but are essential to protecting the homeland. For example, participants felt that the reason there is not a large competitive technology for biosensors is that the government is the only market for them. Unrealistic government expectations for perfection stifle innovation. This model is not productive. There is a need to work across industry and the public sector to establish trust and relationships, which in turn lead to information sharing and further innovation.

The U.S. government should promote and spur innovation in the biodefense sphere, specifically pertaining to intelligent business practices such as flexible manufacturing. There are many ways in which this could be accomplished and allow for sustainability. For example, the DOD has established Advanced Development and Manufacturing (ADM) facilities and capabilities. These ADMs are privately owned and operated, with the ability to surge if needed to host production and manufacturing of products that assist with national security in times of emergency. In late 2016, the DOD announced the opening of the Medical Countermeasures ADM, in Alachua, Florida.[11] This partnership with the pharmaceutical industry allows for the ability to more quickly and less expensively produce countermeasures. Likewise, HHS through BARDA has funded Centers for Innovation in Advanced Development and Manufacturing. BARDA currently funds three Centers of Innovation.

> *"We need to work as a whole of government and protect all Americans, but we need to think innovatively and leverage partners to achieve this."*
>
> —DR. ROBERT KADLEC
> Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS)

[11] Clark, Anthony, & Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense. (20 December 2016). "United States Department of Defense expands medical counter measures capabilities." https://www.jpeocbd.osd.mil/team/news-story/2016/12/20/us-dod-expand-medical-countermeasure

These centers are built on the public-private partnership framework and promote innovation, research, and development, as well as training. The mission of these centers:

> *will help to support and develop the next generation of the medical countermeasure development workforce through training opportunities for current and future industry and government scientists. Most importantly, these centers provide support during public health emergencies, offering manufacturing surge capacity against emerging infectious diseases or unknown threats, including pandemic influenza.*[12]

A suggestion by the biodefense roundtable participants included that HHS should consider the use of contract manufacturing organizations (CMOs) as an adjunct. Participants believe that research demonstrates that having a CMO on standby for use when needed is more cost beneficial than a government built and maintained manufacturing capability. However, it was noted that CMOs are underutilized and under addressed, and capacity will often be a concern. Both the DOD and HHS are exploring how to better use CMOs, which can be further optimized based on the actions taken in support of the National Biodefense Strategy.

By utilizing advanced manufacturing facilities and being more strategic as to what actually needs to be produced (e.g., vaccines can be diluted and still be potent), the government can decrease unnecessary costs as well as be more efficient in times of need. Of course, once a product is developed and produced, it also needs to be sustained. The participants remarked that the government maintains a stockpile, yet often experiences difficulty in having it readily available at the proper location at the right time (supply chain). In the past, the nation's biodefense strategy has been viewed as a public health problem rather than a supply chain problem. However, the strategy needs to include the whole process, which requires better analysis and implementation.

The ability to agree and have an understanding that the government does not always have to "chase perfection" (i.e., "good enough" is also a solution) fosters innovation within the manufacturing industry. Participants highlighted the importance of leveraging lessons learned from successful examples of higher innovation as they pertain to addressing immediate needs. DRIVe, the innovation division within BARDA is supporting innovation and research in early recognition and diagnosis for sepsis and Early Notification to Act, Control, Treat (ENACT)

[12] United States Health and Human Services, Public Health Emergency. (2019). "Department of Health and Human Services' Centers for Innovation in advanced development and manufacturing." https://www.medicalcountermeasures.gov/barda/core-services/ciadm.aspx

program, which is leveraging health technology to allow patients to be more aware of their health.[13] BARDA is working with DARPA as a transition partner with these efforts. Examples such as these – where agencies leverage mutual interests to create a market and influence innovation in the life sciences to address current and emerging biological challenges – are showing immediate impacts.

Biodefence Working Group Roundtable, Washington D.C., October 2018

[13] United States Health and Human Services, BARDA DRIVe. (2019). https://drive.hhs.gov

OPERATIONALIZING THE STRATEGY

Strategic Communications, Information Sharing, and Associated Technology

Engaging the public is critically important for the adoption of this strategy where it pertains to civilians. Again, similar to fostering relationships with the private sector, the government also ensures that the general public is also benefiting from the engagement. In order to allow for open communication, an understanding of the most beneficial communications platforms is needed. It is equally important to grasp how different communication resonates with different populations. There are a multitude of studies that depict this as well as public health communication lessons learned. It is essential that strategic communications be performed effectively as it has a direct relationship to how receptive the public will be to government cooperation and collaboration.

Recommendations from the roundtable participants include taking into account the public's role and making information more accessible to the public. It is necessary to establish an experienced marketing team to build transparency and engage people in all generations. Buy-in from the public would build trust in the government, especially in the current digital age. A key avenue for engaging the public in biological threats is through FDA/CDC recalls. However, biological issues do not garner the same public attention as other types of disasters. The construction of these educational campaigns need to be successful in reaching a broad audience (e.g., leverage social media, create catchy slogans). The message must be as appealing to older generations as to younger generations. This leads to the question of how to create a market for technology that is directly personal or dually beneficial. Until a market is created, industry will not develop the products that could assist with biodefense efforts.

Participants considered other areas in which data could be harnessed. This included the idea of partnerships with the healthcare industry. Considering that healthcare plans own provider networks, participants indicated that perhaps companies could begin looking at this data for trends and detecting early indicators of a biological threat or hazard. The pharmaceutical industry is constantly innovating and changing. As the healthcare industry evolves, trends can be examined to determine where the information is being reported and stored.

Enabling the Use of Technology

There has been a growing acceptance for personal health monitoring devices and other technology that employ indicators to help people understand their daily health and the environment. Self-provided information is another possible resource that can be better utilized (e.g., StreetRX[14] for illicit drug use). This would be done in such a way that the information could be freely shared while maintaining user privacy. This information could be used as an early indicator for anticipating when a potential public health crisis may be expected.

In terms of capability for using data and detecting threats, environmental surveillance (e.g., Biowatch) was specifically cited. Even though Biowatch is not always mentioned in a positive light, it is still a valuable resource. Both DHS and DOD should work collaboratively to enhance this capability and reduce the likelihood of false alarms. By utilizing a top-down process for product development, the right people have the authority to make decisions especially under time-sensitive and urgent circumstances. Going forward, the participants recommend this process to advance Biowatch or similar capabilities. As an approach to modernize technology, participants noted that the Public Health Medical Countermeasure Enterprise[15] (PHEMCE) is also being reorganized.

Ensuring Effective Usage of Data

One of the most important and popular aspects of biodefense is biosurveillence. In design, the current biodefense model/framework is considered good, but most agencies lack the willingness or ability to share raw data. As such, a functional solution is needed to promote information sharing between agencies and experts to interpret the data. Many agencies have established mechanisms for data sharing within their respective organizations or only with another single entity. The Department of Veterans Affairs, the National Biosurveillance Integration Center, CDC, and Defense Threat Reduction Agency have already established these. Participants agreed that agencies need to get to a point where they can use the data for action and gain additional data input from the private sector.

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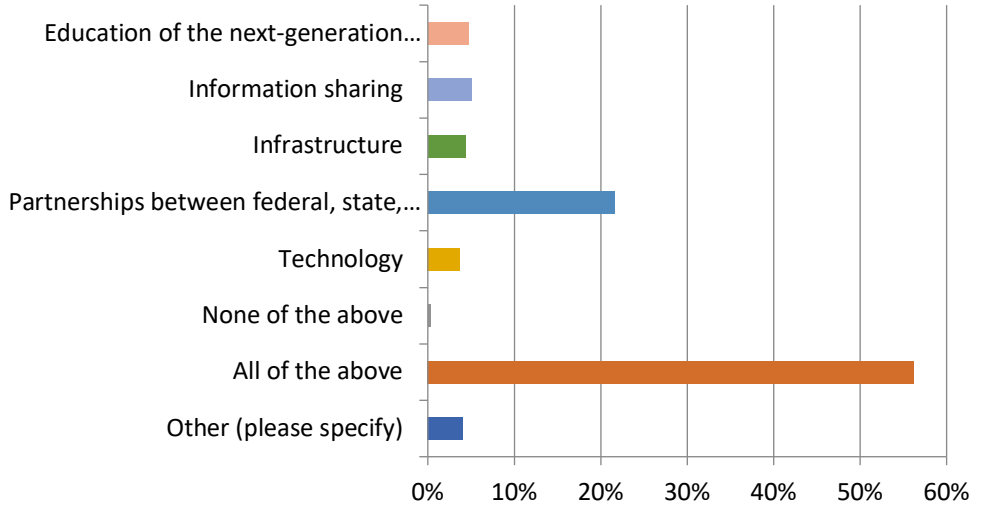
[14] StreetRx. (2019). https://streetrx.com

[15] United States Department of Health and Human Services, Public Health Medical Countermeasure Enterprise. (2019). https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx

Figure 8: To better prepare for a biological event, in which areas should the federal government apply more financial resources?



Despite many disparate data collections efforts, sharing data between agencies is still a challenge. Agency officials state that they are overwhelmed with data, but do not have an effective mechanism for receiving good information. The government could garnish a lot of value from the private industry. Participants indicated that perhaps they should learn from companies such as chip manufactures, mass distributors, and digital data providers. Understanding how these companies are perceived by consumers would make a difference in how to approach outreach and articulate a value proposition. People use and create large amounts of data every day. It is important to understand where the data is and what it looks like.

Without interoperability, it is difficult to get the right information at the right time. The participants recommended first clarifying which key elements to overlay and what information to share. Individual systems and different legal frameworks may also have privacy restrictions that are dictated by law and cannot be legally circumvented. Participants reminded the group to consider the legal repercussions for various government actions before those actions are implemented.

In terms of governance, there are barriers to sharing and storing this data (i.e., the Health Insurance Portability and Accountability Act of 1996). In a digital world driven by individuals

with handsets, data needs to be captured and anonymized to some degree. Private sector entities can do more with data than the government is able to, but they do not share this data without value to themselves. It is recommended that filters are applied to the data according to policies and authorities to ensure all legal and privacy authorities are applied.

Survey respondents that indicated "other" in survey Question 8 specified that more financial resources should be applied to program management of activities, funding critical lifeline infrastructures, and enhanced surveillance and laboratory testing capabilities.

ENGAGING WITH STATE AND LOCAL ENTITIES

Risks are constantly changing and becoming more complex. With state and local entities being integral in protecting the homeland from biothreats, participants provided a recommendation for the need to develop a separate plan on how to engage, incentivize, and resource these entities. However, coordination at the federal, state, and local levels vary significantly. Participants recognized that a significant amount of improvement is needed at all levels. The government could leverage partnerships under the FEMA National Preparedness Program to assist in this effort as well as to promote continuous communications to these stakeholders.

Participants also discussed how the Office of the Assistant Secretary for Preparedness and Response (ASPR) is promoting collaboration on the local level, through Health Care Coalitions (HCC). HCCs incentivize diverse and often competitive healthcare organizations with differing priorities and objectives to work together. HCCs collaborate to ensure that each member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency. For many disasters, regional assets are the best solution because local resources could be devastated.

ASPR is building standing capacity to care for more patients than previously available. However, since informal networks also exist, ASPR is leveraging those networks to increase the number of trained providers to address special incident management (e.g., burns, radiation, pediatric trauma). Participants recommended that Disaster Medical Assistance Teams (DMATs) as well as emergency medical providers receive annual training. DMATs are critical

for disaster management and are often used to serve in first responder type responsibilities, which they were never designed to do. There are currently 56 DMAT teams, all of which were deployed in 2017.

ASPR is now revising the structure to increase those teams and implement an annual training cycle and summit every three years, as opposed to the current five-year training cycle. A key aspect of this emphasis on communication to state and local entities is also having situational awareness. Having a venue or platform and incentivization for all levels to share their research should be explored. Even if the federal government coordinates efforts, any lack of state coordination would hinder efforts. Thus, they must determine the best way to maintain continuous engagement. Therefore, healthcare coalitions need to bring together disparate organizations to help close regional gaps. Participants agree that modest investments in coalitions do make a positive difference.

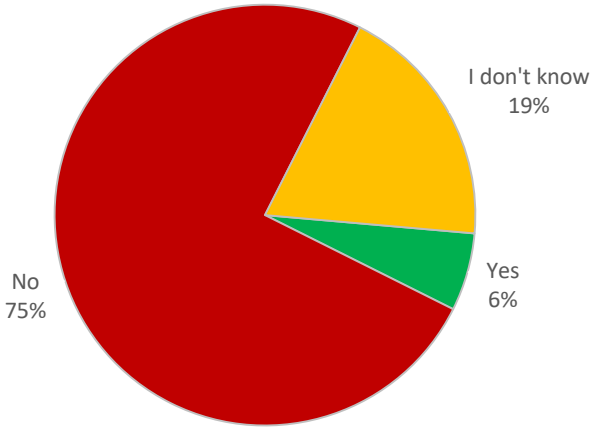
RECEIVING CONGRESSIONAL SUPPORT

Congressional support is critical to the implementation and operationalization of the strategy. Participants in the biodefense roundtable strongly recommend having national associations involved in the strategy as well as mayors and other local authorities. The establishment or refinement of a government structure to invest in things that are currently working and provide sustainability is key. Participants felt that continuous engagement with the Economic Council will resonate with Capitol Hill as well with everyone else, as demonstrated by response efforts for national disasters. This also includes the development of a stakeholder engagement plan for engaging with members on the Hill.

FINANCIAL ASSESSMENT

Biosecurity is a national security issue. However, the economic security issue aspect of it has still not been fully addressed. The Council of Economic Advisors has not conducted studies that were incorporated into the strategy. This argument needs to be made. The business impact is a strong case because of the financial effect a biological event would have on the economy if rapid cleanup were not possible. Participants encourage decision makers to remember it is not the same for everyone. They need to step back and conduct the stakeholder analysis. There also needs to be an assessment on how much funding should actually be applied to biodefense. In previous years, experts have indicated that the amount allocated has not been enough. Many believe that materials were bought, but no investment was made in infrastructure.

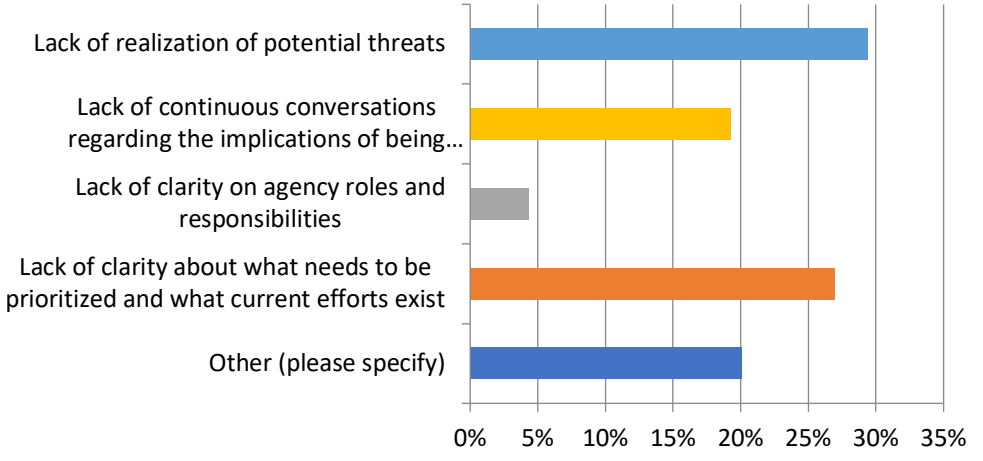
Figure 9: Do you believe there is sufficient federal funding to protect the homeland against biological threats?



Participants proposed that the federal government should buy bulk countermeasures (e.g., $1.5 billion in biodefense grants should be spent on the interconnectedness and governance structures). After the events of 9/11, the government decided that a few billion dollars could make a change in homeland security. However, that money went mostly into buying equipment and products without enough thought on sustainment and future needs. Also important to note,

some jurisdictions only get funding when all key stakeholders are included. However, when government funding stops, the training also stops. In addition, participants emphasized that preparedness grants are not proactive. There is a call for preparedness, but the challenge is an evolving crisis. The middle ground is a gray area for the Stafford Act and other preparedness/response transitions. Participants agreed that determining how to make adequate funding a priority – to keep up with *emerging risks* – is essential, especially prior to a biological threat.

Figure 10: If you answered no to Question 9, what in your opinion is the reason why Congress is not more supportive of biodefense investments?



Survey respondents that indicated "other" for survey Question 10 proposed that Congress is not as supportive of biodefense investments due to: attention focused toward other threats (real or unreal), expending funds too quickly, lack of understanding on the likelihood of an event (intelligence gathering), and inability to be proactive instead of reactive to an event. Therefore, participants indicated that the issue needs to be personal to increase involvement. Stakeholder outreach and coalition building must focus on building trust. Finding influential people within a community can have an enormous impact. For instance, the Department of Homeland Security's Plum Island Animal Disease Center has been successful at stepping back, building relationships and partnerships, and reaching out to influential people. Innovative thinking is needed to effectively reach older and younger people alike.

CONCLUSION AND ACTION PLAN

Following are key takeaways and recommendations that participants feel would help the government implement and operationalize the National Biodefense Strategy.

Key Takeaways and Recommendations:

- Working groups with multiple agencies come together after events, but wane over time. Sustainment is a challenge and needs to be addressed. Have the National Security Council push to sustain working committees (senior leadership from the Office of Management and Budget and the National Security Council need to be at all meetings).
- Senior level buy-in and engagement is needed at meetings.
- All cabinet departments and committees need to rally behind the effort and speak out to build buy-in for both financial and physical resources.
- How this is operationalized is key, so it is critical for the government to keep listening. These are local and healthcare issues, so local and healthcare stakeholders must be involved.
- Advocacy will get national associations involved in the strategy as well as mayors and other local authorities. A government structure should be set up to invest in efforts that are currently working and provide sustainability.
- Buy-in from the public is needed for them to trust government agencies. The government needs to involve the public role and make information more accessible, with a good marketing team to build transparency and engage people in all generations.
- Data calls that are burdensome do not have a good response rate. The government needs to design programs in a low-burden way for state and local entities to increase responsiveness.
- The approach to implement and operationalization the biodefense strategy should capitalize on what others have done (e.g., establish centers of excellence for biodefense).
- There needs to be a consistent message of priorities to both senior government officials as well as the public to gain and maintain support and long-term buy-in.
- The government should eventually apply the strategy and collaboration to chemical, radiological, and nuclear threats.

APPENDIX A
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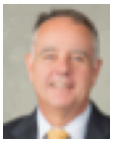

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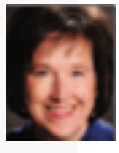

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APPENDIX D
Demographics of DomPrep Respondents

Representatives from Domestic Preparedness distributed the incorporated survey questions to participants from 25vFebruary 2019 to 18 March 2019. Over 600 responses were received from a diverse skill level (upper and middle management, technical/operational, administrative, and training officials) and incorporated into this report.

In which sector are you employed?	
Sector	*Percentage of Responses*
Public Health	15.1%
Emergence Management	13.1%
Fire Service	10.0%
Hospital (including VA)	9.8%
Privately Owned Company	8.5%
Federal Government	6.8%
State/Local Government	6.6%
Academic Institution	6.5%
Law Enforcement	5.1%
EMS	5.0%
Non-Government Organizations	4.6%
Retired	3.7%
Self-Employed	2.3%
Publicly Traded Company	1.0%
Military	1.0%
Student	0.7%
Not Currently Employed	0.2%
Elected Office/Legislative Body	0.0%

What type of position do you hold?	
	Percentage of Responses
Upper Management	30.13%
Middle Management	22.31%
Operations	17.26%
Other (please specify)	12.05%
Training	7.49%
Technical	6.84%
Administration	3.92%

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"The nation needs to move in a different direction to address emerging challenges and threats. If a biological event is not cleaned up quickly, an entire city would need to be evacuated. Not only would this be of national security interest, but it is of great interest for the economic health of the nation (agriculture and biological related innovation). We haven't seen this before – used to be focused specifically on public health not economy or innovation. We are calling for the support of the bioeconomy – more investments in things that would address not only pandemics, but also other emerging and future threats."

—DR. ROBERT KADLEC
Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services (HHS)

UNDERWRITER

Booz | Allen | Hamilton