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BLUE RIBBON STUDY PANEL ON BIODEFENSE

BUDGET REFORM FOR BIODEFENSE

INTEGRATED BUDGET NEEDED TO INCREASE RETURN ON INVESTMENT

Bipartisan Report of the Blue Ribbon Study Panel on Biodefense

February 2018

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BIPARTISAN REPORT OF THE
BLUE RIBBON STUDY PANEL ON BIODEFENSE

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EXECUTIVE SUMMARY

Biological threats to America and its interests overseas are increasing. Intentionally introduced, accidentally released, and naturally occurring diseases continue to pose a risk to the nation. While we have managed to contain many of these diseases and prevent major losses of life, it is only a short matter of time before a large-scale event exceeds the ability of our country and the world to prevent biological catastrophe.

Myriad federal departments and agencies are responsible for defending against these threats. Referring to their activities as a federal biodefense enterprise suggests a coordinated interagency endeavor unified in achieving common goals, but this is not the reality that exists currently. America is more vulnerable today than it should be to a biological crisis of any scale.

The ultimate success of the recently mandated National Biodefense Strategy depends on the prioritization of the activities it directs and the attachment of funding to those activities. At present, departments and agencies request funding individually, rather than collectively and for mutual benefit. They each negotiate their annual budget requests with the Office of Management and Budget (OMB), which then submits the President's Budget Request to Congress on a department and agency basis. OMB does not provide an analysis of biodefense spending across the government as part of this submission. Subsequently, multiple congressional subcommittees make funding decisions only for programs within their purview, but without considering overall biodefense spending or mission goals.

Such an integrated budget for biodefense would overcome the opaque, non-strategic spending approach characteristic of the status quo. An integrated budget (and the process needed to develop it) would facilitate coordination and reveal areas that would benefit from interagency funding initiatives and complementary investments. Performance evaluations and evidence-building metrics that accompany the budget would expose areas of effectiveness and ineffectiveness. This information would then support decision makers in making sound fiscal investments, closing capability gaps, and eliminating duplication of effort and resources – all of which would strengthen our national biodefense.

The White House should predicate its vision for long-term investment in biodefense on the National Biodefense Strategy. The Vice President of the United States should provide the leadership needed to facilitate this effort. OMB should develop an integrated biodefense request as part of the President's Budget Request that includes: (1) a biodefense budget crosscut; (2) performance outcomes for

biodefense projects, programs, and activities (PPAs); (3) an analysis of how PPAs contribute to the goals and objectives of the National Biodefense Strategy; and (4) a five-year budget plan.

Congressional leadership should convene a bicameral, bipartisan Biodefense Working Group (BWG) to determine the structures and processes for streamlined and comprehensive biodefense oversight. The BWG should make recommendations to reform congressional authorizations, budget resolutions, and appropriations with regard to all elements of the biodefense enterprise – prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation. To stay ahead of the ever-increasing biological threat, Congress should also mandate the establishment of a Future Years Biodefense Budget Program, requiring estimated expenditures and proposed appropriations for at least the current and four succeeding fiscal years.

A cohesive, integrated federal budget request for biodefense would help ensure that decision makers in the Executive and Legislative Branches comprehensively understand existing investments and priorities. Informed by the National Biodefense Strategy, Congress and the White House should take up the following recommendations to strengthen America's biodefense and use taxpayer dollars wisely.

LEADERSHIP AND DIRECTION

Development of an integrated biodefense budget begins at the White House with:

- An empowered Vice President who provides political leadership of the biodefense enterprise and helps set major budgetary priorities.
- A dedicated Deputy Assistant to the President for Biodefense within the National Security Council who supports the Vice President and provides day-to-day policy direction and coordination.
- An invested OMB Program Associate Director who provides management and budgetary guidance for biodefense.
- An allied Biodefense Coordination Council that prioritizes interagency biodefense activities and spending.

BUDGET DEVELOPMENT, EVALUATION, AND SUBMISSION

Execution of an integrated biodefense budgeting process continues with:

- Departments and agencies that base requests to OMB on mission requirements.
- OMB examiners who assess the performance and outcomes of federal projects, programs, and activities.
- OMB examiners who evaluate department and agency requests against the National Biodefense Strategy.
- A White House that submits an integrated budget request, a five-year biodefense budget plan, and a budget crosscut to Congress.

AUTHORIZATION AND APPROPRIATION

Culmination of an integrated biodefense budgeting process occurs in Congress with:

- Authorizers who use the National Biodefense Strategy as a benchmark for oversight, and require a Future Years Biodefense Budget Program plan.
- Budget Committees who consider long-term biodefense funding requirements.
- Appropriators who jointly evaluate the President's Budget Request, coordinate funding priorities across appropriations subcommittees, harmonize spending, and use multi-year funding mechanisms.
- Public-private partnerships in which all parties contribute to the development of viable incentives for research and development.
- A Public Health Emergency Fund composed of no less than $2 billion in no-year money and replenished with regular annual appropriations.
- Sustained U.S. contributions to international programs, including the Global Health Security Agenda.
- A bicameral and bipartisan Biodefense Working Group, temporarily established and empowered to make recommendations to House and Senate Leadership on the most impactful and feasible ways to achieve these goals and objectives.

BUDGETARY STATUS QUO

The process by which the government funds federal biodefense-related programs and activities precludes strategic allocation of dollars. The current system does not enable decision makers to evaluate the return on investment in existing programs, identify mission-critical gaps, or prioritize funding across requirements. The creation and sustainment of an effective national biodefense enterprise, however, depend on each of these elements. Specific weaknesses inherent in the budgetary status quo include:

- **Budgetary misalignment with the threat.** Threats should drive funding, but instead, predetermined or historic funding levels often dominate annual biodefense requests and appropriations. This results in some mission areas, like environmental biodetection, receiving millions of dollars annually even when their security value is questionable, and others, like hospital preparedness, receiving pennies per person despite gaping needs. Outdated budget development and appropriations processes disconnect funding from addressing the threat, leaving the nation vulnerable and wasting resources.
- **An opaque and uncoordinated federal interagency structure.** Strategic budgeting requires identification of all federal entities that do, should, and should not play a role in biodefense. Presently, the government distributes biodefense activities across a large number of departments and agencies (Figure 1). OMB does not provide a list of these entities, their activities, and their expenditures to Congress (or the public), which obfuscates Congress' ability to provide comprehensive oversight and make appropriations decisions in context.
- **Insufficient accounting.** The *Congressional Budget and Impoundment Control Act of 1974*, also known as the *Budget Act* (Pub. L. No. 93-344), does not require the annual President's Budget Request to be specific to any department, agency, or activity area. While OMB does submit department- and agency-level funding requests, it does not submit detailed biodefense expenditures. The Committees on Appropriations neither require nor request an accounting for overall biodefense spending.
- **Inadequate accountability.** Some programs do not sufficiently meet or reduce the biological threat while others are too expensive relative to the benefit they provide. The *Government Performance and Results*

Act (GPRA) of 1993 (Pub. L. No. 103–62, amended in 2010) provided some needed guidance for program performance, and assigned OMB responsibility for establishing crosscutting policy priorities. However, GPRA focuses on measures of performance, rather than outcomes. This does not meet the need for a biodefense system that makes the nation more secure.

- **Under-coordinated appropriations.** The subcommittee structure of the House and Senate Committees on Appropriations does not facilitate mission-oriented integration of funding. All subcommittees should share information and coordinate efforts, but they lack formal mechanisms with which to do so. The same is true for the many authorizing committees of jurisdiction responsible for informing the appropriations process.

- **Unpredictable funding.** Congress funds most discretionary programs annually, making program implementation and long-term planning subject to unpredictable funding decisions. Further, discretionary funds have been under pressure from the Budget Control Act of 2011, as amended in the *Bipartisan Budget Act of 2015* (Pub. L. No. 114-74). Volatile funding inhibits private sector capital investments in government-led efforts. Moreover, it prevents state, local, tribal, and territorial (SLTT) governments from building and sustaining needed capacities and capabilities. Reliance on continuing resolutions delays the issuance of funding to jurisdictions and interferes with planning, training, and exercising cycles.

- **Cost-prohibitive outbreak response.** The financial impact of major biological events is staggering (Figure 2). The direct and indirect economic costs of outbreaks and the response to them now regularly extend into the billions. The costs are so high (and unaccounted for in annual budgets) that supplemental requests and appropriations have become the norm to deal with them (e.g., $7.7 billion in 2009 for H1N1, $5.4 billion in 2014 for Ebola, $1.1 billion in 2016 for Zika). As these requests increasingly become the standard means for addressing public health security crises, debate over the need for funding response heightens. Delays mount and case counts rise: the *emergency* Zika supplemental took seven months to pass through Congress. Further demonstrative of the prohibitive and unsustainable nature of these costs, part of the Zika response was funded through redirection of resources from existing biodefense programs. Although a response fund is needed, more strategic and comprehensive annual budgeting that addresses pre-event requirements – like prediction research, hospital preparedness, and medical countermeasure development – would also reduce the risk and thereby mitigate some of the need for massive post-event supplemental funding.

FIGURE 1

Diffusion of biodefense activities across the federal government. The Study Panel has identified biodefense activities at the departments, independent agencies, and one independent institution listed here, and believes that there could be more with biodefense responsibilities.

DEPARTMENTS

Department of Agriculture

Department of Commerce

Department of Defense

Department of Education

Department of Energy

Department of Health and Human Services

Department of Homeland Security

Department of Housing and Urban Development

Department of Interior

Department of Justice

Department of Labor

Department of State

Department of the Treasury

Department of Transportation

Department of Veterans Affairs

INDEPENDENT AGENCIES

Central Intelligence Agency

Environmental Protection Agency

General Services Administration

National Aeronautics and Space Administration

National Nuclear Security Administration

National Science Foundation

Office of the Director of National Intelligence

United States Postal Service

INDEPENDENT INSTITUTION

Smithsonian Institution

OPPORTUNITIES FOR BUDGET REFORM

To improve extant budget processes, the Panel issued the following recommendation in its 2015 report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*:

> **Recommendation 4: Unify biodefense budgeting.** Congress should mandate the development of an integrated budget that allows Congress and the Administration to understand how the government funds the entire biodefense enterprise.

a. **Develop and execute a mandatory annual biodefense call for data.** The President and congressional appropriators should require the Director of OMB to conduct this data call, coordinated by the Vice President. Each department and agency should catalogue all of their biodefense programs and indicate which support specific biodefense requirements in the National Biodefense Strategy and which do not. The submissions should include historical annual expenditures for each program and predicted future needs.

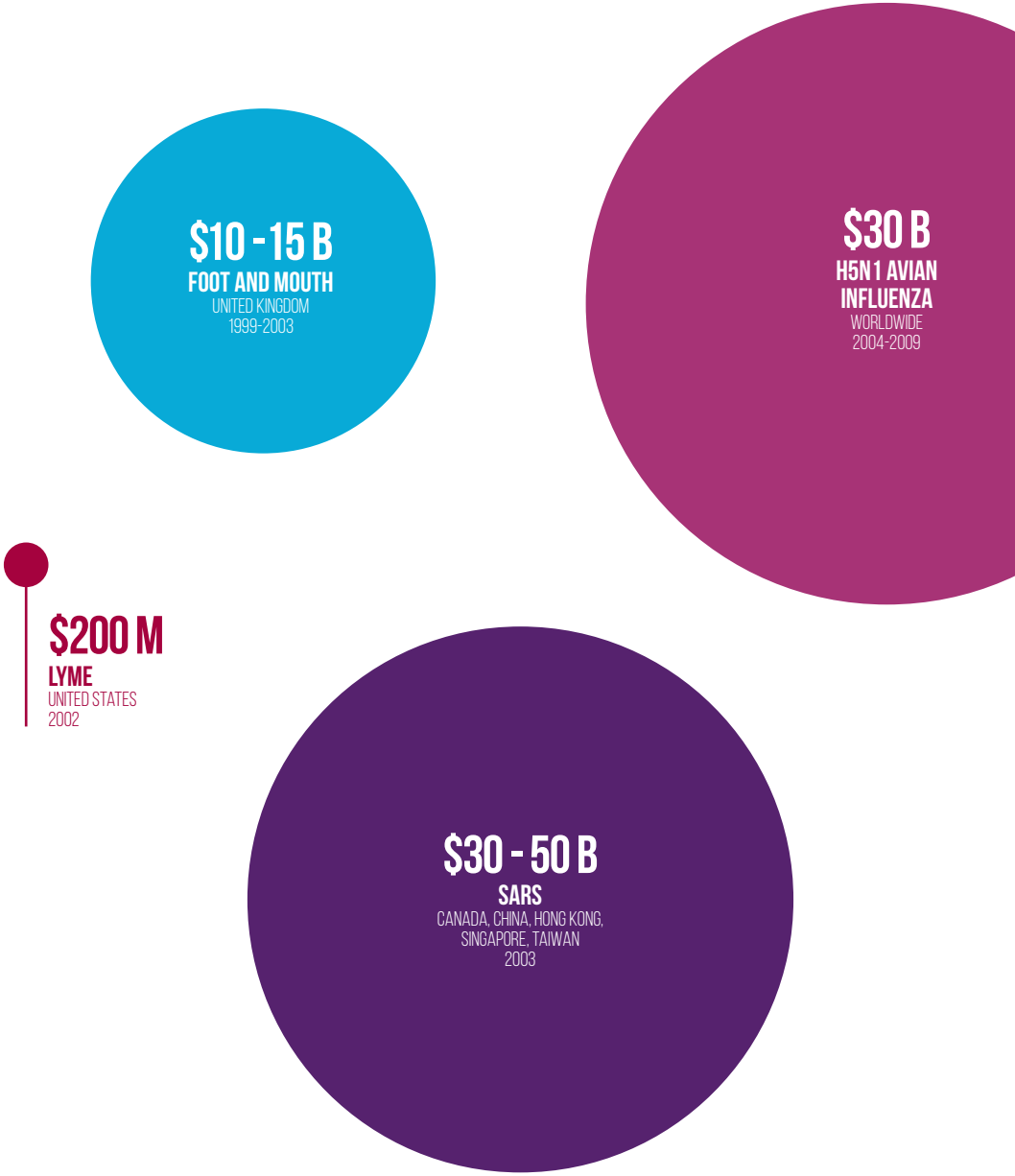
b. **Conduct a crosscutting biodefense budget analysis.** Using the information collected in the data call, the Vice President and the Director of OMB should identify gaps and overlaps in and among federal programs. OMB should use this analysis to inform the budgetary guidance it sends to departments and agencies for the coming fiscal year.

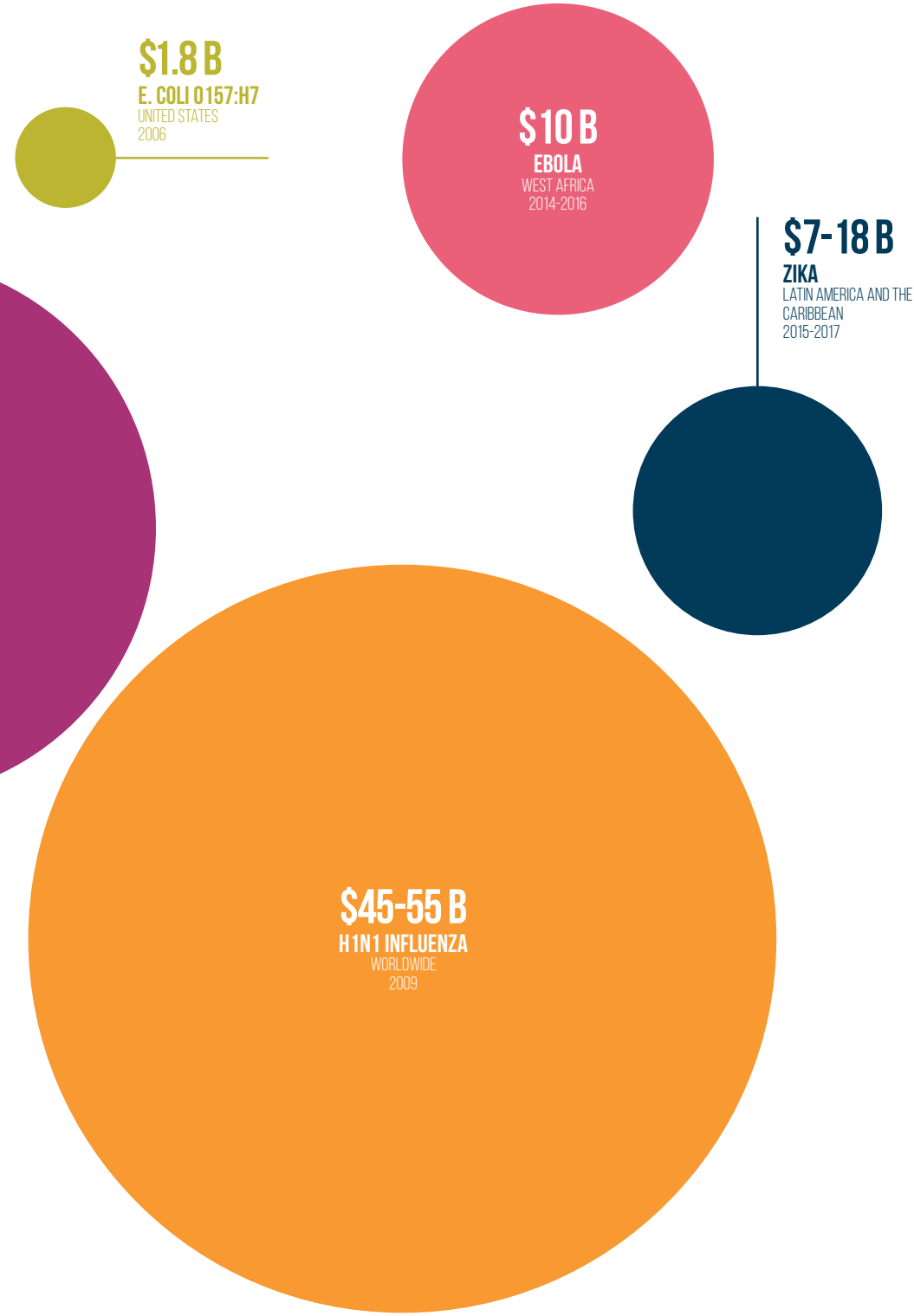
c. **Align budget items to the National Biodefense Strategy of the United States of America.** The Director of OMB should require that all annual budget request submissions pertaining to biodefense adhere to the guidance from OMB, based on the National Biodefense Strategy and the budget crosscut.

d. **Provide predictable and multi-year funding for all biodefense programs.** The President should request funding for all biodefense activities in the annual budget request, including multi-year requests for those programs that the Vice President and Director of OMB determine would benefit from such forward funding. Additionally, departments and agencies should provide multi-year grants, contracts, and/or cooperative agreements wherever possible.

FIGURE 2

Estimated economic impact of selected infectious disease outbreaks. Infectious disease outbreaks are placing an increasingly high economic burden on local, national, and global economies. The displayed costs show a sampling of direct and indirect economic impacts of selected human, livestock, and zoonotic outbreaks. Information is based upon BioEra, World Bank, and United Nations Development Programme data. Data gaps and the use of varying methodologies limit full accounting and figures are not drawn perfectly to scale. Refer to EcoHealth Alliance and World Bank for data and more information on the economic impact of emerging infectious diseases.

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UNITED STATES
2006
$10 B
EBOLA
WEST AFRICA
2014-2016
$7-18 B
ZIKA
LATIN AMERICA AND THE CARIBBEAN
2015-2017
$45-55 B
H1N1 INFLUENZA
WORLDWIDE
2009

The passage of the *National Defense Authorization Act of 2017* (Pub. L. No. 114-328) means that – for the first time – the federal development of a comprehensive national strategy for biodefense is law. As the drafting process necessitates consideration of the entire spectrum of biodefense activity occurring across the federal government, implementation will also require consideration of budgets to pay for it. The completed National Biodefense Strategy will thus provide a strong platform from which planners and decision-makers can ensure coordination and funding of efforts to meet the biological threat.

Policymakers, therefore, have an opportunity to transform the status quo. A series of changes to structure and process as outlined herein could greatly improve national security and the way taxpayer dollars are spent.

EXECUTIVE BRANCH

White House Leadership. The Panel previously recommended that the Vice President should provide the political leadership of the biodefense enterprise. This leadership should include oversight of the biodefense budget. For day-to-day policy development and coordination, the President should designate a Deputy Assistant to the President for Biodefense in the National Security Council to support the Vice President in this endeavor. The OMB Director should also empower a Program Associate Director (PAD) to manage the entire biodefense portfolio. The Deputy Assistant, with the input of the designated PAD and the newly established Biodefense Coordination Council at the White House, should provide biodefense budget recommendations to the Vice President.

Precedent: The DCI and the DNI

Prior to the intelligence reforms instituted after September 11, 2001, the Director for Central Intelligence (DCI) was responsible for gathering and submitting the budgets of all intelligence agencies at once. While the DCI could not influence agency budget submissions, the DCI could express to the President and Congress concerns regarding budget gaps and redundancies. Today, the Director of National Intelligence (DNI) is in charge of the National Intelligence Program budget and works with the Under Secretary of Defense for Intelligence to develop the Military Intelligence Program budget. Both budgets are fully visible to and influenced by the DNI.

Biodefense Coordination Council. The Panel previously recommended that the White House establish and manage a Biodefense Coordination Council. Through this Council, the Vice President should prioritize interagency activities, ensure department and agency accountability, and provide policy and budgetary

recommendations for biodefense. The Vice President should populate the Council with Deputy Secretaries from all departments and agencies with biodefense responsibilities, as well as non-federal stakeholders. The Biodefense Coordination Council should maintain communication with all other White House Councils to coordinate and exchange information.

Department and Agency Budget Requests. Deliberations of the White House officials and the Biodefense Coordination Council described above should inform the annual funding guidance provided by OMB to the departments and agencies. This guidance should stress the importance of both agency-level and broader mission requirements as drivers of funding requests to OMB. Departments and agencies should provide evidence of program effectiveness in meeting these requirements in their annual requests, as evaluation of PPA effectiveness depends on the availability and use of strong metrics. The Administration should categorize biodefense as a Cross-Agency Priority (CAP) Goal in accordance with the *GPRA Modernization Act of 2010* (Pub. L. No. 111-352), and develop such metrics in keeping with the Implementation Plan for the National Biodefense Strategy. The Deputy Director for Management at OMB, through the Performance and Personnel Management Directorate and in conjunction with the biodefense PAD, should work with the White House on the creation and implementation of performance targets for the biodefense CAP Goal. Agencies should base their budget requests to OMB on performance and outcome measures that exceed GPRA requirements. Doing so would provide legitimate support for continued investment in useful activities and allow decision-makers to consider options for activities in greater need. For major projects, the White House and Congress should require departments and agencies to develop business plans that emphasize interagency coordination and public-private partnerships.

OMB Analysis and Evaluation. The Study Panel previously recommended undertaking an analysis to delineate capability gaps based on the National Biodefense Strategy, and then mapping those gaps to resource needs. As part of this process, OMB should annually issue a mandatory biodefense call for data, using a clear definition for biodefense (in accordance with the National Biodefense Strategy) to help departments and agencies determine what constitutes biodefense activities and programs. OMB should use these data to conduct a crosscutting budget analysis. With congressional fiscal support, OMB should develop and implement a web-based portal to facilitate this information collection. This portal should capture spending and activity data in a structured and relational manner to enable evidence-based policymaking. For instance, data should be coded to reflect not only fiscal expenditures, but also the means by which resources (e.g., personnel) are invested to achieve biodefense mission requirements. OMB should leverage authorities already provided by the *Digital Accountability and Transparency*

Act of 2014 (Pub. L. No. 113-101), which requires rigorous public disclosure of expenditures. Submissions from departments and agencies based on strong performance and outcome measures would help OMB evaluate requests in the context of all biodefense programs and activities across the federal government. The Office of Science and Technology Policy (OSTP) should play an integral role in the evaluation of biodefense research and development requests.

OMB Submission to Congress. Using the data, information, and analysis provided through the above process, OMB should provide an integrated biodefense budget request to Congress. This submission should be a holistic presentation of all department and agency requests across the federal government, ensuring that the overall request aligns with the National Biodefense Strategy and aids congressional appropriations and related authorization decisions. The following should comprise the request: (1) the biodefense budget crosscut conducted per the data call described above; (2) the performance outcomes for biodefense PPAs; (3) an explanation for how PPAs contribute to the goals and objectives of the National Biodefense Strategy; and (4) a five-year Future Years Biodefense Budget Program plan.

Precedent: National Arctic Research Budget

The *Arctic Research and Policy Act of 1984* (Pub. L. No. 98-373) established the U.S. Arctic Research Commission, primarily charged to develop a comprehensive national Arctic research policy. A key element of the law directed OMB to consider all federal agency requests related to Arctic research as one integrated request. The law required the establishment of an interagency committee that would provide the coordination, data, and assistance to prepare an integrated, multiagency budget request for Arctic research. The law also required OMB to review the request for its adherence to a five-year plan for Arctic research (required by the same Act), and directed OSTP to review all budget requests related to the Arctic.

OMB should display the information in various ways, such as by National Biodefense Strategy goals and objectives, and by functional area (e.g., biodetection and biosurveillance, medical countermeasures, preparedness). OMB should develop the request by planning for sustained and, where appropriate, increased funding to prevent erosion of capability and capacity in core programs (those OMB deems effective, long-term, and thus subject to inflation). This request would incentivize private sector participation and planning. OMB should include a Future Years Biodefense Budget Program plan in the annual budget submission. Similar to the Department of Defense (DOD) Future Years Budget Program (10 U.S. Code § 221), this plan should summarize all biodefense programs and resources, and address at least five years – the current fiscal year for which funds are being

requested, and the following four fiscal years. This display of and plan for predicted expenditures would force advanced and strategic planning, encourage private sector participation, and enable Congress to consider at least five years of cost data during the appropriations process.

FIGURE 3

Process for Developing the Biodefense Budget

LEGISLATIVE BRANCH

Congress retains tremendous power to ensure the adequacy of the federal biodefense enterprise in general, and to mandate an integrated approach to budgeting and appropriations. As the Executive Branch improves its process through development of a National Biodefense Strategy and an integrated budget aligned to that Strategy, Congress has a parallel opportunity to refine its own processes with respect to authorization and appropriations.

At present, numerous committees and subcommittees in both the House and the Senate share authorizing responsibility for biodefense. This largely reflects the Executive Branch's own structure. It also mirrors shared congressional homeland security jurisdiction, which increases the difficulty of advancing homeland security legislation. Committees undertake oversight along jurisdictional lines ascribed to them through House and Senate rules, but only a few spend substantial time focusing on biodefense as a comprehensive topic. This selective oversight reflects insufficient congressional engagement to address many of the most significant biodefense challenges America faces, except when a crisis occurs and reaction becomes imperative. Conversely, fragmented jurisdiction has resulted at times in excessive interest, leading to unnecessary disputes over real and perceived legislative purview. No incentive or structures currently exist to encourage further coordination and cooperation amongst these disparate jurisdictions.

Similarly, the subcommittee structure of the House and Senate Committees on Appropriations does not facilitate mission-oriented integration of funding. All subcommittees need to share information and coordinate efforts, but lack formal mechanisms with which to do so.

Congressional Biodefense Working Group. Early in 2018, House and Senate leadership should jointly establish a temporary, bicameral, bipartisan Biodefense Working Group (BWG), appointing representatives from all committees of jurisdiction. The primary task of the BWG would be to determine what structures and processes would enable streamlined and comprehensive biodefense oversight. Because biodefense requires broad governmental activity, the health consequences of biological events alone should not drive working group membership or chairs. Rather, Leadership should appoint committee chairs, ranking members, and other members from committees with responsibility for prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation of biological threats to sit on the BWG. Leadership must also allocate resources and staff sufficient to support the group.

The BWG should issue a series of recommendations to House and Senate leadership no later than the end of the 115th Congress. They should implement them at the start of the 116th Congress. These recommendations should address:

Authorization reform. The National Biodefense Strategy and its implementation plan will be the first comprehensive tool provided to Congress to enable oversight of the entire enterprise. The BWG should assess whether the current designation of responsibilities across authorizing committees adequately covers all elements of biodefense described by the Strategy. It should evaluate how Congress can best provide legislative guidance regarding elements of the Strategy, not on an ad hoc basis, but in a coordinated fashion. A Biodefense Authorization Act could be a powerful tool for regular congressional focus and input on the issue. The working group should determine the role and process to create such an Act, and the frequency of reauthorization. Authorization of specific spending levels in this bill would establish authorizers' priorities for appropriations. The bill should reflect the input of all authorizing committees of jurisdiction, but particular committees should spearhead its development. The BWG should identify which existing committee or committees in the House and Senate could best serve as that focal point or whether leadership should appoint a special committee.

Budget reform. The House and Senate Committees on the Budget produce annual budget resolutions in their respective chambers. Each Committee's budget resolution should include a figure for overall biodefense spending. The Committees should utilize the annual integrated biodefense budget submission from OMB in their decision-making. The BWG should propose how the Committees on the Budget should use the National Biodefense Strategy, Biodefense Authorization Act, and other means to inform the annual budget resolutions better. The group should consider the advantages of multi-year funding for certain types of programs when developing its recommendations.

Appropriations reform. The BWG should determine how the Appropriations Committees could best evaluate an integrated biodefense budget request. Twelve subcommittees comprise the Appropriations Committee in each chamber and work annually to develop twelve appropriations bills. Upon submission of the integrated biodefense budget request to Congress each fiscal year, these subcommittees should work together to identify areas of programmatic overlap and gaps in their respective jurisdictions. The subcommittees should coordinate with each other to appropriate funds in accordance with the biodefense budget request, the National Biodefense

Strategy, and levels authorized in statute by the Biodefense Authorization Act or elsewhere. The appropriations committees should work closely with their corresponding authorizers to ensure unity in biodefense appropriations and policy. They should also require a strong evidence base for continued support of PPAs, consistent with the recent congressional focus on evidence-based outcomes, as recommended in September 2017 by the bipartisan Commission on Evidence-Based Policymaking.

Integrated Budget Request. Congress recently eliminated a long-standing requirement for OMB to issue an annual homeland security budget crosscut (previously, 31 U.S.C. § 1105 (a)(35) 1974), which included information relevant to biodefense. This provision should be reinstated and adjusted to require more detail and analysis than had become the norm for the crosscut in recent years. Congress should consider requiring the development of an integrated biodefense budget submission that includes a thorough crosscut and analysis via further amendment to this statute, if OMB chooses not provide such a submission voluntarily.

Future Years Biodefense Budget Program. Congress should amend 31 U.S.C. § 1105 (a)(35) 1974 to establish a Future Years Biodefense Budget Program, requiring the Director of OMB to submit to Congress a yearly Future Years Biodefense Budget Program plan with the President's Budget Request. The plan should include the estimated expenditures and proposed appropriations for at least the current and four succeeding fiscal years. The amendment should require the Director of OMB to ensure that expenditure estimates and proposed appropriations for any fiscal year are consistent with the total estimated expenditures and appropriations deemed necessary to support the biodefense PPAs of all departments and agencies.

ESSENTIAL FINANCIAL TOOLS

Multi-year Funding. The yearly nature of budgetary and appropriations processes makes long-term planning and stability for critical security programs difficult, if not impossible. Congress requires recipients to use, obligate, or relinquish most funding by the end of the fiscal year. However, Congress can explicitly make funds available for use in more than one year. Generally, Congress authorizes such multi-year funding because some programs will take years to execute fully, and they, therefore, require funding over an extended period. OMB and Congress should commit to providing multi-year, long-term funding for certain biodefense programs and grants.

One type of multi-year funding is the advance appropriation, in which funding becomes available after the year in which an appropriations act passed. This prevents programmatic gaps that can occur due to annual appropriations variability, and demonstrates longer-term commitment to certain activities beyond a yearlong funding cycle. For MCM development and other costly long-term research, it is imperative that Congress commits resources to federal and private sector efforts. Such an approach is not without precedence in biodefense. A ten-year advance appropriation for Project BioShield (FY 2004-2013) became law because Congress justified it and the Vice President supported it. This type of guarantee provides strong incentives for research and development programs that might otherwise be abandoned.

Precedent: Project BioShield Advance Appropriation

In 2004, Congress passed the *Project BioShield Act* (Pub. L. No. 108-276). This law created a 10-year Special Reserve Fund of $5.6 billion to be available from FY2004-FY2013 for the procurement of MCM. This advance appropriation helped generate a market for much-needed countermeasures that the private sector would otherwise have had no incentive to develop. The market stability it created helped enable the successful addition of 14 MCM products to the Strategic National Stockpile.

At a minimum, Congress should reinstate the advance appropriation for the BioShield Special Reserve Fund (SRF). The BWG should also evaluate other areas that would benefit from multi-year funding, including grants that strengthen public health security. Congress should rightly retain budgeting flexibility and caps on advance appropriations in order to ensure the integrity of allocations. However, Congress should also commit to long-term funding for select elements of biodefense, similar to its commitment to national defense.

Private Sector Incentives. While relatively expensive, MCM development, capabilities, infrastructure, and assets have far-reaching impact, enabling a range of core capacities including deterrence, preparedness, and response. Attention to MCM development has waned, however, and investments are orders of magnitude below what they should be for a comparable threat. With no guarantee of predictable and sustained public sector support, profit, or patients for clinical trials, companies find it difficult to justify investments in MCM development, straining the public-private partnerships required to execute this mission. The Strategic National Stockpile may be in much better shape than it was a decade ago, but its sustainability is in doubt and gaps continue to persist.

Congress and the Administration must renew their commitment to a BioShield SRF advance appropriation. They also need to create additional incentives to encourage private sector investment that complements government commitments, and

to ensure investment in MCM that the SRF does not cover (e.g., for emerging infectious diseases, influenza). The public and private sectors should cooperatively discuss, develop, and implement a set of incentives that may include traditional authorities (e.g., other transactional authority) and creative financing methods (e.g., securitization of an MCM asset portfolio). The Department of Health and Human Services Assistant Secretary for Preparedness and Response and the DOD Deputy Assistant Secretary of Defense for Chemical and Biological Defense should lead this initiative, which should involve substantive partnerships with the Department of the Treasury, White House Council of Economic Advisors, and National Economic Council. The government must ensure that the return on investment by both performers and investors is commensurate with the risk they assume and the high value of the goods and services they provide to our national security.

BIOLOGICAL DISASTER RESPONSE FUNDING

Domestic Public Health Emergency Funding. The Disaster Response Fund (DRF) for natural disasters, the Public Health Emergency Fund (PHEF) for widespread human health emergencies, and the Commodity Credit Corporation (CCC) for agricultural emergencies are some of the institutionalized means by which the federal government funds response to different events. Among these, only the PHEF does not receive an annual appropriation or reimbursement. In 1983, Congress appropriated $30 million for the fund, an amount insufficient to address a public health catastrophe. Congress has not explicitly appropriated any money for the PHEF since 1993. Today, only about $57,000 remains. Recent history reveals that adequate response to public health emergencies requires resources that are far more substantial. In 2014, in response to the Ebola outbreak, Congress appropriated $5.4 billion in emergency funding. When the Zika virus emerged in 2016, the Obama Administration requested almost $1.9 billion to address the threat and Congress ultimately appropriated $1.1 billion.

The nation requires a rapid response fund triggered not only by a declared public health emergency, but also, at times, in advance of any such declaration to preempt a major problem. Congressional proposals to seed such a fund have ranged from $300 million to $5 billion. Viewed in the context of historical supplemental funding levels described above and taking these proposals into consideration, $2 billion is a reasonable level of baseline funding for now. This level can be revisited if strategic annual biodefense investments ultimately mitigate response costs. The Administration and Congress, therefore, should: (1) infuse no less than $2 billion into the PHEF; (2) commit to regular annual appropriations utilizing a consistent methodology and no-year funding for the PHEF, similar to provisions for the DRF

and CCC; (3) provide guidance on triggers for use, which may or may not include declaration of a public health emergency; and (4) update criteria for what events the PHEF will cover. Congress and the Administration should consider the input of SLTT end-users in developing these triggers and criteria.

Global Response Funding. Preventing the spread of disease at its source is less expensive than paying for post-outbreak domestic and international response. Congress and the Administration should commit to playing a long-term role in global health security by sustaining U.S. budget commitments for federal implementing agencies like the Department of State, DOD, U.S. Agency for International Development, and Centers for Disease Control and Prevention. They must also support international institutions such as the World Health Organization (WHO) and World Bank, as well as novel public-private partnerships like the Coalition for Epidemic Preparedness Innovations. At a minimum, as the initial U.S. financial commitment to the Global Health Security Agenda reaches its five-year endpoint, the Administration and Congress should recommit to funding and supporting the American contribution to this program. Prevention forestalls outbreaks, but when prevention is not possible, global response efforts are critical. The United States should assume a leadership role in transforming the existing WHO-centric response model into a distributed response framework predicated on global public-private partnerships.

Mitigating Risk. Beyond MCM lie additional opportunities for public-private partnerships that will increase mission effectiveness while sharing costs. Leveraging private sector models for risk management, such as catastrophe models used by the insurance industry that allow insurers and reinsurers, financial institutions, corporations, and the government to evaluate and manage catastrophic risk, could elevate the government's risk tolerance. The federal government should also encourage other countries, global companies, and international organizations to invest in biodefense by offering to partner with them through multilateral agreements, cooperative agreements, and other such mechanisms.

CONCLUSIONS

The Executive Branch and Congress do not comprehensively assess how the government currently spends its biodefense dollars. This lack of clarity prevents departments and agencies from identifying gaps and setting long-term strategy. A comprehensive and systematic analysis of redundancies and gaps across the biodefense enterprise is a critical step toward assigning responsibilities, resources, and metrics to meet those needs.

It will take time to produce an integrated biodefense budget. The White House should first establish the recommended leadership and coordination structure, while Congress establishes the BWG. These elements will enable all other activities, including:

- Federal department and agency requests for funding in keeping with their biodefense responsibilities;
- OMB evaluation of biodefense spending across the government; and
- Congressional authorization and appropriations in accordance with overall spending and mission targets.

The entire process would mature in about three years, but could begin demonstrating value much earlier. The National Biodefense Strategy should provide a foundation for all efforts to implement biodefense policy and law, and help to increase coordination and oversight. The Biodefense Authorization Act would support execution of the Strategy.

Biological events occur too frequently to allow inefficient funding mechanisms and ineffective programmatic efforts to risk lives and our national security. As disease outbreaks, other emergencies, and disasters continue to affect public health security, the nation must take a more business-like approach to biodefense budgeting. Executing the recommendations herein will ensure that the biodefense enterprise uses taxpayer dollars wisely to defend the nation against biological threats.

ACRONYMS

BWG ..... Biodefense Working Group
CAP ..... Cross-Agency Priority
CCC ..... Commodity Credit Corporation
DCI ..... Director for Central Intelligence
DNI ..... Director of National Intelligence
DOD ..... U.S. Department of Defense
DRF ..... Disaster Response Fund
GPRA ..... Government Performance and Results Act
MCM ..... medical countermeasure(s)
OMB ..... Office of Management and Budget
OSTP ..... Office of Science and Technology Policy
PAD ..... Program Associate Director
PHEF ..... Public Health Emergency Fund
PPAs ..... Projects, Programs, and Activities
SLTT ..... State, Local, Tribal, and Territorial
SRF ..... Special Reserve Fund
WHO ..... World Health Organization

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