National Preparedness and Response Science Board (NPRSB)

Assistant Secretary for Preparedness and Response (ASPR) Future Strategies Report

Executive Summary

The National Preparedness and Response Science Board (NPRSB; formerly known as the National Biodefense Science Board [NBSB]) provides expert advice and guidance to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Assistant Secretary for Preparedness and Response (ASPR) on scientific, technical, and other matters related to public health emergency preparedness and response.

The NPRSB was asked to identify future strategies to best support successful achievement of ASPR's mission and that of the HHS to protect Americans' health and safety during emergencies and to foster resilience to withstand and respond to the same.

As a new organization, ASPR has accomplished much in its first decade. Accomplishments include the creation of strong systems to lead and coordinate Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) efforts, development of new vaccines and other medical countermeasures through BARDA, engagement of hospitals and health care systems in emergency preparedness at previously unseen levels, stronger linkages with state and local health agencies, better access to data, and methods for more rapidly sharing resources with international partners. Task 1 of this report encompasses an assessment of these and other key ASPR accomplishments that can inform future strategies.

In addition to learning from past accomplishments, planning future strategies requires looking forward. Task 2 identifies and explores current trends and projected future conditions relevant to ASPR's mission. Among others, these include projections of disaster risk, anticipated demographic and environmental changes, evolving social and entrepreneurial models, trends created by current economic conditions, and the opportunity and risks presented by rapidly expanding data and data computation capabilities.

Examining this information in light of ASPR's current authority and operating strategies, Tasks 3 and 4 make recommendations for ASPR moving forward.

In sum, the NPRSB finds ASPR's authority and responsibility as outlined in the Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA - Public Law No. 113-5) legislation to be adequate and appropriate (i.e., "to provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan"). Moving forward, however, the NPRSB envisions ASPR, on behalf of the Secretary of HHS, far more boldly, visibly, and effectively carrying out the leadership role provided by this legislation. Such empowered leadership is critical to ensuring the nation's capability to respond to public health crises.

In support of the above, the NPRSB recommends the following Future Strategies for ASPR (Task 3):

Strategy 1. Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation -- "The Assistant Secretary for Preparedness and Response shall have lead responsibility

- within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction." (PAHPRA, 2013)
- Strategy 2. Markedly expand, beyond the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches used to address complex social and system issues. This is aimed at more meaningful engagement of stakeholders, better coordination of efforts, and stronger integration of local, state, federal, and private sector preparedness and response systems.
- Strategy 3. Work to assure, through operational and policy-related initiatives, that a sufficient domestic capability to conceive, develop, produce, and replenish medical countermeasures is maintained and enhanced.
- Strategy 4. Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high-priority societal needs. This includes working with partners to mobilize efforts to stabilize and strengthen foundational systems core to national security, including emergency and trauma services and public health systems.
- Strategy 5. Increase public visibility of emergency preparedness and response efforts undertaken by ASPR and others. More openly and actively engage the public on issues pertinent to preparedness, response, and resiliency. Collaborate with key stakeholders towards promoting a stronger culture of personal, organizational, and community readiness.
- Strategy 6. Strengthen disaster risk reduction strategies in ASPR's work and encourage the same with federal, state, and local government and private sector partners.
- Strategy 7. Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense.
- Strategy 8. Continue to seek novel approaches for accessing, analyzing, disseminating, and utilizing data to reduce disaster risk, strengthen resilience, improve preparedness, guide response, and hasten recovery. Work to continuously improve quality and ensure security of data.

In implementing these future strategies, ASPR should keep at the forefront of its efforts the following two overarching concepts:

- A. To advance, and whenever available utilize, scientific investigation and data to learn more about the health effects of disasters and to evaluate and guide approaches to decreasing risk, advancing preparedness, maximizing the effectiveness of response and recovery efforts, and enhancing community resilience.
- B. To utilize performance improvement principles, assuring the organization continuously learns from experience and operates in as facile, rapidly responsive, collaborative, innovative, and effective an environment as possible.

In addition to identifying the above strategies, the report maps ASPR's current state to the desired future state envisioned by the NPRSB and recommends the following near-term priority foci for ASPR in

implementing the above future strategies (Task 4). The discussion accompanying each priority focus offers specific activities for further consideration.

- Priority Focus 1. Intentionally and significantly increase ASPR's visibility and utilize successes to earn further respect and trust. Work to actively brand ASPR as the nation's lead in coordinating across public and private sector health and medical preparedness and response systems and in establishing policy to advance the nation's health security. (Links to Future Strategy 1)
- Priority Focus 2. More strongly focus on and utilize ASPR's existing policy leadership authority and role. (Links to Future Strategy 1, Future Strategy 4, Future Strategy 6, and Future Strategy 7)
- Priority Focus 3. Develop an organizational culture that promotes and expands ASPR's organizational capability to lead and work within facilitated networks, coalitions, collective impact, and other structured collaborative approaches to addressing complex social and system issues. This will likely entail workforce development, policy examination, and access to facilitative and other resources. (Links to Future Strategy 1 and Future Strategy 2)
- Priority Focus 4. Promote and strengthen the foundational systems of public health, health care, and biotechnology upon which the nation's health security fully relies. Engaging others, work to address the rapid erosion of capability currently being threatened or seen in these areas. (Links to Future Strategy 3, Future Strategy 4, and Future Strategy 7)
- Priority Focus 5. Seek to more fully understand the dynamics of how preparedness is achieved at all levels—listening, consulting with, and working alongside state and local agencies, health care systems, researchers, private sector, and community partners earlier and more often. (Links to Future Strategy 2 and Future Strategy 4)
- Priority Focus 6. Significantly increase the use of public dialogue and public engagement on issues relevant to national health security: public health emergency hazard identification; risk tolerance; preparedness and response priorities; the role of personal, organizational, and community preparedness; and societal approaches to family and community resilience. (Links to Future Strategy 5)
- Priority Focus 7. Advance the science behind preparedness and response: more fully engage the public health community, academia, health care systems, and industry in the development and implementation of short- and long-term agendas to increase the preparedness and response evidence base. (Links to Future Strategy 8 and Overarching Concept A)
- Priority Focus 8. Advance ASPR's ability to be a flexible, nimble, innovative, rapidly responsive, and adaptable organization. (Links to Future Strategy 2 and Overarching Concept B)

TABLE OF CONTENTS

xecutive Summary
ntroduction:
ASK 1: Highlight ASPR's accomplishments to date and its impact on national health preparedness and resilience
ACCOMPLISHMENTS TO LEARN FROM AND BUILD UPON:
OTHER KEY ACCOMPLISHMENTS:
ASK 2: Assess environmental, fiscal, policy, and other relevant spheres for potential near- and far- erm conditions that may affect ASPR's mission space
SUMMARY
DISCUSSION OF TRENDS AND CONDITIONS LIKELY TO AFFECT ASPR'S FUTURE MISSION SPACE
ASK 3: Identify potential future resource and capability gaps nationally; suggest adjustments in trategic alignment and changes to legislative authority and/or policy position. (Recommended Futur Strategies)
SUMMARY2
DISCUSSION OF RECOMMENDED FUTURE STRATEGIES
TASK 4: Develop an analysis which compares ASPR's current mission, requirements, strategic objectives, resources, and capabilities against near- and far-term conditions. Provide a prioritized list of suggestions based on the comparative analysis for ASPR to support its continued success in the auture.
ASPR's First 8 years3
ASPR Looking Forward3
fummary of RECOMMENDED FUTURE STRATEGIES and PRIORITY AREAS OF FOCUS for ASPR:
APPENDICES
Appendix A: Organizational Charts4
Appendix B: ASPR Current Efforts and Recommended Future Directions Mapped to National Health Security Strategy Objectives
Appendix C: Future Scenarios4
Appendix D: Task Letter5
Appendix E: ASPR Future Strategies Working Group (FSWG)5
Appendix F: Acknowledgement of Previous National Preparedness and Response Science Board (NPRSB)
Appendix G: National Preparedness and Response Science Board (NPRSB)
Appendix H: Invited National Subject Matter Experts Presenting to the ASPR Future Strategies Working Group (FSWG)

National Preparedness and Response Science Board (NPRSB)

Assistant Secretary for Preparedness and Response (ASPR) Future Strategies Report

Introduction:

The U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) was created by the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA, Public Law No. 109-147) and reaffirmed through the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA - Public Law No. 113-5). The vision established by this legislation is for ASPR to serve a critical cross-agency leadership role, reporting directly to the U.S. Department of Health and Human Services Secretary. That vision is to "provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan." The ASPR builds on this intent, defining its mission as "leading the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security." Organizationally within HHS, ASPR is one of 16 cross-agency offices under the Office of the Secretary (See organizational charts, Appendix A).

The National Preparedness and Response Science Board (NPRSB; formerly known as the National Biodefense Science Board [NBSB]) provides expert advice and guidance to the HHS Secretary and ASPR on scientific, technical, and other matters related to public health emergency preparedness and response. The NPRSB was asked to identify future strategies that will best support successful achievement of ASPR's mission and that of HHS with regard to preparedness, response, and recovery. Requested were long-term strategies aimed at enabling ASPR and the Secretary of HHS to succeed in achieving the goal of protecting Americans' health and safety during emergencies and of fostering resilience to withstand and respond to the same. In developing recommended future strategies, the NPRSB was asked to address the following:

- Task 1: Highlight ASPR's accomplishments to date and its impact on national health preparedness and resilience.
- Task 2: Assess environmental, fiscal, policy, and other relevant spheres for potential near- and farterm conditions that may affect ASPR's mission space.
- Task 3 (reordered): Identify potential future resource and capability gaps nationally; and suggest adjustments in strategic alignment and changes to legislative authority and/or policy position. (Recommend Future Strategies)
- Task 4 (reordered): Develop an analysis which compares ASPR's current mission, requirements, strategic objectives, resources, and capabilities against near- and far-term conditions. Provide a prioritized list of suggestions based on the comparative analysis for ASPR to support its continued success in the future.

¹ Pandemic and All Hazards Preparedness Reauthorization Act, 2013. Public Law 113-5, Section 102. Assistant Secretary for Preparedness and Response. http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf.

² ASPR Strategic Plan, 2014. http://www.phe.gov/about/aspr/strategic-plan2014/Documents/stratplan-2014.pdf .

Approach to Future Strategies Development:

In addressing this request, the NPRSB utilized the following sources of information and input:

- Expert opinion and experience of the Future Strategies Working Group (FSWG) members,
- 2. Feedback and ideas from external organizations and entities that work with ASPR or have overlapping interests,
- 3. Ideas and opinions of ASPR staff from across the agency,
- 4. Discussion with experts in the use of alternative futures in developing future strategies, and
- 5. Published literature and data, where available.

More specifically, the FSWG reached out to a variety of entities both internal and external to ASPR, listening for current and future trends, learning from their experiences working with and/or within ASPR, and identifying ideas and recommendations for future strategies. In addition, the FWSG reached out to those experienced in developing and using alternative futures for planning purposes. To that end, the FSWG developed three potential future scenarios based on current knowledge as well as the identified trends and environments critical for ASPR to consider moving forward. This was undertaken to stretch FSWG member thinking, to intentionally and collectively envision widely varying but possible futures, and to drive identification of strategies aimed at maximizing likelihood of success. Working both forward from current realities (i.e., a more traditional strategic planning approach) and backwards from the aspirational future scenario (i.e., a futures planning approach), the FSWG identified recommended future strategies for ASPR. The FSWG found development of and discussion around varying potential futures to be a useful exercise in both accomplishing its work and in understanding its implications. Given this, the drafted futures are included as Appendix C. These scenarios are not meant to be actual predictions of the future; rather, they are intended to stimulate creative thinking, put recommended strategies in context, and help ASPR envision ways to maximize its own and other health security stakeholders' effectiveness in assuring "the Nation and its people are prepared for, protected from, respond effectively to, and {are} able to recover from incidents with potentially negative health consequences."3

TASK 1: Highlight ASPR's accomplishments to date and its impact on national health preparedness and resilience

ACCOMPLISHMENTS TO LEARN FROM AND BUILD UPON:

Since 2006, public health emergencies and disasters have continued to populate the American and global landscapes. Overall, the nation's preparedness and response capabilities have improved since the passage of PAHPA through the work of a multitude of public and private sector entities, including ASPR. In offering recommended future strategies, it is important to recognize and consider ASPR accomplishments – especially efforts that have uncovered promising practices and effectively implemented lessons learned. To do so, the FSWG listened to external partners and engaged ASPR staff in a review of key ASPR programs and progress made to date. Accomplishments that offer the most

Language excerpted from the definition of National Health Security, National Health Security Strategy. Page 3. 2009. http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf. Accessed 11/16/14. http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf.

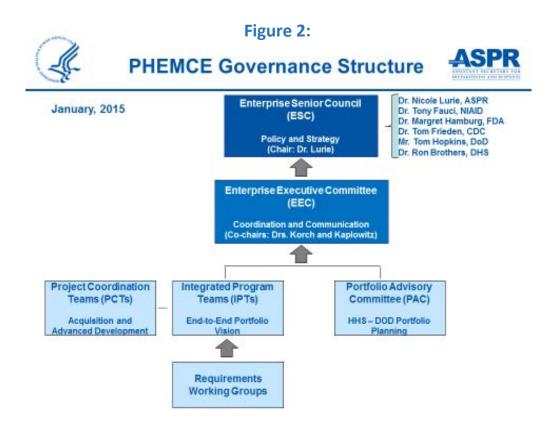
notable approaches relevant to future strategies follow. While multiple accomplishments are highlighted in this report, the FSWG focuses most heavily on the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) due to the many lessons it offers applicable to future strategies.

Medical Countermeasures/PHEMCE/BARDA: The prospective development and acquisition of medical countermeasures (MCMs) to potential threats is a critical component of the nation's preparedness, and the deployment of MCMs is an essential element of an effective response. The PHEMCE was established within HHS in 2006 to advance national preparedness against chemical, biological, radiological, nuclear (CBRN), and emerging infectious disease threats, including pandemic influenza. Over the past decade, the ASPR has effectively coordinated MCM efforts within ASPR, across HHS, and among multiple other federal partners within an otherwise complex PHEMCE structure (Figure 1) with the aim of prioritizing and efficiently advancing the development and availability of novel MCMs.

PUBLIC * STATE LOCAL THE AMERICAN PROFESSIONAL SOCIETIES CDC FDA Requirements Setting Evaluation/ CDC TRIB Distribution Early Stage Dispensing/ Administration PHEMCE A Planning. Advanced Development/ Manufacturing Policy. Guidance and ASPR, BARDA Procurement/ Regulatory SHILL ENTITIES Inventory Science Management Management/ TINDUSTRY * VATEURII Key PHEMCE Mission Components Non-HHS PHEMCE Agencies **HHS PHEMCE Agencies** Non-Federal Stakeholders

FIGURE 1: PHEMCE Structure and Roles

The PHEMCE governance model (Figure 2) provides both structure and a strong forum for collaboration on policy and strategy towards fulfillment of the PHEMCE's mission. This structure aims to support public and private sector partners working together to minimize duplication of effort, to capitalize upon complementary capabilities, and to coordinate activities as efficiently and effectively as possible.



In addition, the ASPR is directly engaged in supporting MCM research and development (R&D) through the Biomedical Advanced Research and Development Authority (BARDA), the primary advanced R&D component of the agency. BARDA's mission is to support development of and make available MCMs for various threats to national health security through product development, innovation, the building of manufacturing infrastructure, provision of technical assistance, and support of the acquisition and stockpiling of MCMs. BARDA has established solid public-private partnerships in efforts to expand domestic and international manufacturing capabilities, supporting retrofitting of existing manufacturing facilities and creation of new facilities. BARDA also created and makes available critical services to assist MCM developers, including the establishment of Centers for Innovation in Advanced Development and Manufacturing, and through the formation of several animal study and human clinical trial networks for MCM evaluation. BARDA's private sector partners include academic research institutions, diagnostic and medical device developers and producers, small biopharmaceutical companies, and large integrated biopharmaceutical companies, each bringing unique and essential research, development, and production capabilities to the MCM enterprise.

Such work can be expensive, lengthy, and involve financial risk. However, the MCMs resulting from this "enterprise" effort are showing results and are significantly contributing to the nation's readiness as well as to its ability to respond globally to emerging public health threats (e.g., recent Ebola vaccine and therapeutic products now in clinical trials are a result of prior BARDA work). Many products resulting from BARDA exploration, by their nature, also have routine applications for use in provision of medical

care and protection of public health. Examples include the FluRSV Point of Care Diagnostic (3M/Focus), antiviral drugs against influenza (Novartis/Protein Sciences Corp.), botulinum antitoxin (Cangene), and portable ventilators (Covidian). BARDA has focused not only on products but also on systems. The ASPR has supported the establishment of surge biological production capabilities across the country to permit the rapid manufacturing and deployment of vaccines and/or biological therapeutics should a need arise, pre-event establishment of fill-finish and clinical trial networks, and a national stockpile for rapid deployment of specific MCMs. The result is a nation that is better equipped to respond to emerging public health threats than it was a decade ago. However, there remain numerous potential threats for which the prospective development of MCMs as well as systems to support their rapid availability and use would still be exceedingly useful (e.g., a universal flu vaccine, host modulating approaches to microbial infection offering broader spectrum applicability).

In many ways, the scope of the country's MCM enterprise serves as a model for advancing the nation's capabilities in preparing for future events. Despite the complex relationship matrix, and at times, uncertain authority within the federal environment, PHEMCE's performance demonstrates that with clarity of mission, leadership, collaboration among stakeholders, and resources, significant progress can be made. Similarly, the effective partnerships created through BARDA have demonstrated that the gap between public and private sectors can be aligned and productively bridged. Much has been accomplished through these efforts over the course of a few years.

Key components to learn from PHEMCE and apply to other programs include the following:

- The importance of a **clear structure** with incorporation of both **strategic and operational components**.
- A strong focus on building partnerships and collaborations that draw upon and integrate the
 expertise and capabilities of multiple entities across sectors at both strategic and operational
 levels. The focus is on advancing common objectives and working to create results with shared
 benefit and risk. The strongest PHEMCE integrations appear to be among federal agencies, then
 with private sector partners.
- PHEMCE has both a **clear mission** and is **comprehensive in scope**.
- PHEMCE focuses on policy and develops such in collaboration with partners and stakeholders.
 It then defines where / who is able to operationalize the policy most effectively, often building and sustaining networks in advance of an event to provide more streamlined and flexible response when needed (e.g., fill-finish network, clinical studies network).
- PHEMCE **seeks innovation**, explores promising approaches, supports development of, and then implements, new technologies.
- PHEMCE has a **defined system for prioritization** of efforts given limited resources.
- Importantly, many components of the PHEMCE have been funded at significant levels and some in multi-year blocks, enabling development and implementation of a more strategic, comprehensive, and effective approach.

OTHER KEY ACCOMPLISHMENTS:

Several other key accomplishments are of note, to both learn from and build upon as examples of ASPR's primary areas of leadership: **coordinating policy, integrating systems, supporting development of foundational elements**, and **fostering innovation** aimed at advancing national health security and the health of the public.

Advancing Health Care System Preparedness and Promoting Health Care Coalition Development

The Hospital Preparedness Program has worked extensively in recent years to advance health care system preparedness and promote community-based health care coalitions. ⁴ Through the provision of funding, integration into regulation, and provision of technical assistance, ASPR has helped engage health care partners, especially hospitals, in emergency preparedness and response efforts more extensively than ever before seen. Health care workforce involvement in preparedness training and exercises as well as development of health care emergency operation capabilities have advanced in many, though not all, facilities or systems. While states and communities are still evolving and refining such approaches, health care coalitions appear to be advancing preparedness and response when effectively implemented (i.e., advancing crossagency coordination, supporting use of shared resources, better distribution of event-specific clinical guidance, and better alignment of patient volume and facility capability). ⁵ In addition, it should be noted that establishing and maintaining the Hospital Preparedness Program and its grants create a strong field-based connection for ASPR with state and local health agencies and the nation's health care system. This is critical for ASPR in assuring a realistic understanding of preparedness opportunities and challenges moving forward.

• Development and Use of Regional Emergency Coordinators

Over the last several years, ASPR has effectively developed HHS' Regional Emergency Coordinator (REC) network in ways that better support and advance integration of federal, state, and local preparedness and response efforts. While broader and more extensive work to more seamlessly connect federal, state, and local systems is needed, this network has proved to be a very helpful start. RECs now actively participate in state and local preparedness planning and exercise efforts, provide hands-on support and expertise in planning, assist states and localities to access information on and work with federal assets, and help engage and coordinate among federal agency partners for states. The frequent interaction and field participation of RECs help build relationships and bridge the cultural divide between federal agencies and state and local response systems. Regional Emergency Coordinators emphasize the importance of both field-based and broader system knowledge as well as the importance of developing trusted relationships when working to build integrated response systems that are practical and realistically operationalized.

⁴ Medical Surge Capacity and Capability Handbook. Section I.3.1. A Healthcare Coalition is "a group of healthcare organizations in a specified geographic area that agree to work together to enhance their response to emergencies or disasters. The Coalition also promotes the efficient interface of its member organizations with jurisdictional authorities.... The Coalition serves as a coordinating entity during incident response; it does not supplant the relevant incident command authority." Accessed at

http://www.phe.gov/Preparedness/planning/mscc/healthcarecoalition/chapter1/Pages/healthcarecoalition.aspx

Pole T, Marcozzi D, Hunt R. "Interrupting My Shift: Disaster Preparedness and Response." *Annals of Emergency Medicine*. Volume 63, (5): 584–588. May 2014. DOI: http://dx.doi.org/10.1016/j.annemergmed.2013.08.030.

• Legal and Policy Advances

ASPR has facilitated processes across agencies to establish and implement Emergency Use Authorizations (EUAs), Public Health Emergency (PHE) declaration authorities, and Public Readiness and Emergency Preparedness (PREP) Act protections. It was these types of policies and protections that enabled health care workers to adopt and fully utilize antivirals and newly manufactured vaccines during the H1N1 pandemic. These examples highlight ASPR's role and ability to provide leadership in advancing policies and tools to address common and widely experienced barriers to response efforts across the nation and to enable a more consistent and streamlined approach to response across all jurisdictions.

• Dialogues and Frameworks for Global Sharing and International Coordination of Response While still early and not yet at its full potential, ASPR has actively focused on advancing international collaborations and establishing mechanisms for sharing of resources and reducing risk across borders. Such efforts are critical for establishing the relationships and systems necessary for responding to global health threats and for advancing national health security. ASPR's efforts recognize that it is not only an ethical responsibility for global partners to support each other, but also that global threats left unchecked present national risks. ASPR's efforts include reducing global biological risk and advancing biosecurity, developing International Health Regulations, working with the Global Health Security Initiative, and developing frameworks and operational capacity for sharing of data among international partners.

Advancing the Science Behind Disaster Response and Recovery Through Real-time, Event based Research

Following Hurricane Sandy, ASPR exhibited foresight and led efforts to rapidly secure funding, mobilize, and integrate real-time research efforts into recovery. Funded projects aim to better understand and improve the resilience and recovery of health care systems, understand the roles of social networks in community resilience and recovery, and explore factors supporting mental, behavioral, and physical health response and recovery. Such approaches built into actual response and recovery efforts offer substantial opportunity to advance preparedness science and guide future responses. In addition, grants were coordinated with other response and recovery funding administered through the Centers for Disease Control and Prevention (CDC), supporting more integrated public health system recovery and laying the groundwork for broad dissemination of research findings.

• Engaging Partners to Make Relevant Data Accessible and Usable for Preparedness and Response; Using Data to Inform Preparedness, Response, and Recovery

Data relevant to national health security and emergency response is increasingly collected by a host of federal agencies, private sector partners, and social media networks; however, it is often not available to those who could use such information for preparedness and response or not available in a format that makes it accessible, timely, and useful. ASPR has engaged in innovative initiatives to begin addressing this issue. For example, ASPR facilitated promising

⁶ HHS Press Office. "HHS awards grants for Hurricane Sandy recovery research: Hard hit communities benefit from research on long-term health recovery". http://www.hhs.gov/news/press/2013pres/10/20131022a.html. October 22, 2013.

efforts undertaken with the Centers for Medicare and Medicaid Services (CMS) and field partners to use Medicare claims data in identifying beneficiaries living at home with electricity-dependent medical equipment, individuals often in need of preparedness for and targeted assistance during disasters. In addition, ASPR explored the use of Twitter feeds and other tools to capture medical and public health situational awareness data during Hurricane Sandy, learning key lessons on implementing such strategies for the country. Between the strategies for the country.

Efforts to Coordinate and Better Align Efforts Between CDC and ASPR

In recent years, both CDC and ASPR have put forth significant efforts aimed at better aligning and more fully integrating efforts between the two organizations, especially as each relates to state and local awardees. The goal has been to reduce administrative burden upon awardees and to assure federal policy supports program integration at federal, state, and local levels. Accomplishments to date include the alignment of public health emergency preparedness and health care preparedness capabilities, alignment of grant funding cycles and application processes for the CDC Public Health Emergency Preparedness and ASPR Hospital Preparedness Program grants, and Strategic National Stockpile (SNS) integration into PHEMCE efforts. Although administrative burden upon awardees remains high, progress has been made. More importantly, such efforts help in supporting field-based integration of efforts across public health and health care systems.

It should be noted that each of these accomplishments, while often housed within individual program offices, are "system" approaches requiring coordination of efforts both internal and external to the agency and facilitation of collaborations aimed at reaching defined objectives of mutual benefit. They represent efforts to learn from and to continue building upon implementation of future strategies.

TASK 2: Assess environmental, fiscal, policy, and other relevant spheres for potential nearand far-term conditions that may affect ASPR's mission space.

SUMMARY: The NPRSB identified the following key trends and projected conditions relevant to ASPR's future strategies:

- Trend 1. Disasters and emergencies will remain a significant threat to the health and safety of communities and the security of the nation. By most accounts, events are increasing in frequency, severity, and cost.
- Trend 2. Economic challenges pose major threats to at least three core components of our nation's health security. These include:
 - a. The ability to domestically develop and produce new medical countermeasures and needed technologies,

⁷ Karen DeSalvo, Nicole Lurie, Kristen Finne, Chris Worrall, Alina Bogdanov, Ayame Dinkler, Sarah Babcock, and Jeffrey Kelman. "Using Medicare Data to Identify Individuals Who Are Electricity Dependent to Improve Disaster Preparedness and Response." *American Journal of Public Health*: July 2014, Vol. 104, No. 7, pp. 1160-1164.

⁸ Harris Smith S, Bennett KJ, Livinski AA. "Evolution of a Search: The Use of Dynamic Twitter Searches During Superstorm Sandy." *PLOS Currents Disasters*. 2014 Sep 26. Edition 1. doi: 10.1371/currents.dis.de9415573fbf90ee2c585cd0b2314547.

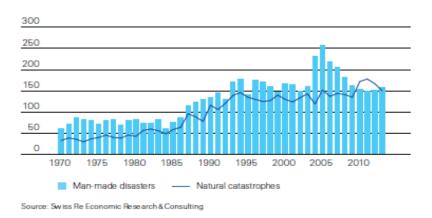
- b. The stability of the nation's public health system and its potential for further growth and maturation, and
- c. The ability of health care systems to engage in and commit to emergency preparedness.
- Trend 3. Disaster risk reduction is a critical component of advancing health security globally and in the United States (US). Much can be done to reduce the likelihood of and prevent events and other health threats from becoming disasters.
- Trend 4. Social and entrepreneurial models are changing. Networks, collaborations, and more decentralized models of leadership are being used to address complex issues, spark and support innovation, advance common objectives, and more widely distribute both benefit and risk.
- Trend 5. Demographic and environmental changes relevant to health security are projected to occur in the United States.
- Trend 6. Data and data computation capacity are rapidly expanding, as is the need for data systems integration and cyber security.

DISCUSSION OF TRENDS AND CONDITIONS LIKELY TO AFFECT ASPR'S FUTURE MISSION SPACE

Trend 1: Disasters and emergencies will remain a significant threat to the health and safety of communities and the security of the nation. By most accounts, events are increasing in frequency, severity, and cost.

Discussion: Data shared by the Federal Emergency Management Agency (FEMA) and others indicate that the number of disasters reported worldwide has increased over the last few decades along with the magnitude of their effects. From 1970 to 2013, the number of disasters increased over time for both man-made and natural disasters [Figure 3].⁹

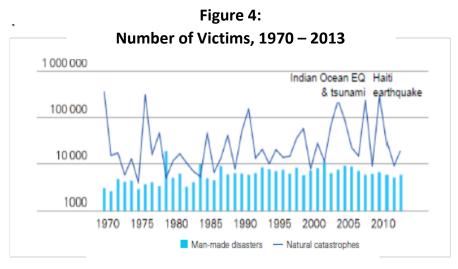
Figure 3: Number of Catastrophic Events,* 1970 – 2013



⁹ Bevere, L. and L. Mueller, "Natural catastrophes and man-made disasters in 2013." sigma No 1/2014. P. Ronke and K. Karl, Editors. 2014, Swiss Re Ltd: Zurich.

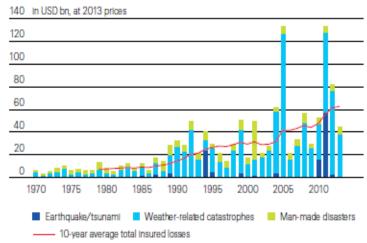
^{*} an event is classified as catastrophic when insured claims, total economic losses or the number of casualties exceed a certain threshold. See Swiss Re reference above for thresholds used.

The severity of disasters across the globe, in terms of both lives lost and cost, has also increased as indicated by the increase in the number of victims (missing or dead) [Figure 4] and the significant spike in insured losses in the past decade [Figure 5]. Other sources note that US disaster declarations have increased in frequency and cost as well. 11,12



Note: Scale is logarithmic: number of victims increases tenfold per band Source: Swiss Re Economic Research & Consulting

Figure 5: Insured Catastrophe Losses,* 1970 – 2013



Source: Swiss Re Economic Research & Consulting

¹⁰ Bevere, L. and L. Mueller, "Natural catastrophes and man-made disasters in 2013." sigma No 1/2014 P. Ronke and K. Karl, Editors. 2014, Swiss Re Ltd: Zurich. Labelling of Fig. 4 events modified by Kaufman, FEMA.

¹¹ Smith, A. and R. Katz, "US billion-dollar weather and climate disasters: data sources, trends, accuracy and biases." *Natural Hazards*, 2013. 67(2): p. 387-410.

¹² FEMA. FEMA Disaster Declarations by Year 2000-2013. Accessed 2014 at http://www.fema.gov/disasters/grid/year.

Likely drivers of the increase in disasters and emergencies include urbanization and other population demographic changes, global travel, changing terrorist threats, and political and societal instability, among others. ¹³ In addition, growing evidence supports the adverse health and economic effects of climate change. ¹⁴ Observed climate trends are projected to impact the occurrence and/or severity of weather-related events, available farm crops, and distribution of infectious diseases and have significant implications for preparedness, response, and recovery. ¹⁵

In sum, disasters and emergencies can be expected to remain a significant threat to the health and safety of communities and the security of the nation.

Trend 2: Economic challenges pose major threats to at least three core components of our nation's health security. These include:

- a. The ability to domestically develop and produce new medical countermeasures and needed technologies,
- b. The stability of the nation's public health system and its potential for further growth and maturation, and
- c. The ability of healthcare systems to engage in and commit to emergency preparedness.

Discussion: Changes to the economic environment are creating serious challenges for scientific research and innovation and are reducing public health system stability. In addition, the health care sector is in a state of rapid change, with adaptations underway to health care delivery models, health care systems, and health care financing. In this state of rapid change and uncertainty, with decreasing funds and increasing fiscal pressures, economic and/or service delivery disengagement by public and private sector "safety net" providers and other partners critical to health security (e.g., health departments, hospitals, academic medical centers, biotechnology and pharmaceutical industries) is reported from the field. In addition to the effect of economic change on individual sectors, these same stressors have the potential to further harm relationships among the various components of the larger system including federal-state-local-private sector interactions. These relationships are critical to an effective response.

Exploring conditions of these three core health security system components in light of economic trends reveals that:

a. The nation's domestic workforce, expertise, and facilities to develop and manufacture medical countermeasures are at risk of decline.

The prospective development and acquisition of MCMs to potential threats is a critical component of the nation's preparedness, and the deployment of MCMs is an essential

¹⁴ Melillo JM, Richmond TC, Yohe GW, Eds. 2014: Climate Change Impacts in the United States: The Third National Climate Assessment. U.S. Global Change Research Program, Washington, DC: U.S. Government Printing Office 841 pp. doi:10.7930/J0Z31WJ2. Accessed January 2015 at http://nca2014.globalchange.gov/.

¹³ FEMA. Crisis Response and Disaster Resilience 2030: Forging Strategic Action in an Age of Uncertainty. 2012; Available from: http://www.fema.gov/media-library-data/20130726-1816-25045-5167/sfi report 13.jan.2012 final.docx.pdf.

¹⁵ FEMA. Strategic Foresight Initiative. *Climate Change: Long Term Trends and their Implications for Emergency Management*. Available at: http://www.fema.gov/pdf/about/programs/oppa/climate change paper.pdf. August 2011.

element of an effective response. Over the past decade, ASPR has made significant progress and effectively led collaborations to advance the nation's ability to identify, develop, manufacture, and distribute MCMs (See Accomplishments). The result is a nation that is better prepared to respond to emerging public health threats than it was a decade ago. Yet, there remain numerous potential threats for which the prospective development of MCMs is still very much needed. In addition, novel approaches to classes of disease show promise (e.g., oligonucleotide therapeutics, development of tools to stimulate the immune system, genomics, and gene therapy).

This ASPR-led "enterprise" for MCM development encompasses many critical partners beyond federal government agencies. These partners include academic research institutions, diagnostic and medical device developers and producers, small biopharmaceutical companies, and large integrated biopharmaceutical companies. Each brings unique and essential research, development, and production capabilities to MCM efforts. In many ways, the scope of the country's MCM enterprise serves as a model of the nation's capabilities in preparing for future eventualities.

An assessment of current trends affecting the MCM enterprise partners, however, shows the following:

- A decline in "real" funding levels for those federal agencies that are essential to the enterprise, particularly the National Institutes of Health (NIH) and the CDC ¹⁶
- Associated declines in academic research funding, particularly for investigators¹⁷
- Decreased private sector productivity for new drug, vaccine, and medical/diagnostic device development¹⁸
- Consolidation of the nation's biopharmaceutical industry, and the associated downsizing of in-country R&D and manufacturing resources^{19,20}
- A decline in the number of highly trained scientists employed in biomedical research.²¹ With limited opportunities, the number of scientific/medical researchers in areas relevant to the development and production of MCMs, including microbiology, drug and vaccine manufacturing, and medical device production, may also decline moving forward.

The preponderance of this data supports the conclusion that the enterprise will likely not be as effective in the future as it has been in the recent past. While insufficient funding levels can be reversed "quickly," the same is not true for eroded operational and trained personnel deficits or production capacity. Accordingly, if these trends are permitted to

¹⁹ Bloomberg Data, http://www.bloomberg.com/infographics/2014-05-01/pharma-mergers.html;

Johnson, J.A., Congressional Research Service, 2013; CDC Fact Sheet, http://www.cdc.gov/fmo/topic/budget%20information/appropriations-budget-form-pdf/Sequester-Impacts.pd

¹⁷Atkinson, R.D. and Stewart, L.A., 2011, *Report of the Information Technology and Innovation Foundation*.

¹⁸ Scannell, J.W., et al., 2012, *Nature Reviews Drug Discovery* 11: 191.

²⁰ LaMattina J., *Forbes*, http://www.forbes.com/sites/johnlamattina/2014/06/10/biopharmaceutical-industry-consolidation-diminishes-future-drug-discovery/.

²¹ NIH: *Biomedical Research Workforce Working Group Report*. June 2012. Accessed December 2014. URL: http://acd.od.nih.gov/biomedical research wgreport.pdf.

continue for an extended period, the nation's prospective MCM R&D efforts will likely become severely compromised.

b. Reductions in public health funding and the approaching exodus of an aging public health workforce do not align with anticipated future needs, potentially leaving the United States vulnerable to emerging infectious diseases and at risk of poor responses to disasters.

Public health agencies are on the frontlines of health threats, both anticipated and unanticipated. With emerging infectious diseases, the threat of bioterrorism, and increasing natural disasters, public health institutions and personnel assume broad and complex responsibilities for health and medical emergency preparedness and response. To mobilize and respond appropriately, state and local public health agencies must be strong, effective, and stable.²²

The governmental public health system is facing many new and growing challenges. In addition to response to emerging deadly infectious diseases such as Ebola, Middle East Respiratory Syndrome (MERS), pandemic influenza, and Severe Acute Respiratory Syndrome (SARS), these challenges include work to reduce and address epidemics of chronic diseases; a growing need for integration into and adoption of health information technology systems; changing population demographics presenting new and different needs (e.g., an aging population, immigration); rising health care costs impacting service delivery; the approaching exodus of an aging public health workforce; ²³ climate change; and societal consequences of the economic recession. ^{24,25,26,27}

At the same time, in an effort to increase efficiency, accountability, and transparency, public health and health care systems are implementing efforts towards accreditation of public health agencies and quality improvement programs. They are also working to influence and respond to changes in national, state, and local health care policies as well as passage of the Affordable Care Act. ^{28,29} Many public health agencies now face both the great opportunities presented by and challenges involved in leading and participating in multiorganizational efforts aimed at advancing community health. Central to all these efforts are public health skills of applied epidemiology, risk assessment, surveillance, the ability to execute public health laboratory network capabilities, and the ability to coordinate efforts across organizations and sectors. Each of these every day skills are also core components of

²² Landesman LY et al. 2008. "Roles and Responsibilities of public health in disaster preparedness and response." In *Public Health Administration: Principles for Population-based Management*, edited by Lloyd Novick. 2nd edition. Jones and Bartlett Publishers.

²³ School of Public Health, University of Washington. *Public Health's Aging Workforce, Aging Leaders*. Accessed December 2014. URL: https://www.nwpublichealth.org/web-specials/aging-leaders.

²⁴ Institute of Medicine (US). For the public's health: Investing in a healthier future. Washington, DC: The National Academies Press. 2012.

Novick LF. "Local health departments: Time of challenge and change." *Journal of Public Health Management and Practice*. 2012:18 (2): 103-105.

²⁶ Bodenheimer T, Chen E, Bennet HD. "Confronting the growing burden of chronic disease: Can the U.S. healthcare workforce do the job?" *Health Affairs*. 2009; 28 (1): 64-74.

Henry J. Kaiser Family Foundation. *U.S. Health Care Costs. 2012.* http://www.kaiseredu.org/issue-modules/us-health-care-costs/background-brief.aspx.

²⁸ Koh HK, Sebelius KG. "Promoting prevention through the Affordable Care Act." *N Engl J Med*. 2010; 363(14): 1296-11299.

²⁹ U.S. Department of Health & Human Services. *2012 Annual Progress Report to Congress. National Strategy for Quality Improvement in Health Care.* April 2012.

public health emergency response. Public health and health care workers trained and skilled in these essential core competencies are critical to national health security and to the health of the nation more broadly.³⁰

Despite growing demand and an increasing focus on community health, resources to accomplish emergency preparedness and other public health work are unstable and declining. For example,

- Targeted public health and health care preparedness funds (i.e., Public Health Emergency Preparedness and Hospital Preparedness Program grants) are now at 70% and 50%, respectively, of funding levels a decade ago.
- Funds in response to specific disasters come as large influxes for short time frames and with targeted purposes.
- The Prevention and Public Health Fund, a fund envisioned to expand the nation's public health and disease prevention systems using evidence-based and innovative partnership approaches, is not funded at its original recommended level and is not targeted to be restored to intended levels until 2022.³²

The pattern of declining funds with intermittent surges around specific disasters makes strategic investments, maintenance of a stable workforce, and sustainment of core response capabilities challenging.

As a result of these and other funding losses as well as funding unpredictability

- State health agencies report over 11,000 jobs cut since 2008 (91% of states). 95% of state health agencies report reductions in services and 71% full program cuts over this timeframe.³³
- Local health departments have lost almost 44,000 jobs since 2008. During 2012 alone, 48% of all local health departments reduced or eliminated services in at least one program area.³⁴
- Collectively, public health job losses since 2008 represent a decline of over 19% of the nation's state and local public health workforce. ³⁵

As health departments across the country struggle with funding cuts in the face of growing service need, they are increasingly facing difficult choices around both basic public health

³⁰ Landesman LY et al. "Roles and Responsibilities of public health in disaster preparedness and response. " In *Public Health Administration: Principles for Population-based Management,* edited by Lloyd Novick. 2nd edition. Jones and Bartlett Publishers. 2008.

³¹ National Center for Disaster Preparedness. Columbia University. *Trends and Impacts in National Health and Medical Preparedness Funding*. http://www.scribd.com/doc/242986387/Trends-and-Impacts-in-National-Health-and-Medical-Preparedness-Funding#force seo . Published October 14, 2014.

APHA. *The Prevention and Public Health Fund*. Issue Brief. http://www.apha.org/~/media/files/pdf/topics/aca/apha prevfundbrief june2012.ashx . June 2012.

ASTHO. Budget Cuts Continue to Affect the Health of Americans. http://www.astho.org/budget-cuts-Sept-2014/. September 2014.

National Association of County and City Health Officials. *Local Health Department Job Losses and Program Cuts:* State-Level tables from January/February 2012 Survey. April 2012.

http://www.naccho.org/topics/infrastructure/lhdbudget/upload/State-level-tables-Final.pdf.

³⁵ ASTHO. Budget Cuts Continue to Affect the Health of Americans. http://www.astho.org/budget-cuts-Sept-2014/. September 2014.

service delivery and reducing disaster readiness capabilities. While not identical, the workforce and skills sets for the two are closely related.

 Health care delivery systems, including academic medical centers, are working to significantly reduce operating costs. This contributes to a reduced focus on research, education, service, and emergency preparedness planning – all critical to the nation's health security.

In the drive to reduce operating costs and compete in the current economic climate, both non-profit and for-profit health care providers and delivery systems are engaging process improvement and expense reduction as core strategies towards increasing the efficiency of their clinical operations. Even academic medical centers, institutions historically operating with higher costs, are being compelled to become more cost competitive ^{36,37,38} From a health care marketplace perspective, and under normal daily operating conditions, a leaner and more efficient health care system is desirable and offers value to patients and insurers. However, these financial pressures combined with substantial reductions in Hospital Preparedness Program funding also come with unintended consequences, most notably, an increasing challenge to meaningfully engage health care entities in health security planning and an increasingly limited capacity to address large-scale emergencies. ³⁹

In the aftermath of cost-reduction efforts, most health care systems no longer function with the same space, staff, equipment, or supplies they had previously, as it is too expensive to sustain intermittently or underutilized resources. Cost reductions and shortages of available skilled staff, such as within nursing, have often translated to lower clinical staff-to-patient ratios. Hospitals and clinics have consolidated clinical space, merging or closing patient care units, or reducing outpatient exam room space. Health care organizations now maintain leaner stockpiles of routine supplies, medications, and key equipment. Hospital inpatient facilities operate much closer to full capacity, and while most hospitals have back-up capacity systems to allow modest expansion, many are not nimble in this exercise, given lack of timely access to additional skilled staff. From a mass casualty event preparedness perspective, the systematic reduction of surplus resources and shortages of available clinical staff effectively limit surge capacity within health care systems. 40,41 The growing prevalence of emergency department overcrowding, driven largely by inadequate inpatient capacity,

³⁶ PWC Health Research Institute. *The Future of the Academic Medical Center: Strategies to Avoid a Margin Meltdown.* Price Waterhouse Cooper, February 2012. Available at: http://www.pwc.com/us/en/health-industries/publications/the-future-of-academic-medical-centers.jhtml.

³⁷ Dzau VJ, Cho A, ElLaissi W, et al. "Transforming academic health centers for an uncertain future." *NEJM* 2013; 369(11):991-993.

Enders T, Conroy J, AAMC Advisory Panel on Health Care. Advancing the Academic Health System for the Future. Washington, DC: Association of American Medical Colleges, 2014.

³⁹ Smith WM. *Financing surge capacity and preparedness. Medical Surge Capacity Workshop Summary.* IOM Forum on Medical and Public Health Preparedness for Catastrophic Events. Washington, DC: National Academies Press; 2014.

⁴⁰ Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. "Medical Surge Capacity." Washington (DC): National Academies Press (US); 2010.

⁴¹ "Nursing shortage may have adverse impact on public health emergency preparedness." *AHRQ Research Activities*, 01 April 2011, vol./is. /368(10-10), 15370224, Publication Date: 01 April 2011.

offers suitable evidence of poor surge capacity. 42,43 The steady annual growth of patient visits to emergency departments, and large volumes seen during influenza and other viral illness seasons, indicate the absence of sufficient surge capacity in the ambulatory care sector. 44 Pre-hospital emergency care 45,46 and long-term care facilities certainly face economic and capacity challenges as well.

In addition, with focus on cost reduction, profit margins previously available from clinical services are decreasingly available to fund non-clinical activities, including research, education, community outreach, and public service. This, combined with diminishing extramural funding from grants, contracts, and foundations, has caused health care organizations of all types and sizes, including academic medical centers and safety-net hospitals, to make increasingly critical decisions about important services that offer great benefit to both their organization and the local community, but are neither based on nor generate sustainable funding. This includes emergency preparedness activities.

Trend 3: Disaster risk reduction is a critical component of advancing health security globally and in the US. Much can be done to reduce the likelihood of and prevent events and other health threats from becoming disasters.

Discussion: With greater understanding of the burden of disease and cost of health care, there is growing emphasis on and discussion of prevention in both economic and health policy realms. The World Bank notes that given the alarming trend of rising disaster losses, disaster risk management is increasingly at the core of its business. ⁴⁷ This risk reduction focus equally applies to health security, for much can be done to prevent events and health threats from becoming disasters. Disaster risk reduction is the concept and practice of reducing disaster risks through systematic efforts to analyze and address the causal factors of disasters. Reducing exposure to hazards, lessening vulnerability of people and property, wise management of land and the environment, and improving preparedness and early warning for adverse events are all examples of disaster risk reduction. ⁴⁸

Many, though by no means all, health preparedness and response efforts undertaken by public health and health care systems in the US focus heavily on "response" or "reaction" to disasters. Often, less emphasis is placed on the prevention or mitigation components of our preparedness

⁴²Hoot NR, Aronsky D. "Systematic review of emergency department crowding: causes, effects, and solutions." *Annals of Emergency Medicine* 2008; 52(2):126-136.

⁴³ Moskop JC, Sklar DP, Geiderman JM, et al. "Emergency department crowding, part 1—concept, causes, and moral consequences." *Annals of Emergency Medicine* 2009; 53(5):605–611.

⁴⁴ Stockwell MS, Rausch J, Sonnett M, et al. "Parental reasons for utilization of an urban pediatric emergency department during the 2009 h1n1 influenza epidemic." *Pediatric Emergency Care* 2011; 27(4):261-265.

⁴⁵ Gabriel E, Pons P, Foltin G, et al. "Prehospital care." In Phillips SJ, Knebel A, eds. *Mass Medical Care with Scarce Resources: A Community Planning Guide*. Prepared by Health Systems Research, Inc., Agency for Healthcare Research and Quality 2007. Accessed 1-21-15 at URL: http://archive.ahrq.gov/research/mce/mceguide.pdf.

⁴⁶ Van Milligan M, Mitchell III JP, Tucker J, et al. *An Analysis of Prehospital Emergency Medical Services as an Essential Service and as a Public Good in Economic Theory*. (Report No. DOT HS 811 999a). Washington, DC: National Highway Traffic Safety Administration. May 2014.

⁴⁷ World Bank. *Managing Disaster Risks for Resilient Development*. Accessed 12-30-14 at URL: http://www.worldbank.org/en/results/2013/04/12/managing-disaster-risks-resilient-development.

⁴⁸ United Nations Office for Disaster Risk Reduction. "What is Disaster Risk Reduction?" URL: http://www.unisdr.org/who-we-are/what-is-drr. Accessed 12-12-2014.

framework. Disaster risk reduction incorporates a broader, more prospective focus on prevention. While serious health hazards cannot always be prevented from occurring, choices made in advance (e.g., regulatory policy, land use, building regulation, climate change action, safety standards, cybersecurity systems, reducing procurement of or enhancing containment of nuclear material, early warning systems) can reduce the likelihood of these risks becoming disasters.

Global efforts towards disaster risk reduction as a primary means of improving health security and decreasing the costs of disaster response is outlined in the Hyogo Framework. ⁴⁹ Increasing societal, political, and private sector recognition and value placed on prevention make it an opportune time to more intentionally incorporate disaster risk reduction concepts and principles into policies and practices aimed at enhancing health security.

Trend 4: Social and entrepreneurial models are changing. Networks, collaborations, and more decentralized models of leadership are being used to address complex issues, spark and support innovation, advance common objectives, and more widely distribute both benefit and risk.

Discussion: Models of collective impact, ⁵⁰ governing by network, ⁵¹ and other such approaches introduced in recent years work to address complex, societal issues through collaborative leadership. They are aimed at aligning related efforts towards common goals, sparking and supporting innovation, sharing benefit, and distributing risk in order to advance progress. These models often enable multiple and sometimes disparate organizations and sectors to work together. Such collaborative approaches are being applied in both private and public sectors. Small biotech and information technology companies collaborate to innovate change and mobilize new technology. Philanthropic and other funding organizations are engaging diverse players to address large platforms by "acting as conveners, champions, and matchmakers, connecting people, ideas, and resources." In some models, governments shift roles from one of providing centralized control over public programs to one in which they instead work to be a "generator of public value." They facilitate networks and support collaborations that engage and link stakeholders and generate novel, more mutually embraced and effective approaches to common and often complex societal objectives (e.g., education, health, community development).

Managing networks and facilitating collective impact can require different skill sets than managing divisions of public employees or targeted top-down programs. In addition, such shifts can be challenging for large, hierarchical organizations governed by regulations and sometimes complex bureaucratic processes, each aimed at serving an important and specific purpose. At

ASPR Future Strategies Report.

17

⁴⁹ UNISDR. "Hyogo Framework for Action 2005-2015: Building the resilience of nations and communities to disasters." http://www.unisdr.org/we/coordinate/hfa. Accessed December 2014.

⁵⁰ Kania, J., Kramer, M. "Collective Impact." *Stanford Social Innovation Review*. Winter 2011. http://www.ssireview.org/articles/entry/collective_impact. Accessed December 2014.

⁵¹ Goldsmith, Stephen, and William D. Eggers. 2004. *Governing by Network: The New Shape of the Public Sector*. Washington, D.C.: Brookings Institution Press.

⁵² Grantmakers for Effective Organizations. *Catalyzing Networks for Social Change*. http://www.geofunders.org/resource-library/all/record/a0660000008GpukAAC. October 5, 2011.

⁵³ Goldsmith, Stephen, and William D. Eggers. 2004. *Governing by Network: The New Shape of the Public Sector.* Washington, D.C.: Brookings Institution Press.

the same time, if organizational cultural shifts can be made and agency flexibility increased, using such collective impact or networked approaches can offer new, innovative, and often more effective solutions to complex social issues, shifting away from superficially interacting "silo" systems. In addition, they can foster development of relationships and plans enabling rapid and more facile problem solving at times of crisis. The development of robust response systems to manmade and natural disasters and the advancement of community resilience are complex societal issues that could benefit from increased use of such approaches.

Trend 5: Demographic and environmental changes relevant to health security are projected to occur in the United States.

Discussion: Planning for future ASPR strategies must account for what the population and environment are anticipated to look like in the future. Major changes are projected to occur in the US population, including size, geographic distribution, age structure, racial diversity, socioeconomic status, and cultural beliefs. Specific trends can be found elsewhere, but include:

- Continued increases in US population for several years⁵⁴, with much of the driver being immigration, primarily from Latin America and Asia.⁵⁵
- An aging population, ⁵⁶ suggesting implications for the types of support assistance that may be needed by states during natural emergencies (e.g., durable medical equipment) or increased susceptibility for emerging infectious diseases in certain segments of the population (e.g., infants, elderly, those with weakened immune systems).
- Societal changes in family structure and mobility⁵⁷ suggest that while many individuals will
 continue to be able to draw on resources from family for preparation and response to
 public health emergencies, a growing percentage may need assistance from neighbors,
 friends, and governmental or other assistance organizations for events presenting
 significant health threats.
- Some urban centers are projected to continue increasing in population. 58,59
- Increases in internet connectivity and energy-efficient transportation, leading to economic opportunities in services and manufacturing, suggest a possible reversal of the steady

⁵⁴ Grayson K. Vincent and Victoria A. Velkoff. "The Next Four Decades: The Older Population in the United States: 2010 to 2050." *Current Population Reports*. U.S. Census Bureau, U.S. Department of Commerce, Economics and Statistics Administration. 2010.

⁵⁵ Kotkin, J. The Changing Demographics of America. The United States population will expand by 100 million over the next 40 years. Is this a reason to worry? 2010. Accessed November 2014 at http://www.smithsonianmag.com/40th-anniversary/the-changing-demographics-of-america-538284/#TTEz9PX4JSVUHyL6.99.

Grayson K. Vincent and Victoria A. Velkoff. "The Next Four Decades: The Older Population in the United States:
 2010 to 2050, Current Population Reports." Current Population Reports. U.S. Census Bureau, U.S. Department of Commerce, Economics and Statistics Administration.

⁵⁷Copen, Casey E., Kimberly Daniels and William D. Mosher. "First Premarital Cohabitation in the United States: 2006-2010 National Survey of Family Growth." *National Health Statistics Report*, No. 64. April 2013.

⁵⁸Kotkin, J. "The Changing Demographics of America. The United States population will expand by 100 million over the next 40 years. Is this a reason to worry?" *Smithsonian*. August 2010. Accessed November, 2014 at http://www.smithsonianmag.com/40th-anniversary/the-changing-demographics-of-america-538284/#TTEz9PX4JSVUHyL6.99.

⁵⁹ Gyourko J., Mayer C, and Sinai T. "Superstar Cities." *American Economic Journal: Economic Policy*, 5(4):167-199. 2013. http://dx.doi.org/10.1257/pol.5.4.167.

- decline that has taken place in many small town communities dramatically affected by market forces of the late 20th century. Similarly, growth in the energy sector is leading to a reversal of population decline in some more rural locations as well, with population expansions at times exceeding available infrastructure and services.
- Individuals are increasingly connecting through large and distributed technology and social networks, often rapidly spanning communities and continents. Social media, crowd-sourcing, and other technology-based networks have become tools for information dissemination, service delivery, and societal change. Novel collaborations with such entities, data sharing, and meta-data analysis offer opportunities to more fully understand social behavior, actions, and beliefs in real time before, during, and after disaster. This can support informed policy more effectively addressing current challenges and better channeling communications. While helpful for rapidly sharing information, multiplying information dissemination, and understanding varying viewpoints, it must also be recognized that such systems can be used to disseminate information of varying accuracy and intent.
- On the environmental front, key for consideration are influences of climate change, including likely alterations of weather patterns and severity, water availability, coastline disturbances, infectious disease risk, and food production, each having both acute and long-standing public health consequences. ^{60,61,62,63,64} The impact of climate change is often location, risk, and population specific. There is, therefore, both the opportunity and the need to actively integrate climate change data and its implications into preparedness policy and strategy.

Trend 6: Data and data computation capacity are rapidly expanding, as is the need for data systems integration and cyber security.

Discussion: Data are being produced at enormous volume and speed. A 2013 article reported that 90% of all data in the world was generated in the previous 2 years. ⁶⁵ These data are being stored and analyzed by both public and private entities, and catalog essentially all aspects of behavior and health across the globe.

Opportunities that arise from the availability and distribution of data span both preparedness and response. For example, high-resolution movement data can be acquired from search

⁶⁰ Environmental Protection Agency. "Future Climate Change." Accessed November, 2014 at http://www.epa.gov/climatechange/science/future.html .

⁶¹ Climate Central. *Surging Seas* Website. Estimates based on information from interactive models. Accessed November, 2014 at http://sealevel.climatecentral.org/.

⁶² Environmental Protection Agency. *Climate Impacts in the Southwest*. Accessed November, 2014 at http://www.epa.gov/climatechange/impacts-adaptation/southwest.html.

National Climatic Data Center. 2014 US Temperature Exceeds 20th-Century Average for the 18th Consecutive Year. National Oceanic and Atmospheric Administration. Accessed January, 2015 at http://www.ncdc.noaa.gov/sotc/summary-info/national/2014/12.

⁶⁴ Melillo JM, Richmond TC, Yohe GW, Eds. *2014: Climate Change Impacts in the United States: The Third National Climate Assessment*. U.S. Global Change Research Program, Washington, DC: U.S. Government Printing Office 841 pp. doi:10.7930/J0Z31WJ2. Accessed January, 2014 at http://nca2014.globalchange.gov/.

⁶⁵Dragland, A. SINTEF. "Big Data, for better or worse: 90% of world's data generated over last two years." *Science Daily*. 22 May 2013. Accessed December, 2014 at www.sciencedaily.com/releases/2013/05/130522085217.htm.

engines, social media, or tracking of mobile phone use to inform evacuation and emergency response planning. 66,67 Data on health collected through mobile applications (e.g., Apple Health) and electronic medical records provide unprecedented opportunities to define high-risk populations, bolster preparedness, and target response to disasters. At the same time, social media can massively amplify the dissemination of public messaging; a recent analysis of "tweets" on Twitter after storms in New York City demonstrated that actionable storm notifications were retweeted approximately 24 times per message. 9

There are also risks that arise from data availability and distribution systems, including intended or unintended disclosure of protected health information, the malicious use of potentially harmful data, or the disruption of information infrastructure. These risks reflect the fact that cybersecurity as well as the need to contain dangerous data, including information that could support CBRN agent procurement or deployment, is a central component of global health security. While much of this falls largely outside the purview of ASPR, communication, collaboration, and coordination with those addressing such issues is critical. In addition, protection against and preparedness for health care disruption due to attacks on the information infrastructure is an important area of potential near- and long-term focus for ASPR.

TASK 3: Identify potential future resource and capability gaps nationally; suggest adjustments in strategic alignment and changes to legislative authority and/or policy position. (Recommended Future Strategies)

SUMMARY: The NPRSB recommends the following Future Strategies. Some strategies represent new directions while others envision further strengthening of existing strategic approaches. The latter are included to emphasize the importance of expanding and building upon such efforts.

- Strategy 1. Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation -- "The Assistant Secretary for Preparedness and Response shall have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction." (PAHPRA, 2013).
- Strategy 2. Markedly expand, beyond the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), ASPR's facilitation of and participation in networks, coalitions,

⁶⁶ Palchykov, V., Mitrovic, M., Jo, H. H., Saramaki, J., and Pan, R. K. "Inferring human mobility using communication patterns." *Scientific Reports* (4)6174. 2014. Accessed at http://arxiv.org/abs/1404.7675.

Wang Q, Taylor JE. "Quantifying Human Mobility Perturbation and Resilience in Hurricane Sandy." *PLoS ONE* 9(11): e112608. doi:10.1371/journal.pone.0112608. November 2014.

⁶⁸ Stevens, Lee. "Electronic Health Records Access During a Disaster." *Online Journal of Public Health Informatics* 5.3 (2014): 232. PMC. Accessed Jan 2015 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3959913/.

⁶⁹ Genes, N., Chary, M., and Chason, K. (2014). "Analysis of twitter users' sharing of official New York storm response messages." *Medicine 2 0*. 2014 Mar 20;3(1):e1. doi: 10.2196/med20.3237.

⁷⁰ Gostin, L. O., and Phelan, A. (2014). "The global health security agenda in an age of biosecurity." *JAMA* 312, 27-28.

⁷¹ Gostin, L. O., Phelan, A., Stoto, M. A., Kraemer, J. D., and Reddy, K. S. "Virus sharing, genetic sequencing, and global health security." *Science* 345, 1295-1296. 2014.

collective impact initiatives, and other structured collaborative approaches used to address complex social and system issues. This is aimed at more meaningful engagement of stakeholders, better coordination of efforts, and stronger integration of local, state, federal, and private sector preparedness and response systems.

- Strategy 3. Work to assure, through operational and policy-related initiatives, that a sufficient domestic capability to conceive, develop, produce, and replenish medical countermeasures is maintained and enhanced.
- Strategy 4. Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high-priority societal needs. This includes working with partners to mobilize efforts to stabilize and strengthen foundational systems core to national security, including emergency and trauma services and public health systems.
- Strategy 5. Increase public visibility of emergency preparedness and response efforts undertaken by ASPR and others. More openly and actively engage the public on issues pertinent to preparedness, response, and resiliency. Collaborate with key stakeholders towards promoting a stronger culture of personal, organizational, and community readiness.
- Strategy 6. Strengthen disaster risk reduction strategies in ASPR's work and encourage the same with Federal, state, and local government and private sector partners.
- Strategy 7. Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense.
- Strategy 8. Continue to seek novel approaches for accessing, analyzing, disseminating, and utilizing data to reduce disaster risk, strengthen resilience, improve preparedness, guide response, and hasten recovery. Work to continuously improve quality and ensure security of data.

In implementing each of these future strategies, ASPR should keep at the forefront of its efforts the following two overarching concepts:

- A. To advance, and whenever available utilize, scientific investigation and data to learn more about the health effects of disaster and to evaluate and guide approaches to decreasing risk, advancing preparedness, maximizing the effectiveness of response and recovery efforts, and enhancing community resilience. 72,73
- B. To utilize performance improvement principles, assuring the organization continuously learns from experience and operates in as facile, rapidly responsive, collaborative, innovative, and effective an environment as possible.

⁷² Nelson CD, Beckjord EB, Dausey DJ, Edward Chan, Lotstein D, Lurie N. "How can we strengthen the evidence base in public health preparedness?" *Disaster Medicine and Public Health Preparedness* 2008; 2(4):247-250.

⁷³ Lurie N, Manolio T, Patterson AP, Collins F, Frieden T. "Research as a part of public health emergency response." New England Journal of Medicine 2013; 368:1251-1255.

DISCUSSION OF RECOMMENDED FUTURE STRATEGIES:

Strategy 1: Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation -- "The Assistant Secretary for Preparedness and Response shall have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction." (PAHPRA, 2013)

Discussion: ASPR and its partners should work with HHS leadership, policymakers, and stakeholders to collectively assure that ASPR has the necessary visibility, support, skills, delegated authorities, and resources to carry out the leadership role envisioned by and given in its authorizing legislation. As noted recently by the Presidential Commission for the Study of Bioethical Issues, empowered leadership is critical to ensuring our nation's capability to respond to the next public health crisis.⁷⁴ The ASPR, as a relatively new and evolving position within HHS, has advanced but has not yet fully realized the leadership mission envisioned in its creation. Doing so will require:

- 1. Political, organizational, and Secretarial support for more fully realizing the ASPR's role as outlined in authorizing legislation;
- 2. Increased ASPR visibility within federal, state, and local government, among private sector stakeholders, and with the public;
- 3. Greater use of collaborative processes to integrate efforts and to strengthen shared ownership of and accountability for preparedness and response systems;
- 4. A stronger emphasis on identifying and resolving policy barriers; and
- 5. Strong demonstration of ASPR value to preparedness and response stakeholders.

To be clear, the leadership envisioned helps align and enable the work of multiple entities, focusing on policy that supports, resources that enable, and actions that coordinate efforts towards both a common vision and continued learning. It is not meant to replace the remarkable subject matter, technical, communications, operational or other expertise currently existing across and within multiple agencies and systems. Rather it helps coordinate, align, support and build upon such expertise and promotes strong and effective communication utilizing the same.

Realizing this leadership position will require far more than simply support and advancement of authority and visibility. It must be accompanied by successful implementation of several other future strategies outlined in this report. Success in achieving these will require that ASPR leadership focus on continued building and maintenance of trusted relationships, mechanisms for collaboratively identifying and achieving health security goals with stakeholders, an organizational culture that fosters learning and innovation, use of well-aligned incentives, and more efficient and effective operational processes.

Also in support of this strategy, many significant accomplishments of ASPR are not widely known or recognized by policy makers, practitioners, or the public. The central role already being played by the ASPR in preparedness and response, as detailed in this report, should be actively communicated to both the public and elected officials. In addition, ASPR should more actively

⁷⁴ Presidential Commission for the Study of Bioethical Issues. *Ethics and Ebola: Public Health Planning and Response.* February 2015. http://bioethics.gov/sites/default/files/Ethics-and-Ebola PCSBI 508.pdf

and widely promote the forward-reaching projects being collaboratively developed with partners (e.g., PHEMCE, Global Health Security, integrating research into response and recovery efforts) and work to assure their implications are more widely understood. ASPR should also more rapidly and regularly share innovative and emerging tools and resources being worked on with the practice community (e.g., modeling tools for medical countermeasure planning) raising ASPR's visibility and value to communities, policy makers, and the public.

Strategy 2: Markedly expand, beyond PHEMCE, ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches used to address complex social and system issues. This is aimed at more meaningful engagement of stakeholders, better coordination of efforts, and stronger integration of local, state, federal, and private sector preparedness and response systems.

Discussion: This strategy is aimed at strengthening partnerships, better integrating systems, driving innovation, minimizing duplication, building upon strengths, and engaging stakeholders in shared responsibility for results.

To effectively lead efforts to advance national health security, ASPR will need to utilize approaches that increase collaboration and more fully enable sectors and systems working together for collective impact. This strategy builds upon coalition development concepts espoused in ASPR's Hospital Preparedness Program (HPP) as well as the network development and operational successes of novel PHEMCE work. It aims for ASPR to utilize such approaches both more fully and at an enhanced level of engagement.

Collective impact⁷⁵ or other facilitated network approaches are not applicable to every ASPR activity. They are most applicable to health security issues that are large, complex, have defined objectives, involve multiple partners, and benefit from both shared risk and shared ownership of outcome/product. Examples of such areas include National Health Security Strategy and Implementation Plan development; coordinating international health and medical support in disasters; efforts to more fully harness the preparedness and response capabilities among partner nations; and advance development of systems to rapidly and safely bring new or repurposed technologies and MCMs to wide-scale production and use in an event. A near-term result of such efforts should be earlier and more direct communication with and among health security stakeholders at all levels, including, but not limited to, state and local health agencies and those most likely to be affected by an event. Models used should identify shared objectives as well as jointly define and, to the extent available, scientifically establish measures to assess collective progress. Assuring the availability of "backbone organizations" or facilitation approaches to such models is critical to ASPR's success.

This strategy will likely require furthering of existing and/or development of new operational skillsets among ASPR staff for facilitating and/or participating in such work. In addition, it will require leadership commitment to establishing such approaches as a norm of operational practice. Immediate attention should be paid to a review of existing policy, organizational practices, and regulatory structures, identifying those that serve as either facilitators of such efforts or as obstacles -- both real and perceived -- to be addressed. ASPR has a role in not only

-

⁷⁵ Kania, J., Kramer, M. "Collective Impact." *Stanford Social Innovation Review*. Winter 2011. http://www.ssireview.org/articles/entry/collective_impact. Accessed December 2014.

fostering development of such efforts that it facilitates and/or participates in, but also in establishing policy and supporting the same through health security stakeholders and grantees focused on community preparedness and resiliency.

Special attention should be paid to the issue of National Health Security Strategy planning in light of this future strategy. Developing an even more visible and valued national strategy — rather than a federal strategy well-crafted for the nation — will require engagement far more extensive than providing frequent feedback to well-drafted documents. The strategy will need to be developed by public and private sector health security stakeholders from all levels, led by the ASPR, working in a structured collaboration. The desired result is stronger ownership, use, and visibility of the product by all as well as a joint commitment to its implementation. Measures to demonstrate progress should be outcomes-based and at a systems level wherever possible, recognizing both shared responsibility for success and joint accountability for addressing identified challenges or perceived failures. Evaluation should include assessment of the strength and effectiveness of the collaboration itself, with a goal of strengthening the same.

Strategy 3: Work to assure, through operational and policy-related initiatives, that a sufficient domestic capability to conceive, develop, produce, and replenish medical countermeasures is maintained and enhanced.

Discussion: Specific MCMs that support strategic preparedness have been prioritized by the PHEMCE, developed and acquired through BARDA, and have substantially contributed both to the nation's readiness, as well as to the ability to respond globally to emerging public health threats. ASPR should continue to utilize the PHEMCE prioritization process to identify the essential strategic capabilities needed for development and production of MCMs.

To date, BARDA has focused primarily on MCMs against agents of biological terrorism and pandemic influenza, both critical to the HHS-ASPR mission. Recognizing the continued and likely ongoing occurrence of new infectious diseases (e.g., MERS, SARS, Ebola, antimicrobial resistance), ASPR should assure that BARDA has the authority to address and should work to expand BARDA's areas of focus to more fully include emerging infectious diseases. BARDA should work to identify candidate MCMs against such health threats in advance, maintain an inventory of all MCM candidates for each threat, and plan for rapid scaling and production that can be mobilized when events occur. This would enable more rapid and effective responses to health security threats arising both globally and domestically.

The capability to conceive, develop, and manufacture MCMs within the borders of the nation is also a critical component of our national security. Due to industry trends to move research and development capabilities off-shore, the nation is in danger of not having sufficient domestic industrial expertise and infrastructure to develop and manufacture new MCMs to meet emerging threats. In circumstances of global instability/hostility or international pandemics, the nation's security is risked by sourcing MCMs beyond its national borders. The PHEMCE, as part of its strategic mission, should expand its purview to include the maintenance and expansion of an appropriate domestic capability to develop and produce MCMs as needed to support the health security of the country.

Finally, although gap areas have been prioritized for basic research funding (e.g., validated animal models for nerve agents and sulfa mustard), there is often an inability to move into

approval pipelines promising MCMs that do not have a sufficient commercial market. The ability to assure preclinical and clinical trials for promising MCMs (i.e., those addressing prioritized gap areas) will be important moving forward.

Strategy 4: Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high-priority societal needs. This includes working with partners to mobilize efforts to stabilize and strengthen foundational systems core to national security, including emergency and trauma services and public health systems.

Discussion: ASPR should continue and further expand strategic focus on multi- and all-hazard approaches that address both routine and health security related needs.

Most notably, this strategy focuses on continued work to strengthen and engage others in strengthening "foundational" programs core to preparedness -- public health systems and day-to-day emergency and trauma services. This recognizes that the most effective and reliable responses are those built upon and regularly tested through strong everyday systems. ⁷⁶ Examples of such efforts include:

- Greater emphasis on tapping into, partnering with, and supporting efforts to improve day-to-day emergency or preventive care of at-risk populations (e.g., children, seniors, immigrant populations).
- Working with partners to strengthen health care system infection control programs, occupational safety and health programs, environmental safety programs, and programs aimed at reducing health care-acquired infections, in partnership with public health.
- Strengthening interactions with CDC and others advancing health disparity/health
 equity initiatives, recognizing that such not only support a healthier nation, but also
 build communication channels, trust, and advance relationships critical for disaster
 response.
- More actively engaging on Affordable Care Act (ACA) components designed to improve disease prevention and advance public health system accomplishment of the same.
- Helping articulate the importance of and helping assure a more stable and robust public health system at state and local levels, working with partners to identify more stable and predictable funding models, advance workforce size and skills, and further research the link between agency stability/strength and disaster response capability.
- With partners, identifying the top preparedness priorities that would result in a significant return on investment, considering both routine use and disaster response and using these to advocate for increased funds.
- Continuing to seek sufficient funding for and supporting flexible use of preparedness
 grant funds to sustain such core response functions as laboratory response networks,
 epidemiology systems, communication capacity, IT system integration, and partnership
 development, in addition to assuring the organizational infrastructure necessary to
 sustain preparedness and response efforts.
- Exploring mechanisms that would provide more predictable, multi-year funding of state, local, and health care system preparedness programs, allowing for more strategic

⁷⁶ Lurie N, Margolis GS, Rising KL. "The US emergency care system: meeting everyday acute care needs while being ready for disasters." *Health Affairs* 2013; 32(12): 2166-2171.

approaches and a more robust response infrastructure; continuing work aimed at reducing administrative burdens while maintaining accountability in grant management.

Strategy 5: Increase public visibility of emergency preparedness and response efforts undertaken by ASPR and others. More openly and actively engage the public on issues pertinent to preparedness, response, and resiliency. Collaborate with key stakeholders towards promoting a stronger culture of personal, organizational, and community readiness.

Discussion: Directly and in collaboration with partners, ASPR should more actively engage the American public, in addition to elected and appointed officials, the private sector, and stakeholder organizations, in the following:

- Understanding preparedness as a core component of both community health resilience and national defense;
- Accepting shared responsibility for individual, family, and organizational preparedness and community resilience; and
- Determining acceptable risk in a world of limited resources and increasing severity and frequency of disasters.

In support of this dialogue, the ASPR should engage both traditional and newer media platforms.

In the FSWG's deliberations, concerns were raised around a perceived decay in the national cultural value for preparedness and poor public engagement in disaster risk and personal/family readiness. In the absence of a meaningful public dialogue, individuals and families have become less prepared and often develop expectations that others, particularly government, will be there to offer all protections needed during a crisis. Rather, community resilience is likely enhanced when individuals, families, and workplaces take greater ownership in such efforts, when disaster risks are mitigated, and response infrastructure in support of communities is sustained.

The reality of the economic environment, both now and at least in the near-term future, make this strategy both challenging and increasingly necessary. Such conditions require difficult decisions to be made regarding resource allocation. These decisions should be based upon an informed dialogue with key stakeholders, including the public. For example, with several MCMs approaching the expiration of their already extended shelf-life, and with novel opportunities and the need to develop new MCMs for emerging threats, there may not be sufficient funding to sustain all SNS components, or the same supply amounts of certain MCMs going forward without additional funding. Similar discussions can and should be held around decays in public health and health care system preparedness infrastructure. Working with key federal agency leadership (e.g., CDC, FEMA) and other partners, development of scenarios or exercises that engage the public in such dialogue can make the issues real as well as highlight both what has been accomplished and the challenges faced. Providing these and other tools to state and local agencies and partner organizations can support these entities in helping lead such conversations as well.

In sum, critical needs and limited resource dilemmas offer fundamental platforms for the engagement of all stakeholders, including the public, in a discourse on both opportunity and risk tolerance. Such discussions can help drive establishment of more clearly articulated and publically accepted principles around which priorities are established. In addition, dialogue

around these and other preparedness capabilities developed but also in jeopardy can serve to elevate the value and importance of personal preparedness and community resiliency nationally. Finally, if the public's risk tolerance is low, such could also help inform resource decisions made by federal, state, and local governments.

Strategy 6: Strengthen disaster risk reduction strategies in ASPR's work and encourage the same with federal, state, and local government and private sector partners.

Discussion: To date, much of the nation's efforts to advance national health security have focused on building strong response capability for when large scale emergencies occur, an important component of the work needed. Much has been accomplished that requires sustaining and advancing. Efforts to reduce the likelihood of disasters or structural change to reduce community vulnerability have not been as strong a focus. Building upon examples of this approach (e.g., use of climate change data rebuilding after Hurricane Sandy), ASPR should emphasize and more actively work towards reducing the likelihood of events becoming disasters when they strike a community in addition to strengthening preparedness, response, and recovery capability for when disasters do occur. Examples could include:

- More fully integrating mitigation of disaster risk into civil engineering, community development projects, and healthy environment initiatives;
- Building sustainable and robust health care and public health systems (see Strategy 4 above);
- Actively addressing issues of climate change;
- More strongly incorporating projected futures data into both preparedness planning and into rebuilding communities after disaster;
- Supporting efforts of others to reduce procurement or distribution of fissile material;
 and
- Advancing efforts that enable rapid sharing of international public health and medical assistance during emergencies, in an effort to minimize global and domestic spread and/or reduce future economic costs of aid for larger scale emergencies. This includes mechanisms to enable more rapid sharing of MCMs; stronger, more rapid, and better coordinated international support to local disasters of global significance, including deployment and use of medical and public health personnel; and plans for the rapid receipt of assistance from global partners. In addition, there is opportunity to better coordinate and internally integrate international portfolio components of each ASPR program.

The collective impact of risk reduction will be optimized if embraced and pursued as a priority by federal, state, and local government and a broad community of private sector partners. The ASPR is well situated to serve in a leadership capacity facilitating these activities.

Strategy 7: Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense.

Discussion: This strategy supports and builds upon the NBSB's 2013 Community Health Resiliency Report Recommendation: "The NBSB recommends that ASPR lead an effort to definitively link community health resilience policy to other national preparedness or health initiatives—such as Affordable Care Act (ACA) implementation—by embedding health resilience

language and metrics into existing plans, grants and cooperative agreements, policies and requirements and examining ways to incentivize communities to pursue health resilience."

Building upon existing efforts, the HHS Secretary has opportunity, working through the ASPR and other counterparts, to even further promote collaborations and integration of efforts across HHS, for example, with the Office of the Assistant Secretary of Health (ASH) or tapping into the public visibility of the Surgeon General. Examples beyond ACA implementation referenced above could include integration into efforts to build healthy environments, advance a culture of health, reform health care delivery and financing systems, advance and use health information technology, implement regulation, implement certification and accreditation programs, and reduce medical errors and hospital-acquired infections. With mutually defined objectives, ASPR could help identify, support, and more fully integrate disaster risk reduction principles and preparedness components into existing efforts of other federal health programs, including CMS, Health Resources Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA), and CDC program areas.

Incentives are useful tools in integrating programs and efforts. Consideration should be given to exploring such approaches as tax, regulatory, or other incentives for private sector participation in and resource commitment to community preparedness efforts. In addition, clearly defined benefits for meeting preparedness requirements within accreditation or regulatory programs could be beneficial.

Strategy 8: Continue to seek novel approaches for accessing, analyzing, disseminating, and otherwise utilizing data to reduce disaster risk, strengthen resilience, improve preparedness, guide response, and hasten recovery. Work to continuously improve quality and ensure security of data.

Discussion: The opportunities that the magnitude and availability of data now present as well as new ways of analyzing and using it are significant. In addition, assuring data and data systems are both secure and utilized appropriately is important. Recommendations for how to implement this strategy include:

- Working with partners to identify those most useful, develop standardized systems for data collection, management, and processing before, during, and after disasters in order to facilitate collection and sharing of information, coordination of efforts, real-time analysis, and research. The establishment and widespread adoption of these standardized systems could both support the ASPR's role in coordinating health preparedness and response and help advance the science of preparedness and its measurement.
- Partner with governmental agencies (e.g., Department of Defense [DOD], National Oceanic
 and Atmospheric Administration [NOAA], National Aeronautics and Space Administration
 [NASA], as well as local, state, territorial, and tribal health departments) and corporations
 that transparently collect and analyze data relevant to global health security to identify
 opportunities and integrate accessible data into preparedness and response planning.

⁷⁷ Lurie N, Manolio T, Patterson AP, Collins F, Frieden T. "Research as a part of public health emergency response." New England Journal of Medicine 2013; 368:1251-1255.

- Consider establishing a working group among social media companies (e.g., Apple, Twitter, Facebook, Google) with the goal of further exploring opportunities and establishing an action plan for the use of social media in preparedness and response.⁷⁸
- Establish additional public-private partnerships to guide data collection before, during, and
 after disasters. For example, data from retail stores demonstrating real-time surges in
 purchasing could help inform resource allocation and distribution or provide situational
 awareness.
- Partnering with others, develop innovative strategies to bolster resilience within health care information infrastructure. For example, a standardized application for mobile devices that stores a user's medical information could facilitate health care and patient tracking upon damage to information infrastructure.
- Utilizing pre-event linkages to the Department of Homeland Security (DHS) and private companies, encourage a fuller exploration and, where feasible, reduction in health care system cybersecurity risks, recognizing that a cyber-attack could cripple health system response capability, reroute critical resources, and snarl communications.

TASK 4: Develop an analysis which compares ASPR's current mission, requirements, strategic objectives, resources, and capabilities against near- and far-term conditions. Provide a prioritized list of suggestions based on the comparative analysis for ASPR to support its continued success in the future.

SUMMARY: The FSWG finds that ASPR, as a leadership organization established less than a decade ago, has accomplished much. The FSWG finds ASPR's current authority and responsibility as outlined in the PAHPRA legislation to be adequate and appropriate. However, the FSWG does recommend significant advancements in how ASPR carries out these responsibilities, with a goal of supporting ASPR's maturation into the full intent of this legislation.

Mapping ASPR's current state to the desired future state envisioned by the FSWG suggests the following near-term priority foci for ASPR in implementing the above future strategies. The fuller analysis also offers ideas on approaches for operationalizing each.

- Priority Focus 1. Intentionally and significantly increase ASPR's visibility and utilize successes to earn further respect and trust. Work to actively brand ASPR as the nation's lead in coordinating across public and private sector health and medical preparedness and response systems and in establishing policy to advance the nation's health security. (Links to Future Strategy 1)
- Priority Focus 2. More strongly focus on and utilize ASPR's existing policy leadership authority and role. (Links to Future Strategy 1, Future Strategy 4, Future Strategy 6, and Future Strategy 7)

_

⁷⁸ For further information on the use of social media in emergency events, see Merchant RM, Elmer S, Lurie N. "Integrating social media into emergency preparedness efforts." *New England Journal of Medicine* 2011; 365:289-291.

- Priority Focus 3. Develop an organizational culture that promotes and expands ASPR's organizational capability to lead and work within facilitated networks, coalitions, collective impact, and other structured collaborative approaches to addressing complex social and system issues. This will likely entail workforce development, policy examination, and access to facilitative and other resources. (Links to Future Strategy 1 and Future Strategy 2)
- Priority Focus 4. Promote and strengthen the foundational systems of public health, health care, and biotechnology upon which the nation's health security fully relies. Engaging others, work to address the rapid erosion of capability currently being threatened or seen in these areas. (Links to Future Strategy 3, Future Strategy 4, and Future Strategy 7)
- Priority Focus 5. Seek to more fully understand the dynamics of how preparedness is achieved at all levels—listening, consulting with, and working alongside state and local agencies, health care systems, researchers, private sector, and community partners earlier and more often. (Links to Future Strategy 2 and Future Strategy 4)
- Priority Focus 6. Significantly increase the use of public dialogue and public engagement on issues relevant to national health security: public health emergency hazard identification; risk tolerance; preparedness and response priorities; the role of personal, organizational, and community preparedness; and societal approaches to family and community resilience. (Links to Future Strategy 5.)
- Priority Focus 7. Advance the science behind preparedness and response: More fully engage the public health community, academia, health care systems, and industry in the development and implementation of short- and long-term agendas to increase the preparedness and response evidence base. (Links to Future Strategy 8 and Overarching Concept A)
- Priority Focus 8. Advance ASPR's ability to be a flexible, nimble, innovative, rapidly responsive, and adaptable organization. (Links to Future Strategy 2 and Overarching Concept B)

ANALYSIS AND PRIORITIZED ACTIVITIES

ASPR's First 8 years

The FSWG finds that ASPR, as a leadership organization established less than a decade ago, has accomplished much in its first 8 years. Building upon these accomplishments and thinking forward, the FSWG finds that ASPR's current authority and responsibility as outlined in the PAHPRA legislation (i.e., "to provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan") to be adequate and appropriate. The FSWG does not recommend changes to this authority at present. That being said, the FSWG does recommend significant advancements in how ASPR carries out these responsibilities, with a goal of supporting ASPR's maturation into the full intent of the legislation.

Appendix B maps ASPR's current strategic objectives and accomplishments to the National Health Security Strategy (NHSS). It also maps identified trends and recommended future strategies to the same. The analysis below delineates key changes that will be needed for ASPR to even more completely fulfill its legislative intent. It is expected that ASPR will identify other changes to strategic alignment and policy needed for accomplishing this vision as well.

ASPR Looking Forward

To effectively strengthen the nation's health security, the FSWG envisions ASPR, on behalf of and with support from the Secretary of HHS, far more boldly and visibly carrying out the strong and critical leadership role it has been given -- integrated policy coordination and strategic direction for health and medical preparedness and response. This will require more than simply continuing to do the good work presently being accomplished. Adjustments in strategic alignment, organizational capacity, and policy are called for as a next step in ASPR's development. Some alterations are likely to represent more evolutionary change, building upon existing efforts. Others call for more dramatic shifts in tactics and operating practices and are aimed at making the organization both more effective in leading the efforts of multiple agencies, sectors, and systems (i.e., its coordination role) in preparedness and policy development and more rapidly responsive, adaptable, and creative in disaster response leadership (i.e., its response role). These recommended alterations should not be seen in any way as critical of current staff or programs of the ASPR, but rather as significant and logical next steps towards maturation of a relatively recently established agency. To this end, the FSWG notes the following key changes needed, mapping present state to future vision. With each, possible tactics or ideas that arose in presentations or discussions are offered as an attempt to further describe the direction being recommended. ASPR staff and leadership, in conjunction with partners, are fully capable of shaping more specific approaches for achieving these recommended shifts or enhancements of strategy.

Priority Focus 1. Intentionally and significantly increase ASPR's visibility and utilize successes to earn further respect and trust. Work to actively brand ASPR as the nation's lead in coordinating across public and private sector health and medical preparedness and response systems and in establishing policy to advance the nation's health security. (Links to Future Strategy 1)

Current: FSWG members repeatedly heard from external partners and experienced themselves the fact that few in the field (i.e., state and local public health agencies, health care systems, biotechnology partners, Congressional leadership) possess necessary awareness of the responsibility ASPR holds, the scope of activities ASPR undertakes, or the results of ASPR's accomplishments. Entities typically understand the single program they work with (e.g., Hospital Preparedness Program [HPP], PHEMCE), but have little sense of ASPR's overarching role, the challenges faced, or its many successes.

Future (Initial Ideas):

- Much stronger promotion is needed of both the role ASPR plays for the nation and the activities
 ASPR accomplishes. Being much more visible to key stakeholders, clearly demonstrating value,
 and actively displaying the good work and leadership ASPR is supposed to and can bring to the
 system can, in turn, strengthen ASPR's ability to lead responses, set policy, and coordinate
 systems.
- Special attention should be paid to the role that ASPR, as a coordinating lead across health and medical preparedness-related agencies, can play building bridges with Congressional and

Administration staff and in establishing a stronger political commitment to health security. This could include ASPR's being a more visible and available "go-to" presence during emergency responses. For example, tapping into the expertise of various agencies and programs, ASPR could coordinate daily staff briefings/availability on Capitol Hill during events -- summarizing what is known, not known; creating a stronger standing presence for staffers with questions on existing event or threat situations; facilitating access to support tools for addressing concerns of constituent callers; or helping understand the implications of different policy approaches. Leading and/or coordinating federal education and support services among health agencies could also provide a stronger connection point for external partners from across the public health and medical system, advancing the same.

- On a more routine basis, more fully establish ASPR as a key turn-to entity for consultation on incorporating preparedness or disaster risk reduction efforts into broader policy initiatives. This is aimed at both further integrating efforts of agencies and at advancing legislative understanding of ASPR and of broader public health and health care preparedness systems.
- Public dialogue could include greater visibility and discussion during emergencies, using traditional and newer media venues, in coordination with other applicable agencies (e.g., CDC, FDA, NIH, National Institute for Occupational Safety and Health [NIOSH], CMS), providing a stronger and more integrated "HHS" presence by drawing together the expertise and messaging of its various agencies.

Priority Focus 2. More strongly focus on and utilize ASPR's policy leadership authority and role. (Links to Future Strategy 1, Future Strategy 4, Future Strategy 6, and Future Strategy 7)

Current: ASPR has made many strides in this arena, such as Emergency Use Authorizations and PREP Act declarations, policy-driven authorities that have served to expedite emergency response to disaster threats. This is a key area where ASPR has both a unique responsibility and a capability – coordination and establishment of policy within HHS and participating with partners to coordinate and establish policy outside HHS that influences health security.

Future (Initial Ideas):

- Use partnerships to identify priority issues best addressed by changes in policy. Use authority
 and collaborations to establish and advance such policies as applicable and regularly evaluate
 their effectiveness.
- Explore Stafford Act application to public health emergencies.
- Continue to and even more fully integrate with FEMA and CDC on grants.
- Work with partners to integrate preparedness efforts and incentives into accreditation, certifications, and regulations that fall within ASPR's reach or within the reach of partnerships with which ASPR is engaged.
- Increase focus on disaster prevention / risk reduction. More closely examine policies that can support and enhance community resiliency.

Priority Focus 3. Develop an organizational culture that promotes and expands ASPR's organizational capability to lead and work within facilitated networks, coalitions, collective impact, and other structured collaborative approaches to addressing complex social and system issues. This will likely entail workforce development, policy examination, and access to facilitative and other resources. (Links to Future Strategy 1 and Future Strategy 2)

Current: ASPR has made significant strides in reaching out to stakeholders in recent years. However, it appears that many systems and programs still remain top-down and somewhat cumbersome. Partnerships are more often utilized for feedback / input to ASPR-led efforts, often through formal vetting processes, as opposed to ASPR's facilitating jointly owned efforts among partners. While simple feedback is sufficient and appropriate for some efforts, those that are complex and system-focused require more actively engaging stakeholders as critical and equal partners, jointly designing and implementing efforts, tapping into strengths, sharing responsibility for designing and implementing solutions, and jointly being accountable for demonstrating effectiveness of systems developed. PHEMCE has made significant progress with such approaches (e.g., the PHEMCE structure itself, fill-finish networks), but such is seen less so elsewhere in ASPR. The Hospital Preparedness Program (HPP) promotes use of coalitions and can be learned from, as well.

Future (Initial Ideas):

- Undertake a review of rules, regulations, organizational policies, and practices that either enable
 or serve as obstacles (real or perceived) to development of such approaches. Work to address
 barriers identified.
- More widely utilize structures and models that allow partners to engage across sectors and collaborate towards shared outcomes. Existing efforts towards such (e.g., PHEMCE and HPP Coalition focus) should be built upon and models adapted to many other ASPR efforts.
- Assure access to organizations skilled and experienced in serving as "backbone organizations" for collective impact initiatives and other collaborative approaches.
- Provide training for staff and leadership in utilizing and participating in collaborative models aimed at better integrating systems and more fully engaging stakeholders in sharing both ownership of efforts and responsibility for results.
- Consider alternative approaches to developing the NHSS more in line with this strategic shift, focusing on development of a strategy more fully owned by and meaningful to all stakeholder groups.
- Undertake collaborative work with preparedness and response partners and establish policy to
 more fully delineate how Unified Command systems and supporting structures (e.g., Emergency
 Operations Centers [EOCs]) can be used to better coordinate and promote response as an
 integrated system across the federal / state / local / private sector continuum.

Priority Focus 4. Promote and strengthen the foundational systems of public health, health care, and biotechnology upon which the nation's health security fully relies. Engaging others, work to address the rapid erosion of capability currently being threatened or seen in these areas. (Links to Future Strategy 3, Future Strategy 4, and Future Strategy 7)

Current: This understanding is currently strongly established in ASPR's strategic goals (Goal 1, 2, 3, and 5) and clearly drives much of ASPR's work. It is included here to emphasize both the absolute criticality of this issue to the nation's security and to expand upon the ways that ASPR can even more fully support such moving forward. Outlined elsewhere in this report is the current stability of each of these systems.

ASPR develops its approach to these issues in the context of broader experiences and considerations. Some have raised the question, "Should the federal government develop the capability to 'parachute in' during events, to replace community capabilities currently being lost?"

The FSWG finds that recent experiences, both globally and domestically, emphasize that "just in time" public health or health care systems across a nation are neither feasible nor desirable. Relying on such also loses the everyday health benefits such systems provide, benefits that result in a healthier and economically more productive American public. Health and medical preparedness and response stands on the shoulders of strong everyday public health systems working in partnership with strong health care and emergency management systems. Federal assets are a critical part of such systems and can bolster and influence, but not replace, them.

On the biotechnology front, the federal government can advance innovation and identification of MCMs useful for both everyday health threats and large scale disasters (i.e., a position of strength ASPR has through BARDA and PHEMCE) in partnership with the research and development community. Sustaining this capability moving forward, however, will require attention to the nation's future biotechnology workforce as well as domestic capability to either assure ready access to or produce and deliver such MCMs rapidly.

Future (Initial Ideas):

- Recognizing issues are not solely but are substantially related to the erosion of federal as well
 as state and local funding, work with partners to sustain existing and identify alternative
 funding models and sources.
 - More fully engage and align the private and non-profit sectors in public health preparedness, better defining if there is a compelling argument or return on investment for private sector participation in and contribution to such efforts.
 - Explore use of tax, regulatory, or other incentives for private sector participation in and resource commitment to community preparedness efforts.
 - Examine the same related to domestic development and production of MCMs, including bolstering the nation's research, development, and production workforce capacity. (See Future Strategy 3)
 - o Identify and explore policy changes that would enable multi-year funding models and other methods of stabilizing rapid fluctuations in preparedness and response funding.
 - Work with partners to establish prioritization frameworks, including input from public dialogue around the same; PHEMCE has initiated use of such a framework.
 - Drive innovation and advance the evidence base for preparedness in an effort to guide resource use towards most effective approaches.
- Identify operational and policy-related initiatives necessary to assure domestic capability to conceive, develop, produce, and replenish MCMs. (See Future Strategy 3)
 - More fully utilize BARDA's authority to address emerging infectious diseases in addition to its current areas of focus. Work to identify candidate MCMs against such health threats in advance and plan for rapid scaling and production that can be mobilized when events occur.
 - Enable the purview of PHEMCE to include the maintenance and expansion of an appropriate domestic capability to develop and produce MCMs as needed to support the health security of the country.
 - Establish ways for MCMs that are gap measures prioritized for the discovery phase of development to be more rapidly advanced beyond the preclinical phase.
- Across systems, more fully use regulatory levers (e.g., working through CMS or partnering with external organizations, accrediting systems, and certifying bodies) to integrate preparedness

- efforts into existing or developing quality initiatives for public health and health care systems. (See Future Strategy 7)
- Further enhance the provision of practical, field-tested, technical assistance and support. Look for existing tools and resources to share with system partners—e.g., BARDA modeling tools. Develop new tools in accordance with partner- and field-identified need. Upon implementation, evaluate their use and usefulness. Consider additional field-based technical support (e.g., personnel), in coordination with CDC and other agencies.

Priority Focus 5. Seek to more fully understand the dynamics of how preparedness is achieved at all levels—listening, consulting with, working alongside state and local agencies, health care systems, researchers, private sector, and community partners earlier and more often. (Links to Future Strategy 2 and Future Strategy 4)

Current: At present, ASPR's strongest understanding of preparedness and response dynamics and partnerships understandably appears to be with federal level partners. Strong field-based knowledge is housed primarily with Regional Emergency Coordinators (RECs) and the Hospital Preparedness Program, among a few others, and through collaborative partnerships with the CDC's Division of State and Local Readiness. While improving in recent years, barriers to engaging state and local or private sector partners early and regularly in planning, priority setting, strategy, and policy development still appear to exist or are frequently cited.

Future (Initial Ideas)

- Learn from and build upon experiences of other agencies that appear to have been successful in building such outreach systems and external subject matter expert/stakeholder partnerships, including CDC and others.
- Identify and reduce policy barriers hindering ready engagement of field partners for input on projects. Often cited are the need for security clearance, concern around conflict of interest, special government employee status, and regulations regarding the use and scope of federal advisory committees, among others.
- With new-found mechanisms, engage stakeholders earlier and more fully. Regularly provide feedback as to how stakeholder input influenced results.
- Increase participation and utilization of RECs and CDC field-based staff input in ASPR planning and policy development.
- The strongest PHEMCE integrations to date appear to be among federal agencies, then with private sector partners. PHEMCE has started to and should even more fully integrate state and local partners into these efforts.
- Add a public health representative (e.g., from CDC, DOD, states) to Incident Response
 Coordination Teams--helping to do surveillance, set up sheltering, and address concerns
 regarding safety of water or food supply. This addition would likely make for a more effective
 and well-rounded team.
- When filling personnel openings, hire staff with strong field experience and established field credibility.

Priority Focus 6. Significantly increase the use of public dialogue and public engagement on issues relevant to national health security: public health emergency hazard identification; risk tolerance; preparedness and response priorities; the role of personal, organizational, and community

preparedness; and societal approaches to family and community resilience. (Links to Future Strategy 5)

Current: While there is often great public awareness of and attention to public health risks and disaster preparedness and response gaps during events (e.g., H1N1, Hurricane Sandy, Ebola), in general, there is little dialogue with the public or elected/appointed officials on a day-to-day basis. The preparedness issues that typically achieve prominence during events can contribute greatly towards engaging communities or individuals in being better prepared and in setting priorities moving forward.

Future (Initial Ideas):

- Using traditional and newer communication methodologies, more extensively engage the public in issues of understanding risk, establishing priorities, and advancing health security.
 - Directly and with partners, promote awareness of the policies and practices that contribute to community resiliency and an understanding of how all sectors and the public benefit. Leverage community and private sector partners as trusted sources of information in communicating these issues with the public.
 - Engage both the American public and public officials at all levels in dialogue around both the effects of sustaining and the consequences of losing capabilities developed (e.g., public health, health care, emergency management, MCM enterprise).
 - In conjunction with DHS, continue to advance a broader understanding of the value added by personal, family, and community readiness, helping evolve a society where these activities are a cultural norm.

Priority Focus 7. Advance the science behind preparedness and response: Engage the public health community, academia, health care systems, and industry in the development of short- and long-term agendas to increase the preparedness and response evidence base. (Links to Future Strategy 8 and Overarching Concept A)

Current: The current ASPR has written extensively on this issue and ASPR has made significant strides in advancing preparedness science. This should be expanded upon both to strengthen the effectiveness of future responses and to assure even stronger and more informed use of emergency preparedness and response resources into the future.

Future (Initial Ideas):

- In collaboration with partners, review and update existing preparedness research agendas, assess progress made, and work to assure further implementation through various channels.
- Assure identification of and research on promising preparedness and response practices. Promote findings to applicable audiences.
- Further develop decision support systems to take full advantage of available information during events.
- Convene relevant parties post-event to develop the research questions that can inform the next event.
- Looking across multiple events collectively, generate hypotheses to further explore and/or findings that can be applied moving forward.
- Articulate the investment in preparedness; where possible, use science to quantify the cost of preparedness versus the cost of not being prepared.

• Evolve from present reliance on extrapolation of risk assessment based upon prior events to a more forward-thinking approach.

Priority Focus 8. Advance ASPR's ability to be a flexible, nimble, innovative, rapidly responsive, and adaptable organization. (Links to Future Strategy 2 and Overarching Concept B).

Current: As with most large governmental organizations, ASPR could significantly benefit from making processes more efficient; efforts less labor intensive for staff, advisors, and partners; and integration of efforts across the agency more extensive. Of note is the fact that significant improvement has been seen in some processes over recent years (e.g., travel systems).

Future (Initial Ideas):

- Soliciting feedback from both internal staff and external partners, address administrative
 processes and workforce issues identified using proven performance management and quality
 improvement techniques.
- Work to assure ASPR's organizational culture is one that fosters learning, innovation, collaborative approaches, and integration of efforts.
- Assure partnerships regularly evaluate their structure, processes, and effectiveness. Each should set goals, share responsibility for accomplishing them, track progress as a system, disseminate regular feedback, and assure transparency of reporting.

Summary of RECOMMENDED FUTURE STRATEGIES and PRIORITY AREAS OF FOCUS for ASPR:

The NPRSB recommends the following Future Strategies for ASPR (Task 3):

- Strategy 1. Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation -- "The Assistant Secretary for Preparedness and Response shall have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction." (PAHPRA, 2013).
- Strategy 2. Markedly expand, beyond the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches used to address complex social and system issues. This is aimed at more meaningful engagement of stakeholders, better coordination of efforts, and stronger integration of local, state, federal, and private sector preparedness and response systems.
- Strategy 3. Work to assure, through operational and policy-related initiatives, that a sufficient domestic capability to conceive, develop, produce, and replenish medical countermeasures is maintained and enhanced.
- Strategy 4. Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high-priority societal needs. This includes working with partners to mobilize efforts to stabilize and strengthen foundational systems core to national security, including emergency and trauma services and public health systems.
- Strategy 5. Increase public visibility of emergency preparedness and response efforts undertaken by ASPR and others. More openly and actively engage the public on issues pertinent to preparedness, response, and resiliency. Collaborate with key stakeholders towards promoting a stronger culture of personal, organizational, and community readiness.
- Strategy 6. Strengthen disaster risk reduction strategies in ASPR's work and encourage the same with federal, state, and local government and private sector partners.
- Strategy 7. Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense.
- Strategy 8. Continue to seek novel approaches for accessing, analyzing, disseminating, and utilizing data to reduce disaster risk, strengthen resilience, improve preparedness, guide response, and hasten recovery. Work to continuously improve quality and ensure security of data.

In implementing each of these future strategies, ASPR should keep at the forefront of their efforts the following two core concepts:

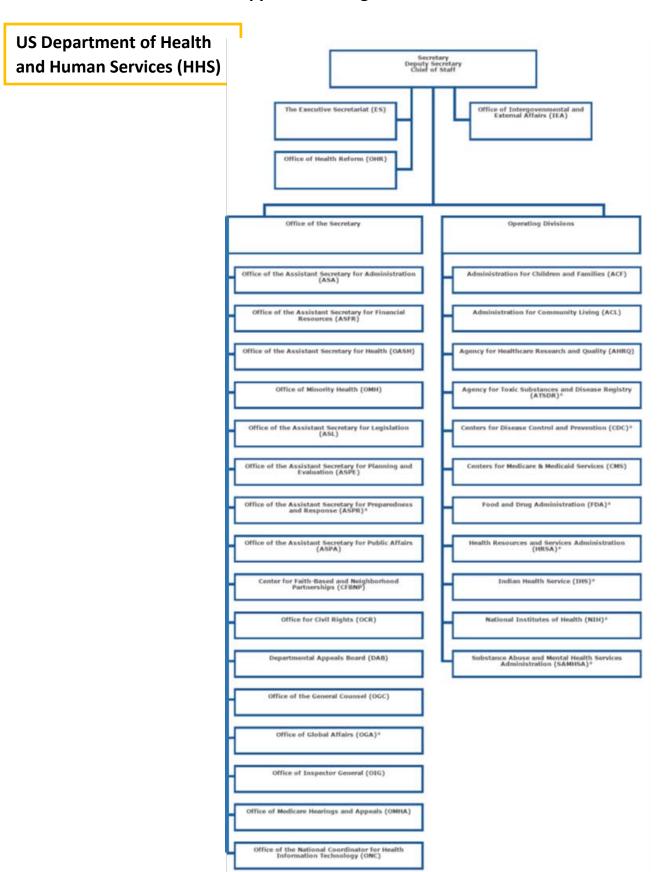
A. To advance, and whenever available utilize, scientific investigation and data to learn more about the health effects of disaster and to evaluate and guide approaches to decreasing risk, advancing preparedness, maximizing the effectiveness of response and recovery efforts, and enhancing community resilience.

B. To utilize performance improvement principles, assuring the organization continuously learns from experience and operates in as facile, rapidly responsive, collaborative, innovative, and effective an environment as possible.

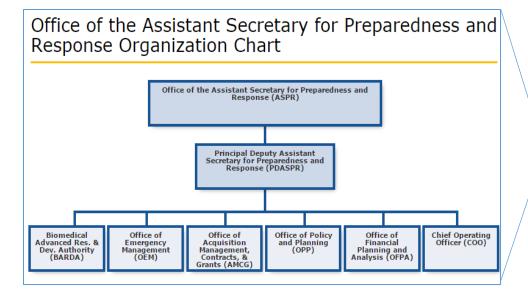
The NPRSB recommends the following near-term priority foci for ASPR in implementing the above future strategies (Task 4). The fuller analysis provided within this report offers more specific ideas for operationalizing each.

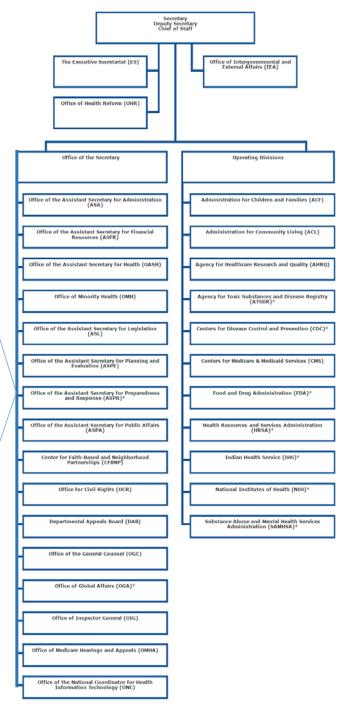
- Priority Focus 1. Intentionally and significantly increase ASPR's visibility and utilize successes to earn further respect and trust. Work to actively brand ASPR as the nation's lead in coordinating across public and private sector health and medical preparedness and response systems and in establishing policy to advance the nation's health security. (Links to Future Strategy 1)
- Priority Focus 2. More strongly focus on and utilize ASPR's existing policy leadership authority and role. (Links to Future Strategy 1, Future Strategy 4, Future Strategy 6, and Future Strategy 7)
- Priority Focus 3. Develop an organizational culture that promotes and expands ASPR's organizational capability to lead and work within facilitated networks, coalitions, collective impact, and other structured collaborative approaches to addressing complex social and system issues. This will likely entail workforce development, policy examination, and access to facilitative and other resources. (Links to Future Strategy 1 and Future Strategy 2)
- Priority Focus 4. Promote and strengthen the foundational systems of public health, health care, and biotechnology upon which the nation's health security fully relies. Engaging others, work to address the rapid erosion of capability currently being threatened or seen in these areas. (Links to Future Strategy 3, Future Strategy 4, and Future Strategy 7)
- Priority Focus 5. Seek to more fully understand the dynamics of how preparedness is achieved at all levels—listening, consulting with, and working alongside state and local agencies, health care systems, researchers, private sector, and community partners earlier and more often. (Links to Future Strategy 2 and Future Strategy 4)
- Priority Focus 6. Significantly increase the use of public dialogue and public engagement on issues relevant to national health security: public health emergency hazard identification; risk tolerance; preparedness and response priorities; the role of personal, organizational, and community preparedness; and societal approaches to family and community resilience. (Links to Future Strategy 5.)
- Priority Focus 7. Advance the science behind preparedness and response: More fully engage the public health community, academia, health care systems, and industry in the development and implementation of short- and long-term agendas to increase the preparedness and response evidence base. (Links to Future Strategy 8 and Overarching Concept A)
- Priority Focus 8. Advance ASPR's ability to be a flexible, nimble, innovative, rapidly responsive, and adaptable organization. (Links to Future Strategy 2 and Overarching Concept B)

Appendix A: Organizational Charts



Organizational Charts -- ASPR within HHS





Appendix B: ASPR Current Efforts and Recommended Future Directions Mapped to National Health Security Strategy Objectives*

Given ASPR's legislative intent and its mission to advance the health security of the nation, this appendix maps **ASPR's Current Efforts** (i.e., Strategic Plan Elements and Accomplishments to Learn from / /Build Upon) and **Recommended Future Directions** (i.e., Relevant Conditions / Trends, Recommended Future Strategies) to the objectives of the National Health Security Strategy, 2015-2018.*

OVERARCHING			
CURRENT ASPR STRATEGIC PLAN ELEMENTS	CURRENT SELECTED ASPR ACCOMPLISHMENTS to LEARN FROM / BUILD UPON	RELEVANT CONDITIONS AND FUTURE TRENDS	RECOMMENDED FUTURE STRATEGIES
Goal 6: improve ASPR adaptability and resilience: maximize workforce potential, develop leadership, and encourage a continuous learning culture	PHEMCE / BARDA – focus on networks and collaborations, coordination, and innovation; strong uses of structure, prioritization frameworks; resourcing - level and structure. Regional Emergency Coordinators – Generate cross-level knowledge and relationships to integrate systems; Help ground theory and align with practical realities. Legal and Policy Advances – Use Policy role to 1) Address widely experienced barriers; and 2) Enable a more coordinated and streamlined approach across agencies, levels, and sectors. Advancing Science through Real-time, Event-based Research – Focus on practical information to guide future efforts; more timely linkages of research funding and learning opportunities. Making Relevant Data Accessible and Useable-Leveraging agency access to information; brokering ways to share it and make it useful. Efforts to Coordinate and Better Align Efforts between CDC and ASPR – focus on improving system integration and decreasing burden.	Trend 1: Disasters and emergencies will remain a significant threat to the health and safety of communities and the security of the nation. By most accounts, events are increasing in frequency, severity, and cost. Trend 2: Economic challenges pose major threats. Trend 4: Social and entrepreneurial models are changing: Networks, collaborations, and more decentralized models of leadership are being used to address complex societal issues. Trend 5: Demographic and environmental changes relevant to health security are projected to occur in the US.	Strategy 1: Strengthen ASPR ability to fulfill the full intent of its authorizing legislation. Strategy 2: Markedly expand ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches. Strategy 5: Increase public visibility of preparedness and response efforts. More openly and actively engage the public. Strategy 7: Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense. Cross Cutting Concept A: Advance and utilize scientific investigation and data to learn about the health effects of disaster and to evaluate and guide approaches. Cross Cutting Concept B: Utilize performance improvement principles assuring the organization continuously learns from experience and operates in as facile, rapidly responsive, collaborative, innovative, and effective an environment as possible.

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

NHSS STRATEGIC OBJECTIVE 1: **Build and Sustain Healthy, Resilient Communities CURRENT ASPR STRATEGIC CURRENT SELECTED ASPR ACCOMPLISHMENTS RELEVANT CONDITIONS AND** RECOMMENDED **PLAN** to LEARN FROM / BUILD UPON **FUTURE TRENDS FUTURE STRATEGIES ELEMENTS** Goal 1: Promote PHEMCE / BARDA – focus on networks and Strategy 2: Markedly expand, beyond PHEMCE, ASPR's Trend 2: Economic challenges resilient collaborations, coordination, and innovation; pose major threats. facilitation of and participation in **networks**, **coalitions**, communities strong uses of structure, prioritization collective impact initiatives, and other structured frameworks; resourcing -- level and structure. Trend 3: Disaster risk reduction collaborative approaches. is a critical component of **Healthcare Preparedness Program (HPP)** advancing health security Strategy 4: Continue to prioritize preparedness 1) Emphasis on coalitions. globally and in the US. Much strategies that address multiple hazards or 2) Establish real-world, field-based linkages and can be done to reduce the synergistically meet both health security and other relationships in areas where ASPR serves a lead likelihood of and prevent events high-priority societal needs. system development role. and other health threats from **Regional Emergency Coordinators** – Building becoming disasters. Strategy 5: Increase **public visibility** of preparedness stakeholder relationships through value-added and response efforts. More openly and actively engage contributions; generating cross-level knowledge Trend 4: Social and the public. and relationships needed to integrate systems entrepreneurial models are and bridge theory and practice. changing: Networks, Strategy 6: Strengthen **disaster risk reduction** strategies collaborations, and more in ASPR's work. **Global Sharing & International Coordination of** decentralized models of Response - Focus on establishing and leadership are being used to Strategy 7: Link with and incorporate preparedness maintaining relationships, resolving barriers, address complex societal issues. policy and incentives into other initiatives shaping the and establishing ways to share resources and health of individuals, communities, the economy, and better coordinate efforts. Trend 5: **Demographic and** national defense. Advancing Science through Real-time, Eventenvironmental changes **based Research** – Focus on practical information relevant to health security are Strategy 8: Continue to seek novel approaches for to guide future efforts; more timely linkages of projected to occur in the US. accessing, analyzing, disseminating, and utilizing data. research funding and learning opportunities. Work to continuously improve quality and ensure Trend 6: Data and data security of data. computation capacity are rapidly expanding, as is the need for data systems integration and cyber security.

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

NHSS STRATEGIC OBJECTIVE 2:			
Enhance the CURRENT ASPR STRATEGIC PLAN ELEMENTS	e National Capability to Produce and Effectivel CURRENT SELECTED ASPR ACCOMPLISHMENTS to LEARN FROM / BUILD UPON	y Use Both Medical Countermea RELEVANT CONDITIONS AND FUTURE TRENDS	RECOMMENDED FUTURE STRATEGIES
Goal 3: Promote an effective MCM enterprise Legal and Policy Advances – Policy and tools to 1) Address widely experienced barriers; and 2) Enable a more coordinated and streamlined approach across agencies, levels, and sectors. Healthcare Preparedness Program (HPP) - 1) Emphasis on coalitions. 2) Establish real-world, field-based linkages an relationships in areas where ASPR serves a leasy system development role. Regional Emergency Coordinators – Building stakeholder relationships through value-added contributions; generating cross-level knowledge and relationships needed to integrate systems and to bridge theory and practice. Making Relevant Data Accessible and Useable Leveraging agency access to information;	Trend 1: Disasters and emergencies will remain a significant threat to the health and safety of communities and the security of the nation. By most accounts, events are increasing in frequency, severity, and cost. Trend 2: Economic challenges	Strategy 2: Markedly expand, beyond PHEMCE, ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches. Strategy 3: Work to assure that a sufficient domestic capability to conceive, develop, produce, and replenish MCMs is maintained and enhanced.	
	1) Emphasis on coalitions. 2) Establish real-world, field-based linkages and relationships in areas where ASPR serves a lead system development role. Regional Emergency Coordinators – Building stakeholder relationships through value-added contributions; generating cross-level knowledge	pose major threats. Trend 4: Social and entrepreneurial models are changing: Networks, collaborations, and more decentralized models of leadership are being used to address complex societal issues. Trend 5: Demographic and environmental changes relevant to health security are projected to occur in the US.	Strategy 4: Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high priority societal needs. Strategy 5: Increase public visibility of preparedness and response efforts. More openly and actively engage the public. Strategy 7: Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense.
	and to bridge theory and practice. Making Relevant Data Accessible and Useable - Leveraging agency access to information; brokering ways to share it, and using technical		

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

NHSS STRATEGIC OBJECTIVE 3: Ensure Comprehensive Health Situational Awareness to Support Decision-Making Before Incidents and During Response and Recovery Operations			
CURRENT ASPR STRATEGIC PLAN ELEMENTS	CURRENT SELECTED ASPR ACCOMPLISHMENTS to LEARN FROM / BUILD UPON	RELEVANT CONDITIONS AND FUTURE TRENDS	RECOMMENDED FUTURE STRATEGIES
Referenced in: Goal 1: Promote resilient communities. and Goal 2: Strengthen leadership and capabilities within public health and emergency management.	PHEMCE / /BARDA — focus on networks and collaborations, coordination, and innovation; strong uses of structure, prioritization frameworks; resourcing - level and structure. Regional Emergency Coordinators — Building stakeholder relationships through value-added contributions; generating cross-level knowledge and relationships needed to integrate systems and to bridge theory and practice. Legal and Policy Advances — Policy and tools to 1) Address widely experienced barriers; and 2) Enable a more coordinated and streamlined approach across agencies, levels, and sectors. Making Relevant Data Accessible and Useable — Leveraging agency access to information; brokering ways to share it, and using technical expertise and field input to make it useful. Advancing Science through Real-time, Event-based Research — Focus on practical information to guide future efforts; more timely linkages of research funding and learning opportunities.	Trend 1: Disasters and emergencies will remain a significant threat to the health and safety of communities and the security of the nation. By most accounts, events are increasing in frequency, severity, and cost. Trend 3: Disaster risk reduction is a critical component of advancing health security globally and in the US. Much can be done to reduce the likelihood of and prevent events and other health threats from becoming disasters. Trend 6: Data and data computation capacity are rapidly expanding, as is the need for data systems integration and cyber security.	Strategy 2: Markedly expand, beyond PHEMCE, ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches. Strategy 5: Increase public visibility of preparedness and response efforts. More openly and actively engage the public. Strategy 6: Strengthen disaster risk reduction strategies in ASPR's work. Strategy 7: Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense. Strategy 8: Continue to seek novel approaches for accessing, analyzing, disseminating, and utilizing data. Work to continuously improve quality and ensure security of data.

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

NHSS STRATEGIC OBJECTIVE 4:			
Enhance the Integration and Effectiveness of the Public Health, Healthcare, and Emergency Management Systems			
CURRENT ASPR STRATEGIC PLAN ELEMENTS	CURRENT SELECTED ASPR ACCOMPLISHMENTS to LEARN FROM / BUILD UPON	RELEVANT CONDITIONS AND FUTURE TRENDS	RECOMMENDED FUTURE STRATEGIES
Goal 2: Strengthen leadership and capabilities within public health and emergency management. and Goal 5: Improve outcomes by strengthening the nation's healthcare system.	PHEMCE / BARDA – focus on networks and collaborations, coordination, and innovation; strong uses of structure, prioritization frameworks; resourcing - level and structure. Healthcare Preparedness Program (HPP) - Focus on coalitions; Establishing real-world, field relationships in areas where ASPR serves a lead system development role. Regional Emergency Coordinators — Generate cross-level knowledge and relationships to integrate systems; help ground theory and align with practical realities. Legal and Policy Advances — Policy and tools to 1) Address widely experienced barriers; and 2) Enable a more coordinated and streamlined approach across agencies, levels, and sectors. Advancing Science through Real-time, Event-based Research — Focus on practical information to guide future efforts; more timely linkages of research funding and learning opportunities. Making Relevant Data Accessible and Useable-Leveraging agency access to information; brokering ways to share it, and using technical expertise and field input to make it useful. Efforts to Coordinate and Better Align Efforts between CDC and ASPR — focus on improving system integration and decreasing burden.	Trend 2: Economic challenges pose major threats. Trend 3: Disaster risk reduction is a critical component of advancing health security globally and in the US. Much can be done to reduce the likelihood of and prevent events and other health threats from becoming disasters. Trend 4: Social and entrepreneurial models are changing: Networks, collaborations, and more decentralized models of leadership are being used to address complex societal issues. Trend 6: Data and data computation capacity are rapidly expanding, as is the need for data systems integration and cyber security.	Strategy 1: Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation. Strategy 2: Markedly expand ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches. Strategy 3: Work to assure that a sufficient domestic capability to conceive, develop, produce, and replenish MCMs is maintained and enhanced. Strategy 4: Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high-priority societal needs. Strategy 5: Increase public visibility of preparedness and response efforts. More openly and actively engage the public. Strategy 6: Strengthen disaster risk reduction strategies in ASPR's work. Strategy 7: Link with and incorporate preparedness policy and incentives into other initiatives shaping the health of individuals, communities, the economy, and national defense. Strategy 8: Continue to seek novel approaches for accessing, analyzing, disseminating, and utilizing data. Work to continuously improve quality and ensure security of data.

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

	NHSS STRATEGI	C OBJECTIVE 5:			
	Strengthen Global Health Security				
CURRENT ASPR STRATEGIC PLAN ELEMENTS	SELECTED ASPR ACCOMPLISHMENTS To LEARN FROM / BUILD UPON	RELEVANT CONDITIONS AND FUTURE TRENDS	RECOMMENDED FUTURE STRATEGIES		
Goal 4: Lead/coordinate policies that support national and international capabilities.	PHEMCE / BARDA – focus on networks and collaborations, coordination, and innovation; strong uses of structure, prioritization frameworks; resourcing - level and structure. Healthcare Preparedness Program (HPP) - 1) Emphasis on coalitions; 2) Establish real-world, field-based linkages and relationships in areas where ASPR serves a lead system development role. Regional Emergency Coordinators – Building stakeholder relationships through value-added contributions; generating cross-level knowledge and relationships needed to integrate systems and to bridge theory and practice. Legal and Policy Advances – Focus on policy and tools that 1) Address high-priority and widely experienced barriers; 2) Enable a more coordinated and streamlined approach across borders, agencies, levels, and sectors. Global Sharing and International Coordination of Response – Focus on establishing and maintaining relationships, resolving barriers, and establishing ways to share resources and better coordinate efforts. Making Relevant Data Accessible and Useable-Leveraging agency access to information; brokering ways to share it, and using technical expertise and field input to make it useful.	Trend 2: Economic challenges pose major threats. Trend 3: Disaster risk reduction is a critical component of advancing health security globally and in the US. Much can be done to reduce the likelihood of and prevent events and other health threats from becoming disasters. Trend 4: Social and entrepreneurial models are changing: Networks, collaborations, and more decentralized models of leadership are being used to address complex societal issues.	Strategy 1: Strengthen ASPR's ability to fulfill the full intent of its authorizing legislation. Strategy 2: Markedly expand ASPR's facilitation of and participation in networks, coalitions, collective impact initiatives, and other structured collaborative approaches. Strategy 3: Work to assure that a sufficient domestic capability to conceive, develop, produce, and replenish MCMs is maintained and enhanced. Strategy 4: Continue to prioritize preparedness strategies that address multiple hazards or synergistically meet both health security and other high priority societal needs. Strategy 6: Strengthen disaster risk reduction strategies in ASPR's work.		

^{*} The mappings in these tables display primary connections / -- items most closely applicable to each strategic objective of the National Health Security Strategy, 2015-2018. This does not mean they do not apply or play a role in other areas as well.

Appendix C: Future Scenarios

The FSWG found discussion and development of potential futures to be useful in both accomplishing its work and in understanding its implications. Given this, three futures are included below for the year 2025. They are not meant to be actual predictions but rather, to stimulate creative thinking, put recommended strategies in context, and help ASPR envision ways to maximize its effectiveness in assuring "the Nation and its people are prepared for, protected from, respond effectively to, and [are] able to recover from incidents with potentially negative health consequences." ⁷⁹

The "Expected" Future

In 2025, the US maintains its leadership role in the world but struggles with growing debt partly as a result of a decade of several global humanitarian efforts. Congress provides emergency stop gap influxes of funding but does not unite to address the total national preparedness and response picture needed. Local public health systems are managing with fewer resources and staff, and heath resilience and preparedness are inconsistent across the country. Federal agencies assist local communities struggling to respond to and recover from disasters. State epidemiology programs are hampered in their ability to track emerging disease trends needed to inform policy and budget decisions. Fewer people are working on building community health resilience. Beyond ASPR, a strong system-wide ownership of or sense of collective responsibility for accomplishing the NHSS is lacking. ASPR works to coordinate activities, but struggles with fragmented and uncertain federal funding and agencies that are frequently focused on a crisis. The President appoints a Surgeon General who is re-building credibility with the public after the position was vacant for several years. Partnerships strengthen through the PHEMCE. An integrated network model with shared responsibility and authority for broader national health security efforts gains cross-sector support and is starting to be operational sporadically, but not nation-wide or at the national level. The CDC mission expands to encompass the HPP and other operational programs. ASPR serves as a point of coordination during global and national disaster responses, mainly to advance the development of MCMs. The non-profit private sector narrows its operational mandate over the years due to restricted funding. The for-profit private sector is heavily driven by market forces. There have been important advances driven by past events and an Ebola vaccine is in production, but the American pharmaceutical industry has little interest in research and development of vaccines, diagnostics, or antibiotics. Academia is also driven by market forces due to less government support for training and research resulting in an inability to capitalize on technological innovations and to prepare the future public health or science workforce. The gap between rich and poor Americans has grown. Higher education costs are prohibitive for many and fewer young people are qualified to fill medical, scientific, and public health jobs. Public support for and engagement in preparedness is strained. Several unfortunate disasters occur with the elderly and young families especially vulnerable. These events result in many deaths, but the US is still doing a moderately good job mitigating damage from these occurrences. The health impacts of climate change are taking a toll, and disease and death rates are increasing. Air quality and clean water supplies are intermittent issues for many communities with increased frequency and severity of weather-related disasters and toxic releases. Weather-related changes are also displacing some communities.

-

⁷⁹ Language excerpted from the definition of National Health Security, National Health Security Strategy. Page 3. 2009. http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf. http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Documents/nhss-final.pdf.

The "If Things Don't Go Well" Future

In 2025, national health security is severely strained. The US lost several thousand public health experts due to retirement, less hiring to fill vacancies, and a lack of trained young professionals entering the field. Some state and local governments allowed their public health programs to dwindle to skeletal programs with minimal staff and capability in major areas of public health. All of the American pharmaceutical companies with expertise in vaccine, antibiotic, and diagnostic development ceased to exist or were absorbed by European and Asian companies. Hospital preparedness funds dried up and most local hospitals have no surge capacity, resources, or staff to collaborate with others. Academic institutions with tight budgets narrowed their research efforts to areas that receive private sector funding. Public health preparedness funds dried up as government and the private sector moved away from supporting these programs. ASPR put much effort for years into health security strategic and implementation plans, but national preparedness has stalled. After a decade of what seemed like endless natural disasters and an international pandemic, Americans don't have the understanding, wherewithal, or resources to be resilient. Epidemics thought to be obsolete or found in other countries threaten the US. Without strong local public health programs, Americans rely on the federal government to rescue them. Yet it, too, is in poor shape after a decade of responding to complex global changes and operating in hierarchal, compartmentalized organizational structures that no longer work. The public has lost confidence in the FDA, NIH, and CDC because of their inconsistent and uncoordinated response efforts, and each receives daily criticism from the media. Instead of collaborating, these agencies compete with each other over fewer programs and scarce funding. The position of the Surgeon General has lost credibility after years of being vacant. The ASPR is a presidential appointee with no disaster preparedness or partnership development expertise. Serious economic, social, and political uncertainties exist globally as many countries are not able to provide food, water, healthcare, education, or jobs to their citizens. Miles of coastal development were destroyed and more is threatened by extreme weather and flooding. Farmlands are drying up and becoming unproductive. People are leaving their communities to find better opportunities in distant large cities and other countries.

The "Aspirational" Future

In 2025, after robust national and local dialogue, broad consensus exists around collectively developed approaches to the occurrence of natural disasters, pandemics, and terrorism. There is both bipartisan and field-based support for a well-executed NHSS that is no longer fragmented within information silos and centralized hierarchal organizations. Many federal agencies utilize ecological organizational models that promote development of, active participation in, and communications through and across facilitated networks. This has resulted in broad stakeholder ownership of and joint investment in more effective and well-coordinated health and preparedness systems nationwide. Relationships support flexible and adaptive responses to unpredictable challenges. The 2024 NHSS is final and implementation plans are in place following a highly successful and generally lauded process undertaken through the now well-established National Health Security Coalition involving wide representation across public and private sectors. ASPR received the Innovation in Government Award for shifting the national strategy from a federal document to a widely embraced strategy owned by all and serving as an integrated blueprint and guide for communities across the nation. Congress realizes that economic stability and world leadership require healthy, resilient, and prepared citizens and invests in health preparedness and a culture of health more broadly. They have modified policy to rebalance the macroeconomics that

ensure strong domestic pharmaceutical, vaccine, and diagnostics industries which are now a national security priority. The private sector shares the vision and goals of the NHSS and works with government organizations to prepare for future uncertainties. With policy and stable funding, US ingenuity flourishes and results in world leadership in these industries and several companies are emerging from startups. The medical and academic community is fully engaged in novel research driving technical innovation and in training a relevant and prepared workforce. Local health departments are fully funded and deliver all essential public health services. Due to proactive succession planning, the aging public health workforce of 2014 was replaced by well-prepared millennials capable of responding to emerging infectious diseases and other threats in their local communities. The well-funded National Public Health Data Governance Plan allows state and local health departments the opportunity to effectively mine meta-data collected on population health through the ACA, social media, and other sources. Consumer health informatics has been a game changer in improving population health status. Americans and visitors have full access to affordable healthcare at the time and place they need it and US healthcare expenditures are at an all-time low. Health disparities are considered in all decisionmaking. Carbon emissions are steadily decreasing and all citizens are participating in climate change mitigation activities. Although there have been several infectious disease outbreaks and an influenza pandemic, US responses were swift, decisive, and effective at mitigating impact. Congress, professional associations, and others have reduced antibiotic overuse by the health care system and agriculture industry. Novel approaches to infectious diseases beyond antimicrobial use have been developed. After 23,000 deaths from drug-resistant infections a decade ago, that number is now nearly zero.

Appendix D: Task Letter DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Preparedness & Response Washington, D.C. 20201

John S. Parker, M.D., Major General (Retired) Chairman, National Biodefense Science Board 656 Lynn Shores Drive Virginia Beach, VA 23452

Dear Dr. Parker and Members of the National Biodefense Science Board (NBSB):

The Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is a leader in preparing the Nation and its communities to respond to and recover from public health and medical disasters and emergencies. The 2006 Pandemic and All-Hazards Preparedness Act (PAHPA), reaffirmed by the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), established the ASPR as the principal adviser to the HHS Secretary, responsible for providing integrated policy coordination and strategic direction with respect to all matters related to public health, medical preparedness, and deployment of the federal response for public health emergencies and incidents.

I would like the NBSB to identify future strategies that best support successful achievement of ASPR's mission and that of HHS with regard to preparedness, response and recovery. The report should suggest long-term strategies that will best enable the ASPR and the Secretary of HHS to be fully successful in achieving its goal of protecting Americans' health and safety during emergencies, and fostering resilience to withstand and respond to emergencies.

Additionally, in making its suggestions, I would appreciate it if the committee would do the following:

- 1. Highlight ASPR's accomplishments to date and its impact on national health preparedness and resilience.
- 2. Assess environmental, scientific, healthcare, fiscal, policy, and other relevant spheres for potential nearand far-term conditions that may affect ASPR's mission space.
- 3. Develop an analysis which compares ASPR's current mission, requirements, strategic objectives, resources and capabilities against the near- and far-term conditions to identify potential future resource and capability gaps nationally; suggest adjustments in strategic alignment; and changes to legislative authority and/or policy position.
- 4. Develop a final report which provides a prioritized list of suggestions based on the comparative analysis for ASPR to support its continued success in the future.

Given the NBSB's expertise and long experience with ASPR, I believe that the NBSB can offer great insight on this issue as an independent scientific body. I look forward to receiving the NBSB's recommendations by January 15, 2015.

Thank you for your continued support in ensuring the public health preparedness of our nation.

Sincerely,

Nicole Lurie, MD, MSPH Assistant Secretary for Preparedness and Response

Appendix E:

National Preparedness and Response Science Board (NPRSB)

ASPR Future Strategies Working Group (FSWG)

Voting Members

Steven E. Krug, M.D. (co-chair)

Head, Division of Emergency Medicine Ann and Robert H. Lurie Children's Hospital of Chicago Professor of Pediatrics Northwestern University Feinberg School of Medicine Chicago, IL

Catherine Slemp, M.D., M.P.H. (co-chair)

Preparedness Director and Acting State Health Officer (retired), West Virginia Bureau for Public Health Catherine Slemp, Public Health Consulting Milton, WV

John S. Bradley, M.D., FAAP, FIDSA, FPIDS

Chief, Division of Infectious Disease Department of Pediatrics, University of California, San Diego School of Medicine Director, Division of Infectious Diseases Rady Children's Hospital San Diego, CA

Virginia A. Caine, M.D.

Director

Marion County Public Health Department Associate Professor of Medicine Indiana University School of Medicine Indianapolis, IN

David J. Ecker, Ph.D.

Divisional Vice President and General Manager Ibis Biosciences, Inc. Carlsbad, CA

Emilio A. Emini, Ph.D., FAAM

Senior Vice President Vaccine Research and Development Pfizer, Inc. Collegeville, PA

Tammy Spain, Ph.D.

Senior Scientist for Biomedical Systems Charles Stark Draper Laboratory Bioengineering Center at USF Tampa, FL

David M. Weinstock, M.D.

Associate Professor
Dana-Farber Cancer Institute and Harvard
Medical School
Medical Advisor
Radiation Injury Treatment Network
Boston, MA

Ex Officio Members

Luciana Borio, M.D.

Assistant Commissioner for Counterterrorism Policy Director, Office of Counterterrorism and Emerging Threats

Acting Deputy Director, Office of the Chief Scientist Office of the Commissioner Food and Drug Administration US Department of Health and Human Services

George W. Korch Jr., Ph.D.

Senior Science Adviser
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services
Washington, DC

Sally Phillips, R.N., Ph.D.

Principal Deputy Assistant Secretary (Acting) Component Acquisition Executive (CAE) Office of Health Affairs US Department of Homeland Security

Ex Officio Member Alternates

Brooke Courtney, J.D., M.P.H.

Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
US Department of Health and Human Services

Carmen Maher, B.S.N., M.A., R.N., RAC

CAPT, US Public Health Service
Deputy Director
Office if Counterterrorism and Emerging Threats
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
US Department of Health and Human Services

Marc Shepanek, Ph. D.

Lead, Aerospace Medicine Office of the Chief Health and Medical Officer NASA Headquarters Washington, D.C.

Federal Subject Matter Experts

Christine Kosmos, RN, BSN, MS

Division Director
Division of State and Local Readiness
Center for Disease Control and Prevention
U S Department of Health and Human Services

Lawrence D. Kerr, Ph.D.

Director Medical Preparedness Policy National Security Council

External Subject Matter Expert

Karen Smith, M.D., M.P.H.

Health Officer/Deputy Director for Public Health Napa County Health and Human Services Agency

Executive Secretariat

Maxine Kellman, D.V.M., Ph.D., P.M.P.

Biotechnology Policy Analyst
Office of the Assistant Secretary for Preparedness
and Response
US Department of Health and Human Services
Washington, DC

Appendix F:

Acknowledgement of Previous National Preparedness and Response Science Board (NPRSB)

To Dr. Parker and former NPRSB members:

With warm appreciation for all you have given of your wonderful energy and expertise, your time, and for your dedicated years of service.

Voting Members

Chair, John S. Parker, M.D., Major General (Retired)

Senior Vice President Leidos Virginia Beach, VA

John S. Bradley, M.D., FAAP, FIDSA, FPIDS

Chief, Division of Infectious Disease Department of Pediatrics, University of California, San Diego School of Medicine Director, Division of Infectious Diseases Rady Children's Hospital San Diego, CA

Virginia A. Caine, M.D.

Director, Marion County Public Health Department Associate Professor of Medicine Indiana University School of Medicine Indianapolis, IN

Nelson J. Chao, M.D., M.B.A.

Chief, Division of Hematological Malignancies and Cellular Therapy Duke University Medical Center Division of Cellular Therapy/BMT Durham, NC

David J. Ecker, Ph.D.

Divisional Vice President and General Manager Ibis Biosciences, Inc. Carlsbad, CA

Emilio A. Emini, Ph.D.

Senior Vice President Vaccine Research and Development Pfizer, Inc. Collegeville, PA

Manohar R. Furtado, Ph.D.

Founder and President Biology for Global Good LLC Life Technologies/Applied Biosystems San Ramon, CA

Noreen A. Hynes, M.D., M.P.H.

Associate Professor of Medicine and Public Health Director, Geographic Medicine Center Division of Infectious Diseases Johns Hopkins University School of Medicine Baltimore, MD

Steven E. Krug, M.D.

Head, Division of Emergency Medicine Ann and Robert H. Lurie Children's Hospital of Chicago Professor of Pediatrics Northwestern University Feinberg School of Medicine Chicago, IL

Sarah Y. Park, M.D., FAAP

State Epidemiologist and Chief Disease Outbreak Control Division Hawaii Department of Health Honolulu, HI

Catherine Slemp, M.D., M.P.H.

Preparedness Director and Acting State Health Officer (retired), West Virginia Bureau for Public Health Catherine Slemp, Public Health Consulting Milton, WV

Tammy Spain, Ph.D.

Senior Scientist for Biomedical Systems Charles Stark Draper Laboratory Bioengineering Center at USF Tampa, FL

David M. Weinstock, M.D.

Associate Professor Dana-Farber Cancer Institute and Harvard Medical School Medical Advisor Radiation Injury Treatment Network Boston, MA

Appendix G:

National Preparedness and Response Science Board (NPRSB)

Voting Members

Chair. Steven E. Krug. M.D.

Head, Division of Emergency Medicine Ann and Robert H. Lurie Children's Hospital of Chicago Professor of Pediatrics Northwestern University Feinberg School of Medicine Chicago, IL

John S. Bradley, M.D., FAAP, FIDSA, FPIDS

Chief, Division of Infectious Disease
Department of Pediatrics, University of California,
San Diego School of Medicine
Director, Division of Infectious Diseases
Rady Children's Hospital
San Diego, CA

Virginia A. Caine, M.D.

Director

Marion County Public Health Department Associate Professor of Medicine Indiana University School of Medicine Indianapolis, IN

David J. Ecker, Ph.D.

Divisional Vice President and General Manager Ibis Biosciences, Inc. Carlsbad, CA

Chirstina Egan, Ph.D.

Chief

Biodefense Laboratory Wadsworth Center New York State Department of Health Albany, NY

Colonel (Ret.) D. Gray Heppner, M.D., FACP, FASTMH, FRGS

Chief Medical Officer BioProtection Systems/NewLink Genetics Corporation Ames, IA

Noreen A. Hynes, M.D., M.P.H.

Associate Professor of Medicine and Public Health Director, Geographic Medicine Center Division of Infectious Diseases Johns Hopkins University School of Medicine Baltimore, MD

Ross D. LeClaire, DVM, Ph.D., MSS, DABT, Fellow ATS

Principal, The Translational Bridge; LLC Corrales, NM

Eva K. Lee, Ph.D.

Director

Center for Operations Research in Medicine and HealthCare
Co-Director, NSF I/UCRC Center for Health
Organization Transformation
Distinguished Scholar in Health System, Health
Systems Institute, Emory/Georgia Tech
Professor, Industrial and Systems Engineering
College of Engineering
Georgia Institute of Technology
Atlanta, GA

Catherine Slemp, M.D., M.P.H.

Preparedness Director and Acting State Health Officer (retired), West Virginia Bureau for Public Health Catherine Slemp, Public Health Consulting Milton, WV

Tammy Spain, Ph.D.

Senior Scientist for Biomedical Systems Charles Stark Draper Laboratory Bioengineering Center at USF Tampa, FL

Sharon A. R. Stanley, Ph.D., RN

Senior Consultant, American Red Cross, NHQ, Office of Nursing & Health
President, Association of Public Health Nurses
Circleville, OH

David M. Weinstock, M.D.

Associate Professor

Dana-Farber Cancer Institute and Harvard

Medical School

Medical Advisor

Radiation Injury Treatment Network

Boston, MA

Ex Officio Members

Executive Office of the President

Andrew M. Hebbeler, Ph.D.

Senior Policy Analyst National Security and International Affairs Office of Science and Technology Policy Washington, DC

Intelligence Community

Anne Dufresne

Associate Deputy Director, Intelligence Integration National Counterproliferation Center Office of the Director of National Intelligence Washington, DC

National Aeronautics and Space Administration

Richard S. Williams, M.D., FACS

Chief Health and Medical Officer Office of the Chief Health and Medical Officer National Aeronautics and Space Administration Washington, DC

National Science Foundation

Amber L. Story, Ph.D.

Deputy Division Director Division of Behavioral and Cognitive Sciences National Science Foundation Arlington, VA

US Department of Agriculture

Randall L. Levings, D.V.M., Ph.D.

Scientific Advisor National Center for Animal Health US Department of Agriculture Ames, IA

US Department of Commerce

Dianne L. Poster, Ph.D.

Special Assistant Associate Director for Laboratory Programs Director's Office National Institute of Standards and Technology US Department of Commerce Gaithersburg, MD

US Department of Defense

Erin P. Edgar, M.D.

COL, Medical Corps Commander US Army Medical Research Institute of Infectious

Diseases

US Department of Defense Fort Detrick, MD

US Department of Energy

Patricia Worthington, Ph.D.

Director, Office of Health and Safety Office of Health, Safety and Security US Department of Energy Washington, DC

US Department of Health and Human Services

Centers for Disease Control and Prevention

Stephen C. Redd, M.D.

Director,

Office of Public Health Preparedness and Response Centers for Disease Control and Prevention US Department of Health and Human Services Atlanta, GA

National Institutes of Health

Hugh Auchincloss, M.D.

Principal Deputy Director

National Institute of Allergy and Infectious Diseases National Institutes of Health

US Department of Health and Human Services Bethesda, MD

Office of the Assistant Secretary for Preparedness and Response

George W. Korch Jr., Ph.D.

Senior Science Adviser Office of the Assistant Secretary for Preparedness and Response US Department of Health and Human Services

Richard J. Hatchett, M.D.

Deputy Director and Chief Medical Officer Biomedical Advanced Research and Development Authority

Office of the Assistant Secretary for Preparedness and Response

US Department of Health and Human Services Washington, DC

Office of the Assistant Secretary for Health

Bruce Gellin, M.D., M.P.H.

Deputy Assistant Secretary for Health Director, National Vaccine Program Office Office of the Assistant Secretary for Health US Department of Health and Human Services Washington, DC

Food and Drug Administration

Luciana Borio, M.D.

Acting Director, Office of Counterterrorism and Emerging Threats
Assistant Commissioner for Counterterrorism Policy Office of the Commissioner
Food and Drug Administration
US Department of Health and Human Services
Silver Springs, MD

US Department of Homeland Security

Sally Phillips, Ph.D., RN

Principal Deputy Assistant Secretary (Acting) Office of Health Affairs US Department of Homeland Security Washington, DC

US Department of the Interior

Lori Caramanian, J.D.

Deputy Assistant Secretary for Water and Science US Department of the Interior Washington, DC

US Department of Justice

Rosemary Hart, J.D.

Special Counsel
Office of Legal Counsel
US Department of Justice
Washington, DC

US Department of State

Judith Garber

Acting Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs US Department of State Washington, DC

US Department of Veterans Affairs

Victoria J. Davey, Ph.D., M.P.H.

Chief

Office of Public Health
US Department of Veterans Affairs
Washington, DC

US Environmental Protection Agency

Brendan Doyle

Senior Advisor

National Homeland Security Research Center U.S. Environmental Protection Agency Washington, DC 20460

US Nuclear Regulatory Commission

Patricia A. Milligan, R.Ph. C.H.P.

Senior Advisor for Emergency Preparedness US Nuclear Regulatory Commission North Bethesda, MD

<u>National Preparedness & Response Science Board</u> Staff

CAPT Charlotte D. Spires, D.V.M., M.P.H., DACVPM

Executive Director

Office of the Assistant Secretary for Preparedness and Response

US Department of Health and Human Services Washington, DC

Cynthia Henderson

Executive Assistant

Office of the Assistant Secretary for Preparedness and Response

US Department of Health and Human Services Washington, DC

Maxine Kellman, D.V.M., Ph.D., PMP

Biotechnology Policy Analyst

Office of the Assistant Secretary for Preparedness and Response

US Department of Health and Human Services Washington, DC

CDR Jyl C. Woolfolk, M.P.H., C.H.E.S.

Senior Policy Analyst

Office of the Assistance Secretary for Preparedness and Response

US Department of Health and Human Services Washington, DC

LCDR Evelyn Seel, M.P.H.

Policy Analyst
Office of the Assistant Secretary for Preparedness
and Response
US Department of Health and Human Services
Washington, DC

Belinda Green

Program Analyst
Office of the Assistant Secretary for Preparedness
and Response
US Department of Health and Human Services
Washington, DC

Justin Willard, M.P.H.

Management Analyst II
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services
Washington, DC

Appendix H:

Invited National Subject Matter Experts Presenting to the ASPR Future Strategies Working Group (FSWG)

Presenters

Michael Anderson, M.D., M.B.A., FAAP

Chair, NACCD
Vice President and Chief Medical Officer at
University Hospitals

James Blumenstock, M.A.

Chief Program Officer, Public Health Practice Association of State and Territorial Health Officials (ASTHO)

Daniel Cotter, M.B.A., M.S.

Director

Office for Interoperability & Compatibility Science & Technology Directorate US Department of Homeland Security

Stanley T. Crooke, M.D., Ph.D.

Founder, Chairman of the Board & Chief Executive Officer

Isis Pharmaceuticals

Dave Kaufman, M.P.P.

Associate Administrator
Office of Policy & Program Analysis (OPPA), Federal
Emergency Management Agency
US Department of Homeland Security

George W. Korch Jr., Ph.D.

Washington, DC

Senior Science Adviser Office of the Assistant Secretary for Preparedness and Response US Department of Health and Human Services

Christine Kosmos, R.N., B.S.N., M.S.

Division Director
Division of State and Local Readiness
Centers for Disease Control and Prevention
US Department of Health and Human Services

Michael G. Kurilla, M.D., Ph.D.

Director, Office of BioDefense, Research Resources, and Translational Research Associate Director for BioDefense Product Development DMID, NIAID, NIH, DHHS

Debra Elkins, Ph.D.

Director of Decision Analysis Strategy, Planning, Analysis and Risk Office of Policy U.S. Department of Homeland Security

Sam Groseclose, D.V.M., M.P.H., DACVPM

Associate Director for Science
Office of Science and Public Health Practice
Office of Public Health Preparedness and Response
(OPHPR)
Centers for Disease Control and Prevention

Jack Herrmann, M.S.Ed., N.C.C, L.M.H.C.

Senior Advisor & Chief
National Association of County & City Health Officials
(NACCHO)

Tom Inglesby, M.D.

Director and Chief Executive Officer UPMC Center for Health Security

Jonathan Peck, M.A.

President & Sr. Futurist Institute of Alternative Futures

Sally Phillips, R.N., Ph.D.

Principal Deputy Assistant Secretary (Acting)
Component Acquisition Executive
Office of Health Affairs
US Department of Homeland Security

Ronald Salazar

Principal Deputy Assistant Secretary Strategy, Planning, Analysis and Risk Office of Policy US Department of Homeland Security

Karen Smith, M.D., M.P.H.

Health Officer/Deputy Director for Public Health Napa County Health and Human Services Agency

Col. Dan Wattendorf, M.D., USAF

Biological Technologies Office
Defense Advanced Research Projects Agency
(DARPA)