

PREPARING FOR THE NEXT PANDEMIC IN THE ERA OF ANTIMICROBIAL RESISTANCE

A REPORT WITH RECOMMENDATIONS

March 24, 2023

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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EXECUTIVE SUMMARY

Historically, some of the most consequential pandemics have been caused by bacterial diseases such as the bubonic plague or cholera. With the advent of effective public health interventions and the introduction of antibiotics, recent pandemics have been associated with viruses while bacterial pandemics have diminished in frequency and scale. The COVID-19 pandemic has highlighted the many challenges faced in preparing for and responding to modern public health emergencies (PHE), and it has spurred efforts to prevent future ones; these efforts, however, have largely focused on viral pathogens. It must not be forgotten that secondary bacterial infections have also played an important role in exacerbating morbidity and mortality during viral pandemics, as observed during the 1918 influenza pandemic, and, to a lesser degree, during COVID-19.^{1,2} With the diminishing power of antibiotics to treat infections due to increasing antimicrobial resistance (AMR), the threat of a bacterial pandemic or a viral pandemic—accompanied by secondary bacterial infections resistant to our available stock of antimicrobials—remains possible.

Antimicrobial resistance is a material threat to the health of all Americans, even in the absence of a pandemic. Nearly 1.27 million deaths were attributed, globally, to difficult-to-treat bacterial infections in 2019.³ A PHE such as a pandemic or other large-scale infectious disease outbreak is likely to exacerbate the problem of AMR and the conditions that support its spread. Therefore, efforts to tackle AMR through crisis-mode planning are our best defenses against a PHE caused by an untreatable bacterial pathogen or a PHE caused by a virus with inevitable secondary bacterial or fungal infections.⁴

As we have witnessed during the most recent example of a PHE with COVID-19, there were challenges with our ability to maintain infection control and antimicrobial stewardship practices due to overcrowded healthcare settings, stresses on the healthcare workforce (including staffing shortages), a lack of rapid diagnostics to guide treatment decisions, and shortages of routine medications and medical supplies, among other factors. Furthermore, the frequent movement of pathogens between humans, companion and food animals, and the environment, profoundly affected the health of the animal care workforce. Moreover, the depletion of the agricultural workers by illness had a negative impact on animal health and food security.⁵

Recognizing the interconnectedness of PHE preparedness and efforts to combat AMR, U.S. Department of Health and Human Services Secretary Xavier Becerra tasked the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) with providing recommendations on how to augment current national pandemic preparedness policies to strengthen our defenses against antimicrobial-resistant pathogens.⁶ In response, the PACCARB established the Pandemic Preparedness

¹ Morens, D. M., Taubenberger, J. K., & Fauci, A. S. (2008). Predominant role of bacterial pneumonia as a cause of death in pandemic influenza: Implications for pandemic influenza preparedness. *The Journal of Infectious Diseases*, 198(7), 962–970. <https://doi.org/10.1086/591708>

² Feldman, C., & Anderson, R. (2021). The role of co-infections and secondary infections in patients with covid-19. *Pneumonia*, 13(1). <https://doi.org/10.1186/s41479-021-00083-w>

³ Antimicrobial Resistance Collaborators (2022). Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. *Lancet (London, England)*, 399(10325), 629–655. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

⁴ No fungal species currently pose an immediate pandemic threat to humans, but the possibility of one emerging with pandemic potential cannot be ruled out.

⁵ Kakaei, H., Nourmoradi, H., Bakhtiyari, S., Jalilian, M., & Mirzaei, A. (2022). Effect of COVID-19 on food security, hunger, and food crisis. *COVID-19 and the Sustainable Development Goals*, 3–29. <https://doi.org/10.1016/B978-0-323-91307-2.00005-5>

⁶ See Annex II.

Working Group to identify opportunities for which federal policy can better address issues that contribute to morbidity and mortality from resistant infections and the spread of AMR. The working group drafted recommendations for consideration by the full PACCARB,⁷ informed by internal discussions, meetings with subject matter experts, and two public meetings.⁸ This included a Pandemic Preparedness Policy Workshop in which a hypothetical novel viral pandemic scenario, exacerbated by a rise in secondary bacterial or fungal infections, served as the backdrop for a discussion of important commonalities between AMR and pandemic preparedness and response.⁹

The conclusion of these activities has confirmed the PACCARB's belief that efforts to tackle AMR through stronger antimicrobial stewardship (AS), infection prevention and control (IPC), and investment into the availability of new medical countermeasures are critical to confronting the current AMR burden and the extraordinary burden that may manifest during a future PHE.

The time to act is now, before the next PHE occurs.

The method to act is by ensuring that the current pandemic preparedness policies focused on viruses also include additional and complementary steps to prevent and combat resistant infections. Specifically, the PACCARB recommends IPC, AS, with focused attention on resistant bacterial and fungal infections to be consistent components with direct objectives included in two high-level national pandemic preparedness policies: the National Biodefense Strategy¹⁰ and American Pandemic Preparedness: Transforming Our Capabilities.¹¹ With expansions on these main topic areas, most of the PACCARB's recommendations presented in this report highlight enhancements to routine, or steady-state, operations in public health, healthcare, animal care, and agriculture that, if realized, would create stronger and more robust systems that are better able to withstand the stresses of an emergency and more prepared to adapt and respond to emergency conditions (see Figure 1). We must strengthen surveillance, healthcare, and animal care systems; build trusting relationships with stakeholders and communities; grow the necessary workforce to support our strained public health infrastructure; and enhance research, development, and regulatory structures.

It is with this underlying premise of immediate action that the PACCARB presents this report with a total of 14 recommendations, portrayed in Figure 1 and summarized in Box 1.

The PACCARB has identified four major areas in which improvements can strengthen our preparedness for future PHEs and reduce the toll of resistant infections now and during a PHE. In each of these areas, investments in steady-state capabilities and capacities are needed to help address the current rise in AMR infections and to respond to the next PHE quickly and effectively.

Infection Prevention and Control and Antimicrobial Stewardship. While IPC and AS core capabilities play critical roles in preventing the emergence and spread of AMR, they are largely

⁷ See Annex IV.

⁸ All proceedings from the PACCARB can be viewed at www.hhs.gov/PACCARB

⁹ See Annex III.

¹⁰ White House Office of Science and Technology Policy & National Security Council. (2021). *American pandemic preparedness plan: Transforming our capabilities*. <https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29>

¹¹ White House. *National biodefense strategy and implementation plan for countering biological threats, enhancing pandemic preparedness, and achieving global health security*. (2022). <https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf>

absent from the U.S. government's key pandemic preparedness policies. These policies should be updated to reflect the importance of these key public health activities in preventing the spread of AMR infections.

Workforce expansion. Many challenges observed during the COVID-19 response were due to and exacerbated by healthcare workforce shortages. Specific gaps include a need for greater recruitment, training, and support of the IPC workforce, nimble utilization of capable practitioners and professionals across the One Health spectrum, and greater diagnostic capabilities and capacities.

Data sharing and security. AMR surveillance data from a variety of human, animal, plant, and environment settings, both domestic and international, is central to effective pandemic preparedness because it enables earlier identification of resistant pathogens, and thus earlier opportunities to intervene. Existing surveillance systems need improvements to expand their reach into more settings across One Health, facilitate interoperability of the many systems in human and animal surveillance, enable deeper data mining and analysis to support decision-making, and ensure data privacy and security.

Product innovation and development (medical countermeasures). Current ability to develop new medical countermeasures *rapidly* in response to a PHE is limited, and significant investment in our ability to develop appropriate AMR therapeutics, vaccines, and diagnostics must be made *before the next PHE occurs*. Our current pipeline of such products is insufficient, particularly for novel therapeutics with new targets and new mechanisms of action to treat secondary resistant infections and for diagnostics to detect and guide treatment of fungal infections. Additionally, advancements in clinical trial infrastructure and regulatory approval processes must be made to facilitate the development of novel medical countermeasures that are safe and effective for all—including vulnerable populations such as the immunocompromised, children, and the elderly.

Across these four areas, the PACCARB makes 12 specific recommendations: Eight recommendations to enhance our steady-state operations in public health, healthcare, animal care, and agriculture, and, by doing so, will strengthen the country's preparedness for the next PHE; complemented by four recommendations to improve our emergency operations when responding to a PHE. However, maintaining and improving an equitable application of resources across all communities and populations is a crucial consideration when implementing the PACCARB's recommendations.

Multiple factors including social, structural, and behavioral dynamics contributed to the limited uptake of public health interventions, both pharmaceutical and non-pharmaceutical during the COVID-19 response. These shortcomings resulted in a weakened response to the pandemic and an intensification of health disparities among marginalized and vulnerable populations. Underlying this limited uptake of interventions, in part, is a lack of trust in our healthcare system as provision of quality healthcare and access to prevention strategies due to systemic and structural inequalities that fall along racial, economic, and political lines.

Therefore, the PACCARB makes two additional, overarching recommendations that apply to all aspects of AMR preparedness and response activities: to prioritize social, structural, and behavioral interventions that build trust in public health guidance and to include marginalized and vulnerable communities during the development, implementation, and communication of policies.

Building the relationships necessary to achieve these goals must begin now, before the next PHE, and cannot be initiated as an emergency is unfolding. These are purposefully listed separately from the recommendations described above for distinction and attention, and their concepts should be applied when implementing all recommendations to advance equity, build trust, and support clearer, more effective communication during a PHE.

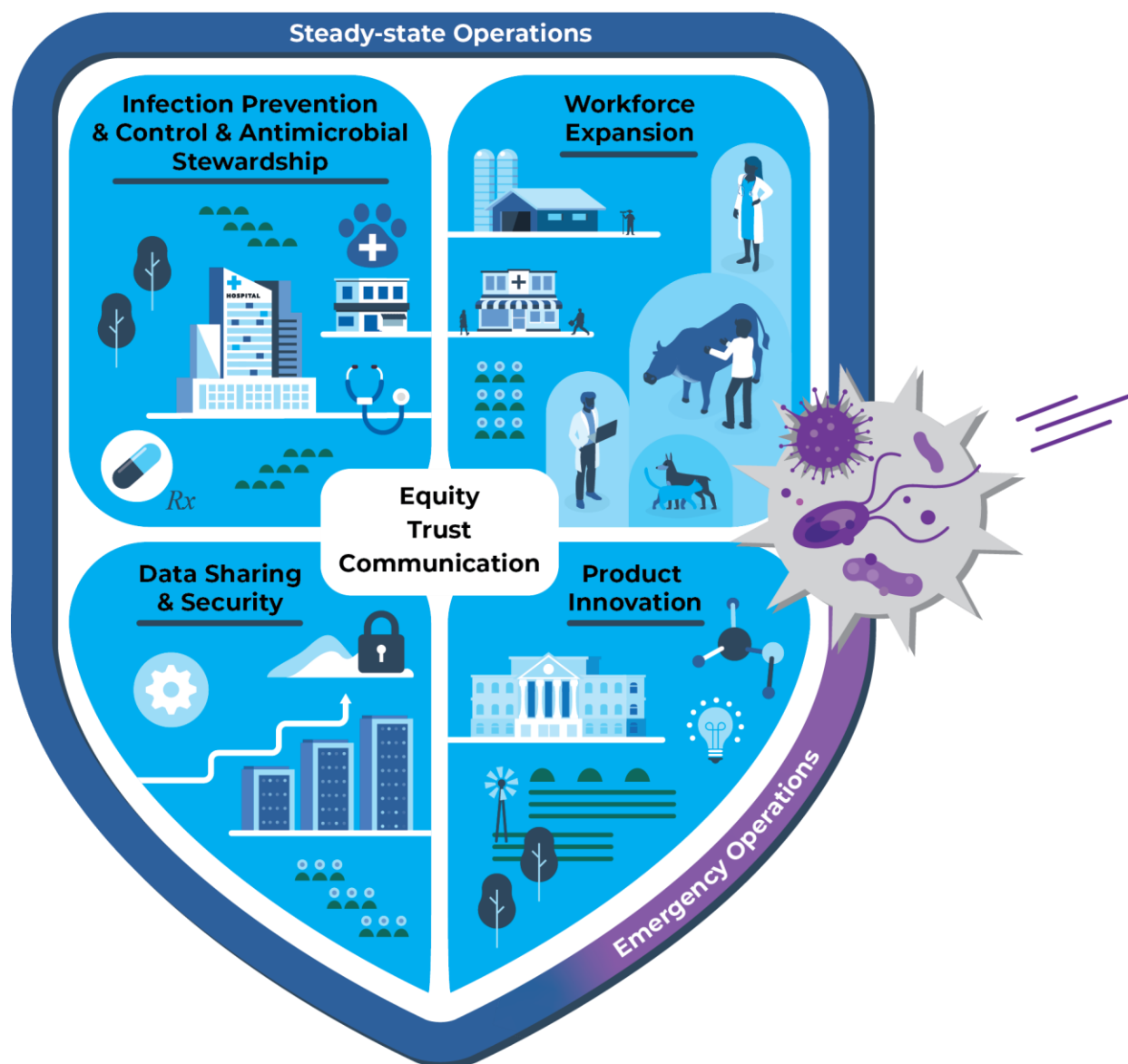


Figure 1. The PACCARB recommends actions to improve preparedness against AMR pathogens that fall under four major categories: antibiotic stewardship and infection prevention and control, workforce expansion, data sharing and security, and product (medical countermeasure) innovation. Improvements in these areas during steady-state operations (i.e., before a public health emergency) will strengthen our public health systems so that the response to a new AMR threat will be strong and efficient. Across all areas of pandemic preparedness and response, the PACCARB recognizes that equity, trust, and communication must be prioritized by engaging all populations and communities before a public health emergency and continuing to include them during an emergency response.

Equity, Trust, and Communication

Recommendation 1: Prioritize social, structural, and behavioral interventions that build trust in public health guidance and increase uptake of both pharmaceutical and non-pharmaceutical interventions in steady-state and during a PHE.

Recommendation 2: Include marginalized and vulnerable communities during the development, implementation, and communication of all pandemic preparedness policies.

Infection Prevention and Control and Antimicrobial Stewardship

Recommendation 3: Include infection prevention and control and antimicrobial stewardship as core capabilities and goals in pandemic preparedness policies including through dissemination of existing and updated guidelines.

Recommendation 4: Create a mechanism for rapid guideline development for appropriate antimicrobial use in response to an emerging AMR pathogen and to maintain antimicrobial stewardship during an emergency.

Workforce Expansion

Recommendation 5: Bolster the workforce by expanding recruitment and support of public health professionals, infection preventionists, and infectious diseases specialists and engaging a broader set of providers in human and animal healthcare.

Recommendation 6: Develop pathways that would allow for qualified practitioners in other One Health domains to provide support to human healthcare during a PHE.

Recommendation 7: Build capacity for both human and animal diagnostic laboratory networks to meet emergency surge testing demands.

Data Sharing and Security

Recommendation 8: Invest in global capacity for AMR pathogen surveillance and early detection of novel AMR pathogens.

Recommendation 9: Expand and diversify sectors participating in domestic AMR surveillance efforts to include outpatient clinical settings, independent/clinical laboratories, wildlife, companion animals, wastewater, and others.

Recommendation 10: Modernize existing surveillance databases for One Health interoperability to accommodate data input from different human, animal, and environmental health sources, as well as variables that capture social determinants of health.

Recommendation 11: Invest in improved data privacy and security to encourage more private entities to contribute data, including AMR data, to federal data management systems used in public health, agricultural, and environmental sectors.

Product Innovation

Recommendation 12: Develop novel antimicrobials, vaccines, diagnostics, and threat-agnostic platform technologies focused on resistant bacterial and fungal pathogens, which are material threats likely to arise during a PHE.

Recommendation 13: In anticipation of a PHE, establish flexible, response-ready clinical trial networks that include outpatient settings and vulnerable populations, such as pediatrics, and that can easily adapt in an emergency to determine the safety and efficacy of novel countermeasures.

Recommendation 14: Develop accelerated regulatory approval pathways to assess novel, unique, or nontraditional technologies or products and ensure sufficient funding and procedures are in place to support and maintain the FDA review process during a PHE.

INTRODUCTION

The United States has affirmed its goal of addressing pandemic preparedness in several high-level policy documents, chiefly American Pandemic Preparedness: Transforming Our Capabilities (AP3)¹² and the National Biodefense Strategy (NBS).¹³ While both provide national policy objectives to protect from and prepare for biological threats—whether natural or intentional—these agenda-setting documents fail to comprehensively address the threat posed by all infectious and resistant pathogens. Particularly striking is the limited attention given to antimicrobial resistance (AMR). While current national and global attention is focused on continuing to address COVID-19 and preparing for the possibility of another viral pandemic, the next large-scale outbreak or pandemic could be caused by a resistant bacterial pathogen. Historically, bacteria have been responsible for some of the deadliest pandemics. For example, cholera, caused by *Vibrio cholerae* bacteria, has been the cause of seven global pandemics and several major outbreaks from 1817 to the present.¹⁴ In fact, the first coordinated international initiative for infectious disease prevention was sparked by the rapid global spread of cholera in 1851 with the establishment of the first International Sanitary Conference.¹⁵ Today, antibiotics (in addition to safe water, improved sanitation, and hygiene) have significantly reduced the frequency of global bacterial pandemics. However, our ability to treat bacterial infections is under-threat by the rising prevalence of AMR, and we cannot allow history to repeat itself. Given the pandemic potential, AMR should always be considered a material threat to our public health security.

Even if the next pandemic is viral, resistant secondary bacterial and/or fungal infections may be significant causes of illness and death. During the COVID-19 pandemic, antimicrobial-resistant infections caused substantial morbidity and mortality in hospitalized patients. For example, U.S. hospitals saw a 15-percent increase in resistant hospital-onset (nosocomial) infections and deaths.¹⁶ The Centers for Disease Control and Prevention’s (CDC’s) analysis, COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022, also highlighted increases in antibiotic prescribing, especially for hospitalized patients, during the first year of the pandemic.¹⁷ Throughout the public health emergency (PHE),¹⁸ workforce shortages affected many health professions and included those tasked with treating and preventing AMR—notably, infectious disease (ID) physicians, infection preventionists, laboratorians, and antimicrobial stewards. Despite rising rates of antimicrobial resistance, limited response resources were allocated for AMR activities, and funding remained focused on the

¹² White House Office of Science and Technology Policy & National Security Council. (2021). *American pandemic preparedness plan: Transforming our capabilities*. <https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29>

¹³ White House. *National biodefense strategy and implementation plan for countering biological threats, enhancing pandemic preparedness, and achieving global health security*. (2022). <https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf>

¹⁴ Morris J. G., Jr (2011). Cholera--modern pandemic disease of ancient lineage. *Emerging infectious diseases*, 17(11), 2099–2104. <https://doi.org/10.3201/eid1711.111109>

¹⁵ Howard-Jones, Norman & World Health Organization. (1975). The scientific background of the International Sanitary Conferences, 1851-1938 / Norman Howard-Jones. World Health Organization. <https://apps.who.int/iris/handle/10665/62873>

¹⁶ Centers for Disease Control and Prevention. (2022). *COVID-19: U.S. impact on antimicrobial resistance, special report 2022*. <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

¹⁷ Centers for Disease Control and Prevention. (2022). *COVID-19: U.S. impact on antimicrobial resistance, special report 2022*. <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

¹⁸ This report uses the term *PHE* rather than *pandemic* to reflect the fact that pandemics are defined as an international outbreak of an infectious agent, yet all PHEs, regardless of their location or cause, require consideration of AMR in outbreak preparedness and response policy.

acute needs presented by the ongoing viral pandemic, including resources for viral diagnostics, patient care, and ensuring access to novel therapeutics.

The U.S. government (USG) must revise its current pandemic policies to better address the lessons learned during the COVID-19 pandemic and implement them immediately during steady-state times. Steady-state operations refers to the periods of time between emergency situations; these are crucial periods of stasis in which most of the preparations and bolstering of our health system should take place to ensure it can withstand the next emergency. In the event of an emergency, it is essential that specific mechanisms are in place to ensure a rapid, effective, and efficient response. This includes many activities that were enacted at later stages in the COVID-19 pandemic, such as enhanced funding for the rapid development of therapeutics and diagnostics and expanded authorizations for skilled professionals to provide care during a PHE. While many of these actions are components to activate during a PHE, it is short-sighted to not consider the necessary steady-state preparations to better facilitate their future rapid execution. Therefore, the bulk of funding, policy, and attention must be paid to addressing key gaps in our health system—illuminated by the COVID-19 pandemic—that need to be addressed *now*. By investing in reducing vulnerabilities and making a more robust health system, emergency policies will be more effective and efficient when deployed to fight the next PHE.

PACCARB's Task and Approach

The authorization of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 underscores the importance of AMR in public health and global health security.¹⁹ Recognizing the critical role of AMR in future pandemic preparedness efforts, U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra tasked the PACCARB on April 13, 2022, with providing recommendations on how to augment current national pandemic preparedness policies to strengthen the country's defenses against antimicrobial-resistant pathogens.²⁰

In response, the PACCARB established the Pandemic Preparedness Working Group, whose deliberations formed the basis of this report. The working group hosted 8 internal meetings in which subject matter experts on pandemic preparedness, across the One Health spectrum, and representatives from the U.S. government provided information on existing policies and practices as well as challenges related to preparing for and responding to infectious disease outbreaks. At these meetings, working group members discussed the gaps in existing preparedness structures especially as they relate to AMR, and formed recommendations to address them. The working group's recommendations were also informed by two public meetings of the PACCARB.

The first PACCARB public meeting, held September 12-13, 2022, was designed as a Pandemic Preparedness Policy Workshop that examined a hypothetical scenario in which a novel viral pandemic occurred, infecting both humans and swine and causing a substantial number of resistant secondary bacterial infections.²¹ This workshop included presenters from across the One Health spectrum representing government, academia, and industry perspectives. The workshop provided working group

¹⁹ See Annex V.

²⁰ See Annex II.

²¹ See Annex III.

members with new perspectives on key issues and critical policy gaps by using a real-world scenario to discuss AMR in relation to pandemic preparedness with human and agricultural implications.

The second PACCARB public meeting, held virtually January 24-25, 2023, focused on the issues of communication and equity as they relate to responding to a public health emergency such as a pandemic. Experts from animal health and human domains were invited to present on unique communication challenges faced both at the federal level and at the community level. Clinicians, academicians, health equity experts, and community organizers were invited to speak about the unique experiences and challenges faced by vulnerable and marginalized communities during a PHE.

Following the public meetings, the working group drafted this report with recommendations which was presented to the full PACCARB at the public meeting on March 23-24, 2023, for further evaluation and discussion. The final version was approved unanimously (with one voting member absent) on March 24, 2023, for transmittal to the Secretary (HHS).

Report Overview and Structure

The workshop and public meeting highlighted that resilient healthcare systems are the foundation of pandemic preparedness. Strengthening the infrastructure and capacity to manage daily operations—or steady-state efforts—builds up community readiness to meet the rapid increase in demand during a PHE effectively and sustainably. Furthermore, the time to strengthen systems, build relationships, expand the workforce, and invest in research and development is before the next PHE occurs. In recognition of this, the report has been organized into recommendations that will improve steady-state public health operations and recommendations that primarily impact response capability during a PHE, although all recommended actions need to be implemented in anticipation of the next PHE, not in response.

The recommendations in this report must also be considered within the context of equity, trust, and communication. During the COVID-19 pandemic, shortcomings in recognizing the social, structural, and behavioral aspects of public health led to poor acceptance of public health interventions, resulting in a weakened public health response and worsened disparities among marginalized and vulnerable populations. This overarching theme represents critical considerations that are necessary to fully address each of the subsequent themes and must be included in all pandemic preparedness policies. The crucial elements of building trust, ensuring equitable health outcomes, and developing clear, consistent communication channels must be addressed before, during, and after a PHE.

Pandemic preparedness cannot be addressed only within the domain of human health. Effective preparedness requires the inclusion of the animal, plant, and environmental health domains. Several definitions of One Health exist; this report uses the definition of the World Health Organization's (WHO's) One Health High-Level Expert Panel as it provides a clear and concise explanation that synthesizes the common themes found in other definitions:²²

²² One Health High-Level Expert Panel (OHHLEP), Adisasmito, W. B., Almuhairei, S., Behraves, C. B., Bilivogui, P., Bukachi, S. A., et al. (2022). One Health: A new definition for a sustainable and healthy future. *PLOS Pathogens* 18(6), e1010537. <https://doi.org/10.1371/journal.ppat.1010537>

One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

The importance of a One Health approach is underscored by the United Nations Quadripartite's²³ 2022 report, One Health: Joint Plan of Action, which directly links the triple planetary crisis of climate change, biodiversity loss, and pollution to AMR.²⁴ As climate change continues to exacerbate the spread of bacterial and fungal diseases (as well as viral, parasitic, and vector-borne diseases) among humans, plants, and animals, there is an opportunity for increased spread of antimicrobial-resistant pathogens with pandemic potential. Therefore, bacterial and fungal agents pose a broad and significant threat to human, animal, and environmental health as well as compounding disease burden during a viral pandemic.²⁵ Combating AMR and maintaining antimicrobial stewardship (AS) are integral to all pandemic preparedness and response.

In this report, the PACCARB provides 14 recommendations built from the considerations described above. First, PACCARB provides two recommendations that address the need to incorporate social, structural, and behavioral elements to advance equity, trust, and effective communication. These broad, high-level recommendations are provided separately to highlight their importance and indicate that they are foundational concepts to be applied throughout all AMR and pandemic preparedness and response activities, including implementation of the specific recommendations that follow. The remaining recommendations from the PACCARB are organized around four major components of PHE preparedness and response:

- Infection prevention and control and antimicrobial stewardship
- Workforce expansion
- Data sharing and security
- Product innovation priorities for medical countermeasures (MCMs)

Within each of these four components, recommendations are first presented with the most relevant goals and priorities stated in the two aforementioned key policy documents, the AP3 and the NBS. Following the recommendations, expanded descriptions highlight detailed approaches to how the recommendations could be achieved, as well as the context and rationale behind them. These suggested approaches—referred to as “specific needs”—are separated into those that will help support steady-state public health activities (which will improve the ability to respond to a PHE) and those directed specifically at needs during a PHE. Importantly, implementation of all recommendations must happen in anticipation of the next emerging threat and cannot wait until we are in the throes of the next emergency.

²³ The United Nations Quadripartite represents the Food and Agriculture Organization of the United Nations, the World Organisation for Animal Health, the United Nations Environment Programme, and the World Health Organization.

²⁴ Food and Agriculture Organization of the United Nations, United Nations Environment Programme, World Health Organization, & World Organisation for Animal Health. (2022). *One Health joint plan of action (2022–2026): Working together for the health of humans, animals, plants and the environment*. <https://doi.org/10.4060/cc2289en>

²⁵ Food and Agriculture Organization of the United Nations, United Nations Environment Programme, World Health Organization, & World Organisation for Animal Health. (2022). *One Health joint plan of action (2022–2026): Working together for the health of humans, animals, plants and the environment*. <https://doi.org/10.4060/cc2289en>

EQUITY, TRUST, AND COMMUNICATION

The PACCARB strongly believes that the promotion of equitable access to prevention strategies and treatment for marginalized and vulnerable populations must be a driving force in implementing the recommendations in this report and any other pandemic preparedness and response activities. Such groups were disproportionately harmed by the COVID-19 pandemic, which exacerbated existing health disparities that have negatively affected the health of these communities for generations. Importantly, the primary missteps during the response to COVID-19 were not biomedical or technological, but social in nature. Effective diagnostics and vaccines were developed at record speed, but public communication about them and their distribution were ineffectively managed. Poor communication of risks and benefits of the recommendations, inequitable distribution of aid and resources, and insufficient consideration of marginalized and vulnerable populations in pandemic planning and response all diminished the effectiveness of interventions. The shortcomings of the COVID-19 response simultaneously stem from and contribute to structural inequalities and a lack of trust in our healthcare system. There are also ongoing issues related to a lack of trust in animal and agricultural communities that impact antimicrobial surveillance and stewardship efforts to prevent the spread of AMR. Addressing inequities in our pandemic preparedness and AMR policies is a moral imperative; we are not safe from public health threats as a country until all of us are equally protected and cared for.

This section focuses on how social, structural, and behavioral elements of communication and provision of healthcare and public health services must be considered to increase adoption of PHE interventions. By acknowledging the barriers faced and using approaches that leverage the social and behavioral sciences, public health interventions can be more effectively and equitably designed, therefore increasing their impact and reducing the effect of existing disparities. Applying these concepts is important to reach a variety of communities, including marginalized communities (such as racial minorities, people living in poverty, migrant workers, and others), vulnerable populations (such as children and older adults), and other historically excluded groups. The PACCARB has two high-level recommendations to guide such activities (Box 2).

Box 2: Equity, Trust, and Communication Recommendations

Recommendation 1: Prioritize social, structural, and behavioral interventions that build trust in public health guidance and increase uptake of both pharmaceutical and non-pharmaceutical interventions in steady-state and during a PHE.

Recommendation 2: Include marginalized and vulnerable communities during the development, implementation, and communication of all pandemic preparedness policies.

The recommendations above address two broad social, structural, and behavioral issues identified by the PACCARB that hinder effective PHE response and further inequity and exclusion of marginalized and vulnerable populations:

- 1) There is a significant lack of trust in public health institutions which is fed by exclusion of some communities from health-promoting interventions during steady-state operations and poor transparency in routine and emergency public health communication.
- 2) The specific challenges and needs of marginalized and vulnerable communities are not adequately considered in current pandemic preparedness and response policies.

Clear, honest, and transparent communication from health authorities is foundational to addressing the public health needs of the diverse communities that comprise the US population. Relationships between public health authorities and the general public can become strained in the context of a PHE when the reasoning behind public health recommendations is opaque, the recommendations change frequently, and there is a high degree of uncertainty about the nature of the threat. These problems are compounded by the historical lack of trust in government and healthcare among many communities, including marginalized and vulnerable populations and within the animal care and agriculture sector. To overcome these barriers, relationship-building among stakeholders must occur before an emergency arises.

When responding to a PHE, information changes rapidly. By providing the rationale for government actions and recommendations, sending out frequent updates with clarity on what has changed and why, and setting expectations of how recommendations may continue to change in the future, agencies can develop a foundation from which trust can be built with diverse communities. Furthermore, designing communications that are tailored to different audiences, developed with their input and in formats accessible to them, will further promote equitable access to public health information.

Disadvantaged and marginalized communities have unique needs in being able to access public health recommendations and in applying those recommendations in their daily lives. Issues such as access to public health communications in a language other than English, transportation to gain access to public health interventions, and access to quality healthcare are often not addressed by the one-size-fits-all approach typically followed by federal planning and response activities. To fully appreciate and address these disparate needs, disadvantaged and marginalized communities should be integrated into the decision-making process throughout the development and implementation of pandemic preparedness and AMR policies. Building relationships is key to this process; public health institutions must work to overcome the mistrust sowed by past inequities by making concerted efforts to engage, listen to, and support communities with material resources that promote health equity. Again, this connection must be made before an emergency arises.

These concepts should be applied across the PACCARB's specific recommendations described in this report. In each section, we highlight some of the equity, trust, and communications concerns and how to consider these factors in the implementation of the recommendations.

RECOMMENDATIONS FROM THE PACCARB

Infection Prevention and Control and Antimicrobial Stewardship

The concepts of Infection Prevention and Control (IPC) and AS are largely absent from national pandemic preparedness policy documents such as the NBS and AP3. Infection prevention and control and AS are core capabilities that play critical roles in preventing the emergence and spread of AMR. During the COVID-19 pandemic, lapses in basic IPC steps were observed (e.g., cessation of multidrug-resistant organism surveillance, decreasing attention to hand hygiene, suspending environmental cleaning audits, interruption of unit-based HAI-prevention quality improvement efforts, competing priorities for PPE usage, reduction in IPC and AS staffing, etc.), which led to the propagation and spread of resistant pathogens, especially in intensive care units.^{26,27} Additionally, AS often lapses during emergencies because there is little or no diagnostic information to guide treatment decisions when the healthcare system is overwhelmed—as was observed during the initial response to COVID-19.^{28,29} Uncertainty around antimicrobial prescription and use may arise in the rapidly changing environment of a PHE; however, emergency standards for AS could be developed to set minimum requirements, so that practitioners could focus on the most important aspects of stewardship during an emergency. Therefore, the PACCARB recommends that future versions of the NBS and AP3 recognize IPC and AS as key elements in the fight against AMR and direct federal efforts to strengthen the nation’s capabilities in these areas.

Furthermore, federal guidance on how to implement AS during emergencies would help ensure that stewardship is maintained before and during PHEs. Crucially, this guidance must be developed through an established, inter-agency pathway that includes set mechanisms for extensive outreach and engagement with healthcare providers, animal health providers, and the public, with specific attention paid to marginalized and disadvantaged communities.³⁰ This pathway must be established during steady-state to allow for its rapid deployment during a PHE. Guidance for emergency AS should reflect local conditions and needs, as communities often have unique situations for which generalized standards may not be appropriate. Therefore, emergency AS guidance should be comprehensive yet flexible enough to apply in all settings and communities across the One Health spectrum, outlining a standard of care that will be available to all communities through all potential clinical touch points. Engagement in developing and applying these guidelines will also provide a basis for open and transparent communication on which trust between marginalized communities and care providers can be built.

²⁶ Perez, S., Innes, G. K., Walters, M. S., Mehr, J., Arias, J., Greeley, R., et al. (2020). Increase in hospital-acquired carbapenem-resistant *Acinetobacter baumannii* infection and colonization in an acute care hospital during a surge in COVID-19 admissions — New Jersey, February–July 2020. *Morbidity and Mortality Weekly Report*, 69(48), 1827–1831. <http://dx.doi.org/10.15585/mmwr.mm6948e1>

²⁷ See Workforce Expansion.

²⁸ Nori, P., Stevens, M. P., & Patel, P. K. (2022). Rising from the pandemic ashes: Reflections on burnout and resiliency from the infection prevention and antimicrobial stewardship workforce. *Antimicrobial stewardship & healthcare epidemiology: ASHE*, 2(1), e101. <https://doi.org/10.1017/ash.2022.240>

²⁹ Centers for Disease Control and Prevention. (2022). *COVID-19: U.S. impact on antimicrobial resistance, special report 2022*. <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

³⁰ PACCARB recognizes CDC and CMS’s partnership around IPC guidance for nursing homes and healthcare facilities in general during COVID-19 and encourages similar relationships be established in the development of guidance.

Box 3: Infection Prevention and Control and Antimicrobial Stewardship Recommendations and Relevant AP3 and NBS Goals and Priorities

Specific Needs for Steady-State Operations

Recommendation 3: Include infection prevention and control and antimicrobial stewardship as core capabilities and goals in pandemic preparedness policies including through dissemination of existing and updated guidelines.

No related AP3 goal
NBS Goal 3.1.4

Specific Needs for Emergency Operations

Recommendation 4: Create a mechanism for rapid guideline development for appropriate antimicrobial use in response to an emerging AMR pathogen and to maintain antimicrobial stewardship during an emergency.

No related AP3 goal
NBS Goal 3.1.4

Specific Needs for Steady-State Operations

Recommendation 3: Include infection prevention and control and antimicrobial stewardship as core capabilities and goals in pandemic preparedness policies including through dissemination of existing and updated guidelines.

- During a PHE, IPC is the first line of defense against an infectious agent and as such must be meaningfully included as an integral part of all pandemic preparedness policies. In addition, AS standards must adapt to meet the challenge of an evolving emergency situation. Current federal pandemic preparedness policies, such as the AP3, focus broadly on biosecurity but fail to identify IPC as a core capability for healthcare providers.

Specific Needs for Emergency Operations

Recommendation 4: Create a mechanism for rapid guideline development for appropriate antimicrobial use in response to an emerging AMR pathogen and to maintain antimicrobial stewardship during an emergency.

- The AS standards in place for routine practice may not provide adequate guidance during a PHE, when administering antimicrobials may be necessary despite uncertainty or due to a lack of diagnostic information. Fully implementing AS when emergency care needs outpace existing healthcare capacity is challenging. Therefore HHS, including CDC, CMS, and the FDA Center

for Veterinary Medicine, should create collaborative pathways that would support the rapid development of antimicrobial stewardship guidance in coordination with stakeholders. Depending on specific emergency needs, this guidance can then be adapted locally and further interpreted by professional societies across the One Health spectrum to ensure alignment between human and animal health practitioners. Emergency guidance that supports identification, implementation, and maintenance of minimum stewardship requirements (e.g., ensuring there is an adequate stewardship workforce) would support effective decision-making during response operations, acknowledging the specific challenges of a PHE (e.g., insufficient or changing information in a rapidly developing situation). National emergency AS guidance should acknowledge uncertainty and be regularly updated with new scientific information. It is essential that any accompanying health promotional materials be made available in languages other than English and tailored to specific communities.

Workforce Expansion

An appropriately staffed, diverse, and trained workforce is needed to support steady-state operations and surge capacities during a PHE. A lack of adequate personnel can lead to increased antibiotic overuse, more healthcare-associated infections (HAIs), and, ultimately, a rise in resistant infections. Given the additional healthcare demands during a medical surge, efforts should be made to utilize all human health providers and look for opportunities to leverage support from other sectors. Qualified animal health practitioners and the agricultural workforce are essential to ensuring animal health, safety, and food security during a PHE, and it is important to recognize the necessity of a robust One Health workforce to ensure systemic preparedness across sectors. Much of the IPC work during outbreaks is carried out by ID practitioners working in public health and IPC fields. The ability to support this expanded workforce has the potential to diminish as the pandemic resolves. It is critical that these groups remain supported between pandemics to build and maintain a trained and effective workforce. This group has too often been neglected in favor of more clinical focused groups.

In addition to general healthcare workforce needs, safe, effective, and competent IPC and AS programs and practices require multidisciplinary collaboration. Infection prevention and control professionals—including infectious diseases specialists, specially trained pharmacists, nurse practitioners, physician assistants, veterinarians, laboratorians, physicians, and public health professionals—help decrease the incidence of infections and guard against antibiotic overuse.^{31,32} Currently, there is a significant shortage of IPC professionals, and this trend appears to be worsening, especially given increased burnout levels caused by a significant workload and stress from the COVID-19 pandemic.^{33,34} This shortage is even

³¹ Health Resources and Services Administration, National Center for Health Workforce Analysis. *Workforce projections*.

<https://data.hrsa.gov/topics/health-workforce/workforce-projections>

³² American Hospital Association. *Fact Sheet: Strengthening the Health Care Workforce*. <https://www.aha.org/fact-sheets/2021-05-26-fact-sheet-strengthening-health-care-workforce>

³³ National Resident Matching Program. *Match results statistics: Medicine and pediatric specialties–2022*. (Report run Nov. 23, 2022). <https://www.nrmp.org/wp-content/uploads/2022/11/Medicine-and-Peds-Specialties-MRS-Report.pdf>

³⁴ Petrino, R., Riesgo, L.G.-C., & Yilmaz, B. Burnout in emergency medical professionals after 2 years of the COVID-19 pandemic: A threat to the health care system? *European Journal of Emergency Medicine*, 29(4), 279–284. doi: 10.1097/MEJ.0000000000000952. This paper concludes, “This situation, if not addressed correctly and urgently by policymakers, is likely to represent a threat to the healthcare system.”

more stark in rural communities, and it poses a serious threat to the foundation of our nation's healthcare system.³⁵

The PACCARB has identified three gaps that must be addressed to ensure a resilient One Health workforce that is equitably distributed across the nation:

- 1) Our current healthcare and public health workforces are neither adequately staffed nor trained to meet the needs of the steady-state healthcare system, let alone the increased demands during a PHE;
- 2) Current regulation and legislation are too rigid to allow other One Health practitioners to provide assistance during a PHE; and
- 3) Both human and animal health laboratories are critical in tracking the spread of a PHE and influencing clinical decision-making yet lack the necessary capacity to be able to maintain current operations and the demand of a PHE.

Addressing these gaps will increase current workforce capacity, build a diverse pipeline of talented professions for the future, and improve equitable access to quality healthcare, particularly among disadvantaged and marginalized populations. Bolstering the public health workforce by recruiting more people from vulnerable and marginalized populations into the ID and IPC workforce will help strengthen their connection with the healthcare system and facilitate culturally appropriate, community-focused healthcare.

³⁵ Pew Charitable Trusts. *Rural Hospitals can't find the Nurses they need to Fight COVID-19*. <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/09/01/rural-hospitals-cant-find-the-nurses-they-need-to-fight-covid>

Box 4: Workforce Expansion Recommendations and Relevant AP3 and NBS Goals and Priorities

Specific Needs for Steady-State Operations

Recommendation 5: Bolster the workforce by expanding recruitment and support of public health professionals, infection preventionists, and infectious diseases specialists and engaging a broader set of providers in human and animal healthcare.

AP3 Goal 6.1
NBS Goals 3.1.1 and 3.1.4

Specific Needs for Emergency Operations

Recommendation 6: Develop pathways that would allow for qualified practitioners in other One Health domains to provide support to human healthcare during a PHE.

AP3 Goal 6.1
NBS Goal 3.1.4

Recommendation 7: Build capacity for both human and animal diagnostic laboratory networks to meet emergency surge testing demands.

AP3 Goal 6.1
NBS Goal 3.1.1

Specific Needs for Steady-State Operations

Recommendation 5: Bolster the workforce by expanding recruitment and support of public health professionals, infection preventionists, and infectious diseases specialists and engaging a broader set of providers in human and animal healthcare.

- The ID and IPC workforce must be bolstered and retained to meet both steady-state and emergency demands. However, supportive funding should be flexible so that the expanded workforce may address several simultaneous infectious diseases rather than be limited to one pathogen at a time. A tailored academic pathway into IPC should be established with the same status as other clinical training programs, rather than including it as supplementary education. Providing funding at the federal level to promote collaborations between public health departments and academic institutions would enhance the knowledge base of and expand the ID and IPC workforce, increasing the capacity to respond to both steady-state and emergency needs. To retain the current ID and IPC workforce, workplace incentives such as flexible work hours, remote and telework options, salary increases, and hazard pay may help to alleviate and compensate for the extreme fatigue facing many front-line workers and promote a better work-

life balance; federal agencies should work with employers to facilitate or incentivize adopting these practices. At the federal level, adequate funding should be provided for loan forgiveness or repayment programs as included in the bipartisan Bio-Preparedness Workforce Pilot Program authorized under the Consolidated Appropriations Act of 2023.³⁶ Additionally, Congress should provide sustainable resources to support CDC's expansion of the public health workforce during the pandemic, especially those staff dedicated to address antimicrobial resistance and use during steady-state times.

- National policies should identify the breadth of professionals needed to appropriately prepare for and respond to a PHE, which includes providing support and resources for facilities and healthcare systems to determine and meet appropriate staffing ratios needed to fully support operations during both steady-state operations and times of medical surge. Notably, engaging and supporting the migrant workforce is essential to ensure the health and safety of these workers as well as that of the millions of people dependent on their labor. Broad measures of support, such as expanded workforce protections and targeted health services, should be considered as key approaches to promoting health, safety, and stewardship within the agricultural sector.
- The public health workforce must be equitably distributed across the nation. Funding should be provided to ensure that public health veterinarians are included in every state, that diagnosticians and laboratory staff are available throughout the country, and that all healthcare locations are adequately staffed with appropriately trained infection preventionists and antimicrobial stewards. To further support and address key shortages of ID practitioners, especially in rural areas, the U.S. government should subsidize an ID consultation telehealth service, along with other novel approaches to support practitioners in remote areas, such as Project ECHO and the Infectious Diseases Society of America's COVID-19 Real-Time Learning Network. Such services allow ID practitioners to have a farther reach, and increase real-time communication, coordination, and information sharing. The same benefits could be realized by supporting such programs for veterinary practitioners. All telehealth programs regulations must include appropriate stewardship standards to avoid inappropriate antibiotic use and minimize the risk of exacerbating AMR spread.
- In anticipation of future PHEs, the U.S. government should identify workforce areas of need for surge capacity, then generate a national program that could be adopted by State, Tribal, Local and Territorial governments to teach community members to respond to an event. For example, the Federal Emergency Management Agency's Community Emergency Response Team (CERT) program could be expanded to include non-technical pandemic response training (e.g., sample collection and community engagement). Funding should be sustained for existing programs that offer high-quality IPC training, such as CDC's Project Firstline, which reaches healthcare professionals and facilities beyond hospitals, such as nursing homes and other long-term care

³⁶ H.R.2617 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2023. (2022, December 29). <https://www.congress.gov/bills/117/congress-house-bill/2617>

facilities. This also includes the agricultural workforce, such as migrant workers, who are critical to ensuring animal safety and food security, which become increasingly important during a PHE.

Specific Needs for Emergency Operations

Recommendation 6: Develop pathways that would allow for qualified practitioners in other One Health domains to provide support to human healthcare during a PHE.

- The PREP Act did allow for other qualified care practitioners (veterinarians, dentists, optometrists, paramedics, emergency medical technicians, midwives, and healthcare students, among others) to provide necessary routine services, such as vaccinations, during the COVID-19 pandemic.³⁷ Therefore, similar flexibility should be extended to private facilities, including laboratories, so that they can also be mobilized to meet surge demands. Effective implementation of this recommendation will require infection prevention and control and antimicrobial stewardship training for the One Health workforce prior to the PHE.
- Veterinary diagnostic laboratories play a key role in emergency response and have the potential to contribute more. After obtaining CLIA certification, veterinary diagnostic laboratories successfully supported COVID-19 testing. The existing technical testing capability within veterinary diagnostic laboratories could be better leveraged during future pandemics with a more streamlined pathway to gaining timely CLIA certification. The National Animal Health Laboratory Network should also be further supported to meet surge testing demands and pilot additional AMR testing and surveillance.

Recommendation 7: Build capacity for both human and animal diagnostic laboratory networks to meet emergency surge testing demands.

- Clinical diagnostic laboratories, such as in hospitals or commercial settings, often support public health laboratories during the response to a PHE. Recent public health crises have highlighted the need for expanded resources to increase laboratory capacity. During the pandemic, the ability of clinical laboratories to continue routine testing was challenged as demand for COVID-19 testing increased dramatically, stressing overall laboratory capacity. Laboratories worked hard to balance COVID-19 testing and routine testing and sometimes made difficult choices about what to scale back to best meet patients' needs. Therefore, diagnostic laboratory capacity for both human and animal networks should be expanded to meet diagnostic surge testing demands while continuing to maintain routine diagnostic testing during a PHE. Federal public health agencies should provide support to help build this important emergency response capacity as these clinical laboratories provide crucial public health services but do not typically receive resources to do so. Expanded capacity for secondary testing of routinely collected samples for genomic surveillance could also help rapidly identify newly emerging strains during a PHE. Congress should provide

³⁷ Administration for Strategic Preparedness and Response. (2021). *Public readiness and emergency preparedness (PREP) act*. Retrieved from <https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx>.

sustainable funding to support CDC's AR Lab Network expansion to ensure additional surge capacity for testing AR pathogens as well as pandemic pathogens.

Data Sharing and Security

Access to robust and complete AMR surveillance data from a variety of human, animal, plant, and environment settings is central to effective pandemic preparedness because it enables earlier identification of resistant pathogens, and thus earlier opportunities to intervene. Domestic and global AMR surveillance systems are the first point of emerging threat detection and must be operating at peak performance during steady-state operations so that as new threats emerge, the country can quickly respond. They should be upgraded and expanded to support this essential monitoring that underpins both routine public and animal health and prepares us to respond to emergencies.

Currently, surveillance efforts cover a too-narrow scope of environments and are often not interoperable, preventing effective One Health collaboration. Existing surveillance databases lack the appropriate data architecture to allow for mining, analysis, and timely sharing of data necessary to inform decision making. Additionally, because much of the data collected is contributed by private data providers, concerns about data privacy and security must be addressed so that entities are comfortable sharing data. Enhancement of surveillance systems should address these main gaps.

Expanding AMR surveillance capacity and reach beyond the hospital setting will also help ensure marginalized and disadvantaged communities are adequately represented in the data that direct public health action. Better representation of diverse communities allows healthcare professionals to understand and track health disparities. At the same time, increased surveillance comes with the responsibility to provide interventions, which are limited by lack of resources for local level response.

Specific Needs for Steady-State Operations

Recommendation 8: Invest in global capacity for AMR pathogen surveillance and early detection of novel AMR pathogens.

Recommendation 9: Expand and diversify sectors participating in domestic AMR surveillance efforts to include outpatient clinical settings, independent/clinical laboratories, wildlife, companion animals, wastewater, and others.

AP3 Goal 4
NBS Goals 1.1.1 and 2.2.5

Recommendation 10: Modernize existing surveillance databases for One Health interoperability to accommodate data input from different human, animal, and environmental health sources, as well as variables that capture social determinants of health.

AP3 Goal 6.2
NBS Goal 1.1.1

Recommendation 11: Invest in improved data privacy and security to encourage more private entities to contribute data, including AMR data, to federal data management systems used in public health, agricultural, and environmental sectors.

AP3 Goal 6.2
NBS Goal 1.1.1

Specific Needs for Steady-State Operations

Recommendation 8: Invest in global capacity for AMR pathogen surveillance and early detection of novel AMR pathogens.

- The vast majority of novel AMR pathogens are likely to emerge outside the U.S. Early detection of these pathogens can help better inform product development and pandemic planning. Pathogen surveillance globally has been a standing feature of many domestic infectious disease programs including for tuberculosis, influenza, and HIV. Current global surveillance for AMR (e.g., the WHO's Global Antimicrobial Resistance and Use Surveillance System) is focused on assessing susceptibility levels and is not geared toward detection of new AR pathogens. Existing systems focused on novel and emerging viral threats should be expanded to cover emerging AR threats. These systems should also include wastewater surveillance and genomic testing of existing pathogens to determine AR threat levels in pathogens with high potential for rapid global dissemination. Investing in country capabilities where resistance is likely to emerge, and

surveillance capacity is low can help prepare for antimicrobial resistance threats at home both in steady state and in a PHE.

- Forward looking analytical approaches to predict the emergence of resistance based on contextual and environmental factors, and use of artificial intelligence tools are needed to get ahead of emergence events.

Recommendation 9: Expand and diversify sectors participating in domestic AMR surveillance efforts to include outpatient clinical settings, independent/clinical laboratories, wildlife, companion animals, wastewater, and others.

- Collection of diverse data is essential to accurately assess the national AMR burden. Current AMR surveillance efforts primarily focus on acute care clinical settings. Although these locations are critical for tracking AMR genes, focusing on acute care settings can mean that key pathogens of public health concern circulating within the community are overlooked. Federal AMR surveillance systems must be adequately resourced to expand in number and diversity of surveillance locations to meet One Health needs. This includes data from private clinics, independent and commercial laboratories, the environment, companion animals (including through animal shelters), as well as non-diagnostic sources (e.g., drug sales, procurement, manufacturing). Collected AMR data must allow for accurate and relevant comparisons to be made across sectors, and raw data (e.g., minimum inhibitory concentrations instead of species-specific breakpoints) should be made accessible so that it may be interpreted appropriately in different settings to facilitate these One Health comparisons.³⁸ Comprehensive surveillance participation strengthens capabilities to detect early disease outbreaks and supports rapid mitigation efforts. When expanding surveillance to include additional sectors and settings, it is important to ensure surveillance systems are collecting data on the most appropriate variables to inform action, which will minimize the burden on those reporting and maximize effectiveness of surveillance systems.
- Wastewater and environmental surveillance systems should be improved and expanded to support AMR tracking during steady-state operations and PHEs. Wastewater surveillance can augment current AMR reporting from clinical samples and has several advantages, including the capacity for community AMR surveillance (in humans, animals, and their immediate environments) outside of the healthcare setting. Wastewater surveillance can act as passive disease surveillance and an early warning system for emerging pathogens. During the COVID-19 pandemic, the CDC's National Wastewater Surveillance System provided community-level COVID-19 data on infection trends by looking for SARS-CoV-2 markers in wastewater. Similar networks can be expanded to detect AMR threats within wastewater. Next-generation genetic sequencing of sewage samples is an essential component of wastewater surveillance. Continuous metagenomic analysis of sewage samples provide a baseline for monitoring changing patterns of resistance over time and the presence of AMR genes in the environment, and it could serve as

³⁸ American Society for Microbiology. (2022). *Updating breakpoints in antimicrobial susceptibility testing*. Retrieved from <https://asm.org/Articles/2022/February/Updating-Breakpoints-in-Antimicrobial-Susceptibili>

sentinel surveillance for AMR in healthcare settings outside of acute care. Therefore, Congress should provide sustainable funding to support the continuity of CDC's National Wastewater Surveillance System (NWSS).

Recommendation 10: Modernize existing surveillance databases for One Health interoperability to accommodate data input from different human, animal, and environmental health sources, as well as variables that capture social determinants of health.

- Existing surveillance systems should be upgraded to facilitate interoperability of data streams across all One Health domains, for example by implementing common data elements and standards (e.g., HL7). Integration of different, multilayered surveillance systems such as the National Respiratory and Enteric Virus Surveillance System, RightSize Flu, wastewater, hospital admission data, syndromic surveillance, air pathogen surveillance, and point prevalence surveys could be woven together to illustrate a more nuanced overall picture of urban vs rural settings.
- The USG should make significant investments in modernization, innovation, expansion, and harmonization of the National Healthcare Safety Network (NHSN), the National Antimicrobial Resistance Monitoring System (NARMS), and other relevant surveillance systems.³⁹ These systems gather tremendous amounts of data and require adequate resources and upgrades to maintain efficiency. Sufficient resources should be allocated to create appropriate data architecture, modernize data collection, and support the analysis of existing data to inform decision making. Support should also be allocated to create standards that allow for automatic data standardization, rapid pooling of data, effective utilization of both laboratory and clinical epidemiology data, and comparative analysis of IPC and AS data. Methods to relay information more rapidly will improve informed decision making, improve infection prevention and control actions, and inform clinical practices and the education of healthcare professionals and the public. Sustainable funding will help ensure continued data collection on healthcare capacity and reporting from nursing homes.
- Mandatory reporting fields in the NHSN should be expanded to include ethnicity, race, and other social determinants of health. Studies evaluating antimicrobial use have identified disparities in incidents of HAIs and prescribing practices depending on patients' race and ethnicity.^{40,41} Therefore, inclusion of patients' ethnicity and race should be mandatory for NHSN data reporting. Identifying existing and new health disparities in AMR mitigation efforts will enable a better understanding of the unique needs and risks of vulnerable populations. The collected data should include broader categories for race and ethnicity, with the option to select multiple races or ethnicities as well as a designation of "other" (and space to elaborate if desired). Sustainable funding is needed to support the pandemic's necessary expansion of NHSN and will help ensure

³⁹ Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2018). *Key strategies to enhance infection prevention and antibiotic stewardship*. <https://www.hhs.gov/sites/default/files/final-ips-report-10-03-2018.pdf>

⁴⁰ Goyal, M. K., Johnson, T. J., Chamberlain, J. M., Casper, T. C., Simmons, T., Alessandrini, E. A., et al. (2017). Racial and ethnic differences in antibiotic use for viral illness in emergency departments. *Pediatrics*, 140(4), e20170203. doi: 10.1542/peds.2017-0203

⁴¹ Bakullari, A., Metersky, M. L., Wang, Y., Eldridge, N., Eckenrode, S., Pandolfi, M. M., Jaser, L., Galusha, D., & Moy, E. (2014). Racial and ethnic disparities in healthcare-associated infections in the United States, 2009-2011. *Infection control and hospital epidemiology*, 35(3), S10-S16. <https://doi.org/10.1086/677827>

continued data collection on healthcare capacity, reporting from nursing homes, automated antibiotic use and resistance reporting, and tracking of patient safety activities including added variables related to ethnicity and race.

Recommendation 11: Invest in improved data privacy and security to encourage more private entities to contribute data, including AMR data, to federal data management systems used in public health, agricultural, and environmental sectors.

- Some existing limitations of and concerns about human and animal AMR surveillance databases stem from issues with data security, quality control, and confidentiality. Systems that rely on data gathered from the public should have more robust protections in place to ensure data privacy and security. Data security can also be improved by modernizing data collection systems with secure electronic case reporting and strong encryption of patient and sample identification data.
- When submission of antimicrobial resistance and use data is voluntary, facilities (e.g., hospitals, animal producers) may be reluctant to share data if they believe the information shared could be perceived as poor performance and negatively impact their business. To assuage these concerns and protect data, AMR surveillance systems should deploy well-described and widely used models for data security and confidentiality, as stakeholders may be unwilling to participate in surveillance efforts without these safeguards. Necessary assurances must be agreed upon and put into place so that healthcare facilities, agriculture producers, and others are comfortable with submitting the needed data. In addition, more robust regulations should be developed to protect the security of animal health data specifically, since there are no statutory protections for this type of data as there are for personal health information.
- The U.S. government should leverage the capacity of trusted organizations to interact with stakeholders. In the veterinary and agricultural spheres, the land-grant system, and its cooperative extension initiatives are trusted sources with broad reach within communities and can be helpful partners in working with stakeholders. Food animal and companion animal veterinarians are also important partners outside of the extension programs.

Medical Countermeasures and Product Innovation Priorities

The urgency of a PHE necessitates the rapid development of novel medical countermeasures (MCMs) including therapeutics, diagnostics, and vaccines. Quick product development is a critical component of responding to a PHE and mitigating the effects of AMR threats. However, the ability to develop new MCMs rapidly and on demand is limited, particularly for AMR products that face a lack of incentives and reimbursement for development.⁴² Supporting the development, approval, and procurement of safe and effective MCMs, including AMR products, before a PHE is a vital component of our emergency

⁴² See PACCARB reports “Recommendations for Incentivizing the Development of Vaccines, Diagnostics, and Therapeutics to Combat Antibiotic-Resistance” and “Recommendation on Proposed Legislation” for additional recommendations on incentivizing the development of AMR therapeutics.

preparedness goals. The PACCARB has identified several gaps that hinder development of new vaccine, therapeutic, and diagnostic technologies:

- 1) The current development pipeline of MCMs to reduce healthcare-associated infections (HAIs) and promote IPC remains limited. The pipeline is particularly insufficient for novel prevention products, such as decolonization agents; therapeutics used to treat resistant infections; and diagnostics, including those to detect and treat fungal diseases.
- 2) The U.S. clinical trial infrastructure is slow and limited in scope, as it focuses primarily on in-hospital settings and often excludes vulnerable populations (e.g., pediatrics), especially during PHEs.
- 3) The regulatory process is rigid and does not facilitate the expedited development and approval of MCMs. It also cannot effectively handle an increase in administrative reviews during an emergency to allow for the continued approval of non-PHE related products.

Addressing these gaps would support development of MCMs during both an emergency and routine times. Furthermore, the AMR and HAI therapeutics and diagnostics that will be most needed during a PHE should be identified, stockpiled, and replenished accordingly in the Strategic National Stockpile (SNS) and the National Veterinary Stockpile (NVS), which can be used by states during declared PHEs. During a PHE, it will be critical to ensure rapid and equitable delivery of stockpiled and new MCMs.

Clinical trials are a critical part of MCM development and therefore must be invested in to ensure greater functionality and the inclusion of vulnerable populations. As seen during the COVID-19 pandemic, vulnerable populations, such as pediatric patients, not only experience unique challenges in the face of a PHE but also are often unable to use rapidly developed MCMs. By deliberately including vulnerable populations in all phases of clinical trials, we can better serve these individuals and communities and ensure their equitable protection during a PHE. Once developed, equitable distribution of MCMs to vulnerable populations and communities in greatest need should be prioritized.

Box 6: Medical Countermeasures and Product Innovation Recommendations and Relevant AP3 and NBS Goals and Priorities

Specific Needs for Steady-State Operations

Recommendation 12: Develop novel antimicrobials, vaccines, diagnostics, and threat-agnostic platform technologies focused on resistant bacterial and fungal pathogens, which are material threats likely to arise during a PHE.

AP3 Goals 2, 9.1, and 11.1
NBS Goals 3.2.3 and 3.5

Specific Needs for Emergency Operations

Recommendation 13: In anticipation of a PHE, establish flexible, response-ready clinical trial networks that include outpatient settings and vulnerable populations, such as pediatrics, and that can easily adapt in an emergency to determine the safety and efficacy of novel countermeasures.

AP3 Goal 11.2
NBS Goal 4.1.4

Recommendation 14: Develop accelerated regulatory approval pathways to assess novel, unique, or nontraditional technologies or products and ensure sufficient funding and procedures are in place to support and maintain the FDA review process during a PHE.

AP3 Goals 11.1 and 11.3
NBS Goals 3.2, 3.4, and 3.5.2

Specific Needs for Steady-State Operations

Recommendation 12: Develop novel antimicrobials, vaccines, diagnostics, and threat-agnostic platform technologies focused on resistant bacterial and fungal pathogens, which are material threats likely to arise during a PHE.

- While the definition of biodefense encompasses naturally or deliberately occurring biological threats, AMR does not directly fit within that definition nor has it been deemed a material threat through a Material Threat Determination (MTD), despite being a current and growing biological threat.⁴³ Assigning AMR as a material threat will help accelerate the development, procurement,

⁴³ Biodefense is defined as those actions designed to counter biological threats, reduce risks, and prepare for, respond to, and recover from bioincidents, whether naturally occurring, accidental, or deliberate in origin and whether impacting human, animal, plant, or environmental health. <https://aspr.hhs.gov/biodefense/Pages/faq.aspx>

and availability of effective MCMs to combat AMR. Doing so would allow for additional investment to develop decolonizing agents and therapies, support new approaches and strategies to IPC and HAI reduction, and create vaccines for antimicrobial-resistant pathogens.

Alternatively, the HHS Secretary should have the capability to access Project BioShield funding to expedite the development of MCMs for conditions that may not be included in the Department of Homeland Security's MTDs and priority lists. These MCMs would be disseminated to any state with a declared PHE. The purview of Project BioShield should also be expanded in accordance with the definition of biodefense to encompass the biological threat of pandemics.

- Advanced research agencies, such as the Biomedical Advanced Research and Development Authority (BARDA) and the Advanced Research Projects Agency for Health (ARPA-H) should support development of threat-agnostic platform capabilities and technologies that allow for the rapid discovery, development, approval, and manufacture of safe and effective novel antimicrobials against a new bacterial pathogen or drug-resistant pathogen. Better communication about products anticipated for approval is needed across regulatory agencies to ensure proper prepositioning of compendial/reference methods so that they are available for rapid deployment and use.
- Novel antimicrobials and diagnostics responsive to material threat requirements should be prioritized and procured, as necessary, as regular components in both the SNS and the NVS. The SNS and the NVS should complement each other's supplies and include AMR and HAI diagnostics and therapeutics, including generic antibiotics, to meet surge demands for interchangeable human and agricultural needs.
- The U.S. government should subsidize and prioritize the development of domestic manufacturing to enhance supply chain resiliency of IPC equipment, personal protective equipment, diagnostics, vaccines, and therapeutic products (including generic antibiotics, drugs, and intravenous fluids).

Recommendation 13: In anticipation of a PHE, establish flexible, response-ready clinical trial networks that include outpatient settings and vulnerable populations, such as pediatrics, and that can easily adapt in an emergency to determine the safety and efficacy of novel countermeasures.

- During a PHE, it is critical to determine safe and effective treatments quickly. During the COVID-19 pandemic, the United Kingdom (U.K.) developed the RECOVERY trial, a simple, multi-arm master protocol design, using standard of care as the control. Through this approach, the U.K. was quickly able to determine which treatments could be successfully used to reduce COVID-19 mortality. The typically smaller U.S. clinical trials, often concentrated at the university level, can take a long time to develop and implement. Therefore, the USG should support the development of a similar program to the RECOVERY trial, working closely with U.S. hospitals.⁴⁴

⁴⁴ Yajima, R., More, A. F., Garvan, C., Harper, C., & Grimes, K. V. (2022). A US clinical trial network is needed for the next pandemic. *Nature medicine*, 28(7), 1330–1331. <https://doi.org/10.1038/s41591-022-01831-1>

- Vulnerable populations, such as pediatric populations or those with compromised immune systems, cannot always use MCMs in the same way as the general population. For example, a pediatric version of the COVID-19 vaccines was needed, which delayed the deployment of the vaccine and relaxation of quarantine protocols for the pediatric population. To avoid similar delays in the use of MCMs during the next PHE, it is imperative to include vulnerable populations in all clinical trials. In addition, clinical trial networks should be established across multiple institutions and organizations, with the understanding that consensus must be reached across all stakeholders. Incentivizing recruitment of diverse patient populations into clinical trial networks and removing barriers to clinical trial participation will ultimately improve representation of vulnerable populations.

Specific Needs for Emergency Operations

Recommendation 14: Develop accelerated regulatory approval pathways to assess novel, unique, or nontraditional technologies or products and ensure sufficient funding and procedures are in place to support and maintain the FDA review process during a PHE.

- The regulatory process for new diagnostic and therapeutic products should be streamlined and expanded to assess all potentially useful products in an efficient and effective manner. In addition, the FDA should generate pathways to approval for alternative products to enable more rapid development of needed products before and during a PHE. Drug repurposing and repositioning is also an important strategy; discovering new uses for approved drugs can provide a quick transition from bench to bedside. However, when a drug has been shown to be ineffective or dangerous, that message should be communicated clearly and emphatically, along with data that support the findings.
- The USDA Center for Veterinary Biologics should create pathways to support the rapid development and approval of animal vaccines.
- Increased federal funding is necessary to establish a standard operating procedure that maintains non-emergency regulatory operations while supporting the FDA Emergency Use Authorization (EUA) process. In addition, the U.S. government should establish mechanisms to allow contracting support to augment existing capacity during emergency situations.

CONCLUSION

On a global scale, morbidity and mortality caused by AMR infections are high with 1.27 million deaths attributed to AMR in 2019.⁴⁵ Resistant infections are a constant challenge to health daily and the rate of AMR infections compounds challenges during a pandemic. Public distrust in the healthcare system and public health agencies, and the neglect of marginalized and vulnerable populations, worsen the burden of a PHE while exacerbating existing health disparities. Centering focus on health equity and ensuring that all populations are appropriately served in the development and implementation of our nation's pandemic preparedness policy is critical to building resilience and strengthening our healthcare system.

As the COVID-19 PHE concludes, we have an opportunity to evaluate and reflect on lessons learned from our nation's response, wholistically. The bulk of funding, policy, and attention must be paid to addressing the key gaps in our health system—illuminated by the COVID-19 pandemic—that need to be addressed *now*. By investing in creating a more resilient health system while keeping the community involved in the process, emergency policies will be more effective and efficient when deployed to fight the next PHE. Across all the PACCARB's recommendations, equity in the development of interventions and deployment of resources must be prioritized. Involving community members to develop targeted and relevant public health guidance, growing and supporting a diverse IPC and One Health workforce, expanding disease surveillance to encompass alternative and nontraditional settings, and enabling equitable development and distribution of MCMs are all essential preparedness activities. Direct and consistent engagement with marginalized and disadvantaged communities will also help to build the necessary trust that is often lacking. Additionally, combating AMR and maintaining IPC and AS are not-to-be forgotten key components of pandemic preparedness and must be consistently integrated into all current and future policies.

The PACCARB applauds the USG's efforts to address the challenges experienced during the COVID-19 pandemic, and much more still needs to be done as our nation continues to suffer from the economic turmoil and burden of disease imposed by almost two years of uncertainty. The USG has certainly recognized the importance of combating the emergence and spread of AMR through its continued dedication to and implementation of its National Action Plan for Combating Antibiotic-Resistant Bacteria (NAP).⁴⁶ In fact, the NBS refers to the NAP in regard to the majority of its AMR components; however, the NAP does not address the surge activities needed during PHEs, such as pandemics. Therefore, the recommendations in this report that aim to augment the NBS and the AP3 are appropriate to ensure a truly comprehensive response to combating AMR as a necessary component of pandemic preparedness.

⁴⁵ Antimicrobial Resistance Collaborators; Murray, C. J. L., Ikuta, K. S., Sharara, F., Swetschinski, L., Robles, G., et al. Global burden of bacterial antimicrobial resistance in 2019: A systematic analysis. (2022). *The Lancet*, 399(10325), 629–655. [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)

⁴⁶ U.S. Department of Health and Human Services. (2020). *National action plan for combating antibiotic-resistant bacteria, 2020–2025*. <https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf>

ANNEX I – ACRONYMS AND ABBREVIATIONS

AMR	antimicrobial resistance
AP3	American Pandemic Preparedness: Transforming Our Capabilities
AS	antimicrobial stewardship
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
COVID-19	coronavirus disease 2019
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
HAI	Healthcare-associated infection
HHS	U.S. Department of Health and Human Services
ID	infectious diseases
IPC	infection prevention and control
MCMs	medical countermeasures
MOU	memorandum of understanding
NBS	National Biodefense Strategy
NHSN	National Healthcare Safety Network
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
PHE	Public Health Emergency
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
USDA	United States Department of Agriculture
USG	United States Government
WHO	World Health Organization

ANNEX II – AP3 AND NBS IMPLEMENTATION PLAN GOALS AND OBJECTIVES

American Pandemic Preparedness: Transforming our Capabilities	
I. Transforming our Medical Defenses	
1. Vaccines	
Goal: Have the ability to rapidly make effective vaccines against any virus family.	
1.1	Vaccine design, testing, and authorization. Enable design, testing, and review of a safe and effective vaccine against any human virus within 100 days after the recognition of a potential emerging pandemic threat.
1.2	Vaccine production. Enable production of enough vaccine for the entire United States population within 130 days and for the global population within 200 days after its recognition as a potential emerging pandemic threat.
1.3	Vaccine distribution. Enable delivery of vaccines rapidly and easily to anywhere in the world, by eliminating challenging requirements for transportation and storage, and enable distributed manufacturing.
1.4	Vaccine administration. Enable rapid, large-scale vaccination campaigns, by simplifying vaccine administration — for example, replacing the need for sterile injection with skin patches and nasal sprays and the need for multiple doses with time-released formulation.
1.5	Vaccine adaptation. Develop ways to rapidly adapt, test, and review modified vaccines to keep pace with changes in the virus.
2. Therapeutics	
Goal: Have a range of therapeutics suitable for any virus family, available before a pandemic or readily created during a pandemic.	
2.1	Inhibiting key viral functions. Develop inhibitors that target essential viral functions, such as cell entry and replication, for any human viruses within a family or subfamily. (Effective inhibitors of this type have been developed for HIV and Hepatitis C.) Viral inhibitors would be valuable for treatment and prevention in both pandemic response and ordinary times (for example, to treat shingles or virally-caused meningitis). Promising approaches to develop anti-viral therapeutics include: (i) broadly-acting, small-molecule therapeutics against key viral functions, in advance of a pandemic and (ii) programmable RNA-based therapeutics targeted against specific viruses, for use during a pandemic.
2.2	Producing neutralizing antibodies against a virus. Develop, to deploy when a pandemic threat emerges, the ability to rapidly identify neutralizing antibodies in recovered patients and manufacture monoclonal antibodies for administration to infected individuals. While this approach is known to yield effective therapies for protecting infected individuals, we have lacked the ability to produce such antibodies at rapid-enough speed and large-enough scale for wide spread use.
2.3	Controlling counterproductive patient responses to infection. Develop and characterize new therapeutics that limit damage from infectious diseases caused by over-or under-active responses of the human body to infection.

3. Diagnostics Goal: Have simple, inexpensive, high-performance diagnostic tests available at large scale within weeks after the recognition of an emerging pandemic threat.	
3.1	Diagnostic test development. Develop diagnostic platforms for rapid, highly accurate tests that can be readily modified to respond to new and multiple pathogens and that can be deployed in a range of settings and use cases, including home, point of care, and central labs. Technologies should be inexpensive and accessible enough to meet national needs for frequent diagnostic testing, screening, and surveillance during sustained periods of high demand — including, if required, enabling daily home testing by an entire population to limit spread and direct medical care.
3.2	Employ these diagnostics in public health. To ensure availability of diagnostic platforms in pandemic response, promote large-scale use of inexpensive, accessible, and reconfigurable testing platforms in medical care and public health in ordinary times, to enable routine testing for circulating viruses, including in home settings.
II. Ensuring Situational Awareness	
4. Early-Warning Systems Goal: Have the ability to detect viruses that pose a pandemic threat soon after they emerge in humans and produce and publicly share the full genome sequence.	
4.1	Viral threat detection in clinical settings. Incorporate into clinical care routine genome sequencing of samples from patients with unexplained fever or respiratory disease in the United States and abroad, in order to detect novel viral pathogens soon after they emerge. Expand capacity for genomic sequencing in clinical settings and data sharing, both domestically and internationally.
4.2	Viral threat detection through environmental monitoring. Expand environmental sequencing, such as through wastewater sampling, in order to detect viruses closely related to known human pathogens circulating in communities, as a complement to viral threat detection in clinical settings.
4.3	Aggregation of public health information. Create systems that connect real-time information about symptoms with genomic and other relevant public health information.
4.4	Global early warning network. Support the establishment of a reliable global system for early warning of emerging pandemic threats. Enhance the effectiveness, interoperability, and connectivity of early threat detection at national and international levels with international partners.
5. Real-time Monitoring Goal: When an emerging pandemic threat has been detected, have the ability to monitor the spread and evolution of the virus.	
5.1	Viral-infection monitoring. Enable effective monitoring, through various means, of virus spread in communities and large populations in order to inform public health response (by the integration of diagnostic, epidemiological, sequencing, environmental monitoring data).
5.2	Tracking viral variants. As a virus spreads in communities, track changes in the genetic code of the virus and the potential impact of such changes on human health and effectiveness of vaccines, therapeutics, and diagnostics.
5.3	Epidemic analysis and forecasting. Strengthen real-time analytics and develop accurate models to improve situational awareness and forecast the course of an outbreak, in order to inform communities and decision-makers about where to direct public health resources, bolster healthcare systems, deploy countermeasures, and communicate to the public. In support of this goal, examine and improve the quality of public health data streams.

III. Strengthening Public Health Systems	
6. Strengthen the U.S. Public Health System by Expanding Capabilities to Respond to Public Health Emergencies Goal: Modernize public health infrastructure, domestically and internationally, to effectively prevent, respond to, and contain biological threats.	
6.1	Strengthen the public health work force. Recruit and sustain a diverse cadre of public health experts at the local, state, and federal levels dedicated to preparing for and responding to public health emergencies, including teams that can be rapidly deployed internationally.
6.2	Invest in public health laboratories and public health digital infrastructure. Ensure that public health labs have the capacity and infrastructure to detect, characterize, and report data (such as genome sequence and functional characterization) on pathogens safely and securely. In support of this, deploy a public health digital infrastructure, based on consistent data standards, which enables real-time data sharing and access across stakeholders involved in pandemic response as well as the public.
6.3	Prioritize vulnerable communities. Develop strategies to mitigate the health inequities exacerbated during a public health emergency, including prioritizing allocation of public health emergency response resources – from public health workers assigned to communities to connectivity of clinical, data, and laboratory systems – to vulnerable and under-served communities.
6.4	Support evidence-based public health communication. Support community engagement strategies, based in social science research, and involving community health workers, faith-based organizations, local leaders, and other community voices, to establish trusted communications channels for conveying critical public health information in preparation for and response to public health emergencies, including pandemics, and to bolster broader public health efforts.
7. Global health Security Capacity to Support Pandemic Preparedness Goal: Establish the international infrastructure and financing needed for pandemic preparedness.	
7.1	Local Capacity and International Systems. Create local capacity and international systems to optimally coordinate on R&D, clinical evaluation, product approval, and distribution of vaccines, therapeutics, diagnostics, and supplies.
7.2	Sustainable financing. Catalyze sustainable international financing for health security capabilities for future pandemics and high consequence biological threats, including sustainable support for a global health security financing mechanism, such as a Financial Intermediary Fund, to support metrics-driven approaches to country capacity for countering biological threats.
IV. Building Core Capabilities	
8. Personal Protective Equipment Goal: Have effective, comfortable, and affordable Personal Protective Equipment (PPE).	
8.1	PPE Innovation. Develop solutions that increase the effectiveness, comfort, reusability, affordability, and manufacturability, including warm or surge capability, of PPE, to provide protection against pathogens with a range of properties.
8.2	Pathogen protection within the built environment: Develop and deploy new technologies to improve indoor air quality, surface materials, and related aspects of transportation, buildings, and other infrastructure to suppress pathogen transmission among people. Invest in retrofitting high-risk infrastructure and incentivize private sector adoption of built environment pathogen suppression technologies for public protection.
9. Stockpiles and Supply Chains	

Goal: Restore and expand the ability of the United States to produce the vital supplies to stop the next pandemic in its tracks.	
9.1	Refill stockpiles. Refill stockpiles that have been depleted by the current pandemic, to avoid near-term shortages while building longer-term onshore and near-shore manufacturing capacity for essential medical supplies.
9.2	Build resilient supply chains. Ensure a stable and secure supply chain for key active ingredients for making vaccines, therapeutics, and diagnostics and for personal protective equipment.
10. Biosafety, Biosecurity, and Prevention of Catastrophic Biological Events	
Goal: Prevent laboratory accidents and deter bioweapons development.	
10.1	Accelerate biosafety and biosecurity innovation. Expand capabilities to identify and minimize safety and security risks in the design and development in biotechnology, and share these tools globally.
10.2	Ensure safe and secure R&D. Ensure R&D involving potentially dangerous biological agents is conducted safely and securely, by fostering a global research environment that adopts and enforces high standards.
10.3	Deter and detect bioweapons development. Strengthen global norms against the development of pathogens as weapons, including by promoting international norms, transparency, and responsible scientific conduct. Strengthen oversight by developing better approaches to detect violations.
11. Regulatory Improvement	
Goal: Improve regulatory capacity to support the development of safe and effective vaccines, therapeutics, and diagnostics.	
11.1	Regulatory approval for platforms. Improve regulatory systems, which typically focus on individual products, to be able to efficiently approve programmable platform technologies for vaccines, therapeutics, and diagnostics, in order to streamline the review of individual products that use these platforms.
11.2	Clinical trial networks. Promote the development and operation of efficient, large-scale clinical trials networks in inter-pandemic times, with the ability to rapidly pivot to pandemic response. Design master protocols, ensure nationwide geographic coverage, train study coordinators to stand up sites quickly, include rural and community hospitals, and develop guidance for data collection and sharing.
11.3	Regulatory capacity. Increase regulatory capacity and expand regulatory approaches at the FDA, in order to keep up with expanding needs in the years ahead.
V. Managing the Mission	
12. Program Management	
Goal: Manage this crucial national endeavor with the seriousness of purpose, commitment, and accountability of an Apollo Program and coordinate work with the international scientific community.	
12.1	U.S. Mission Control. Establish a strong, unified Mission Control to manage, integrate, and ensure accountability for all aspects of the U.S. pandemic preparedness program. Mission Control should have responsibility and authority to develop, update, and execute plans with objective and transparent milestones; regularly assess and report on mission progress, including by drawing on independent scientific panels; and conduct periodic exercises to evaluate national pandemic preparedness by deploying national capabilities, including by rapid product development.
12.2	International Coordination. Galvanize global support and investment in international capabilities to contain pandemic threats wherever they emerge. Support the establishment of an international science and technology expert group to support and review progress toward global pandemic preparedness goals, including the 100 Day Mission.

Implementation Plan for the National Biodefense Strategy	
Goal 1. Enable Risk Awareness and Detection to Inform Decision-Making across the Biodefense Enterprise	
1.1 Early Warning	
1.1.1	Detection and Reporting of Biological Threats
1.1.2	Biological Threat Sequencing and Analytical Data Sharing
1.1.3	Data Integration for Early Warning
1.1.4	Biological Threat Assessment and Characterization Capabilities
1.2. Additional Action	
Goal 2. Ensure Biodefense Enterprise Capabilities to Prevent Bioincidents	
2.1 Global Health Security	
2.1.1	Strengthen Country Capacities
2.1.2	Establish and Maintain Sustainable Global Financing for Health Security and Pandemic Preparedness
2.2 Prevention	
2.2.1	Promote Safe and Secure Biological Laboratories and Practices
2.2.2	Strengthen Responsible Conduct for Biological Research
2.2.3	Accelerate biosafety and biosecurity innovation
2.2.4	Deter Biological Weapons
2.2.5	Reduce Zoonotic Pathogen Spillover
Goal 3. Ensure Biodefense Enterprise Preparedness to Reduce the Impacts of Bioincidents	
3.1 Domestic Health Capacity	
3.1.1	Invest in Domestic Public Health Capacities
3.1.2	Strengthen Capacities to Combat Emerging and Zoonotic Disease
3.1.3	Promote Evidence-Based Health Communication to the Public
3.1.4	Strengthen Healthcare-Associated Infections (HAI) and Antibiotic Resistant (AR) Pathogens Capacities
3.2 Rapidly and Widely Available Diagnostics	
3.2.1	Pathogen Agnostic Tests
3.2.2	Pathogen Specific Tests
3.2.3	Rapid, Low Cost, Point-of-Need Tests
3.3 Resilient and Scalable Supply of Personal Protective Equipment (PPE)	
3.3.1	PPE Capacity
3.3.2	PPE Innovation
3.4 Vaccines	
3.4.1	Vaccine Design, Testing, and Authorization
3.4.2	Vaccine Production
3.4.3	Vaccine Distribution
3.4.4	Vaccine Administration and Allocation

3.5 Agile Therapeutics Development and Production
3.5.1 Therapeutic Development and Manufacturing
3.5.2 Antiviral Development and Manufacturing
3.5.3 Controlling Counterproductive Responses to Infection
3.6 Additional Actions
Goal 4. Rapidly Respond to Limit the Impacts of Bioincidents
4.1 Whole-of-Society Response
4.1.1 Effective Response to Mitigate Biological Incidents
4.1.4 Limited Environmental Impacts of Biological Incidents
4.1.3 Coordinate Real-Time Research for Response
4.1.4 Innovative Clinical-Trial Infrastructure
Goal 5. Facilitate Recovery to Restore the Community, the Economy, and the Environment after a Bioincident
5.1 Whole-of-Society Recovery
5.1.1 Recovery Planning and Implementation

ANNEX III – TASK LETTER FROM THE SECRETARY



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

April 13, 2022

Martin J. Blaser, MD
Henry Rutgers Chair of the Human Microbiome
Professor of Medicine and Microbiology – RWJMS
Director, Center for Advanced Biotechnology and Medicine Rutgers University
679 Hoes Lane West, Room 106A
Piscataway, NJ 08854

Dear Dr. Blaser:

I would like to thank you for your continued leadership of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). Your recent public meeting on global efforts to fight antimicrobial resistance (AMR) and incorporating AMR into pandemic preparedness was an insightful session that emphasized the importance of approaching the issue of AMR from a variety of perspectives. As we move forward, it is critical that we continue to broaden the ways in which we address AMR.

The U.S. has consistently recognized the necessity of addressing AMR as a component of pandemic preparedness. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law No. 116-22) strengthens systems to prepare for significant threats such as AMR. Likewise, preventing naturally occurring infectious diseases, including from antimicrobial-resistant pathogens, is included among the goals in our National Biodefense Strategy and corresponding Implementation Plan. The President's national security memorandum from January 21, 2021, directs a strengthening of health security and pandemic preparedness policies and procedures to improve our response to emerging infectious threats, including resistant pathogens. While we are fortunate that our National Action Plan on Combating Antibiotic Resistant Bacteria truly encompasses a whole of government approach to addressing AMR, we need to further ensure that AMR is also consistently highlighted in all of our current pandemic preparedness and response policies and activities.

Therefore, I hereby request that the PACCARB consider how the U.S. may leverage our existing pandemic preparedness frameworks to strengthen our defense against antimicrobial-resistant pathogens in response to a potential future, large-scale disease event. The Council should examine how existing pandemic preparedness policies may be augmented to address AMR, and whether additional policies or programs may be needed to be best prepared for a large-scale outbreak of a resistant pathogen. Please ensure a One Health approach to this task, identifying lessons learned from the human, animal, and environmental health domains that can be applied

across sectors. To inform your recommendations, the Council should collaborate closely with the Federal Interagency Task Force for Combating Antibiotic-Resistant Bacteria, hold one or more public meetings in 2022 and invite stakeholders and experts in pandemic preparedness and health security to provide insight on the issue. Please prepare a report to present your findings and recommendations and submit it to me within one year of this request.

It is my hope that by improving our ability to prepare for and respond to infectious disease threats, including AMR, the U.S. can be a leader for advancing preparedness and reducing the burden of resistant infections around the world. I look forward to reviewing your recommendations and advancing our fight against AMR.

Sincerely,

A handwritten signature in blue ink, appearing to read "Xavier Becerra", with a stylized, cursive script.

Xavier Becerra

ANNEX IV – PANDEMIC PREPAREDNESS WORKING GROUP ROSTER

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ANNEX V – 2022 PUBLIC POLICY WORKSHOP: DESCRIPTION OF SCENARIO

In this exercise, during the summer of 2022, a rapidly expanding influenza outbreak was identified in several countries. The virus was confirmed as a novel reassortant influenza A virus, although the origin is unclear. Epidemiological data indicates that the virus is highly transmissible. The outbreak continued to spread globally and was declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO) in early July. By mid-July, cases were identified and rapidly rising in multiple U.S. cities, and the Secretary of Health and Human Services declared a public health emergency as our nation's healthcare system became increasingly overwhelmed. Around the same time, the Director General of WHO and world leaders begin to refer to the outbreak as a pandemic.

The influenza pandemic is characterized by a high frequency of severe disease requiring hospitalization, with frequent bacterial superinfection at presentation or developed during hospitalization.⁴⁷ In late August, infections increased to over 250,000 new cases daily, nationwide, with a daily average of 120,000 inpatients and a 30-percent increase in ICU admissions over pre-pandemic levels. As a result, many hospitals are running out of space to admit new patients. Due to the broad sweeping impacts of the pandemic, the President declares a major disaster under the Robert T. Stafford Relief and Emergency Assistance Act of 1988.⁴⁸ The public health emergency and major disaster declarations provide a broad range of funding and resources to strengthen response efforts in hopes of mitigating the impacts of the pandemic.

The influenza pandemic is complicated by a significantly higher than normal rate of secondary bacterial community-acquired pneumonia (CAP) in patients of all ages. The severe viral disease is also leading to increased ventilator use among patients not presenting with CAP, and subsequently, higher than normal ventilator-associated pneumonia (VAP) rates. Many of the secondary bacterial infections are resistant to antimicrobials, leading to a second, underlying AMR pandemic that is responsible for much of the observed mortality; admitted influenza patients contracting a healthcare associated infection (HAI) face a mortality rate of 56 percent. Moreover, the secondary bacterial infections are increasing length of stay in hospitals, and further exacerbating bed shortages. Case fatality proportions of patients with viral infections who are unable to be admitted to a facility are twice that of those receiving inpatient care, and the numbers of patients who have to be treated outside regular facilities is climbing rapidly. Therefore, the secondary AMR epidemic is vastly increasing the health and economic toll of the viral pandemic.

The bacterial agents associated with the observed VAP are similar to those observed prior to the outbreak. Although some local and regional variation exists, these pathogens include methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), carbapenem-resistant *Acinetobacter baumannii* (CRAB), multidrug-resistant *Pseudomonas aeruginosa*, and azole-resistant *Aspergillus fumigatus*. Similarly, the pathogens typically associated with CAP patients are seen

⁴⁷ The Public Health Emergency Fund is a no-year fund at the U.S. Treasury to provide funding in the event of a public health emergency. This is the only immediate and flexible no-year funding source available to ensure a timely response to an urgent event that is declared a public health emergency. More information may be found at <https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>.

⁴⁸ The Robert T. Stafford Relief and Emergency Assistance Act of 1988 (Stafford Act) authorizes the President to provide financial and other assistance to support response, recovery, and mitigation efforts following Presidential emergency or major disaster declaration. More information may be found at <https://www.fema.gov/disaster/how-declared> or in the Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans.

in this outbreak as well, including *Streptococcus pneumoniae* and *Staphylococcus aureus*, which are commonly seen as secondary bacterial pneumoniae associated with seasonal and pandemic influenza, as well as *Haemophilus influenzae*, *Klebsiella pneumoniae*, and *Legionella*. Due to the high incidence and significant attributable mortality of VAP, inpatient prescribers are empirically treating these patients with cefepime, piperacillin-tazobactam or carbapenems (for antipseudomonal activity), vancomycin or linezolid (if risk factors for MRSA are present), ciprofloxacin or colistin. Typically, intravenous ceftriaxone and oral azithromycin are used initially for CAP. Increased demand has strained local supplies of antimicrobials. Other HAIs, in particular resistant *Candida auris* infections, have been observed due to challenges to infection prevention and control (IPC) efforts caused by the high patient loads, longer hospital stays, and staffing shortages experienced by many hospitals.

Meanwhile, the same pandemic influenza A virus strain is spreading rapidly among a susceptible animal population. A high incidence of moderate to severe clinical influenza cases among swine populations leads to increased use of antibiotics to treat secondary bacterial infections. Veterinarians are most concerned about bacterial *Pasteurella multocida*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Glaesserella parasuis* infections, which frequently demonstrate resistance to several antibiotics. Considering the known resistance to tetracyclines among common bacterial pathogens affecting swine, veterinarians are treating herds at finishing barns with tiamulin, lincomycin, or florfenicol added to water. At nursery barns, veterinarians are treating severely ill individual animals with injectable ceftiofur, tulathromycin, or penicillin. When clinically ill pigs are refractory to empirical treatment, they are being treated with injectable enrofloxacin. While susceptibility profiles exist in some regions of the country for certain antimicrobials, these patterns are not necessarily consistent across all routes of administration (e.g., oral administration of a medication may be less bioavailable than injectable administration). Furthermore, susceptibility profiles may differ by geographic region, making accurate and quick determination of the most effective antibiotic regimen difficult.

In addition to the direct effects of influenza virus infections in pigs, farms are seeing a general decline in husbandry and swine health due to a production workforce that has been depleted by human illness from the pandemic, resulting in fewer onsite workers to care for animals, monitor clinical signs, and treat disease. Slaughter facilities are having difficulty keeping up with processing of animals due to workforce shortages, exacerbating challenges at the farm level as pigs have nowhere to move when they reach market weight. Further management challenges, including mixing pigs from different sources, an inability to maintain all-in/all-out management, and increased environmental stress are also contributing to a rise in secondary infections in pigs.

In the resource-constrained healthcare and animal agriculture environments, decisions must be made about the use and allocation of resources, including diagnostics and medical countermeasures, and on IPC and biosecurity measures. In both settings, the effectiveness of standard outbreak response operations is being challenged in this highly antibiotic-resistant environment.

ANNEX VI – PACCARB MEMBERSHIP

SPECIAL GOVERNMENT EMPLOYEES – VOTING MEMBERS

CHAIR

Martin J. Blaser, MD

Henry Rutgers Chair of the Human Microbiome
Professor of Medicine and Microbiology, Robert
Wood Johnson Medical School
Director, Center for Advanced Biotechnology and
Medicine
Rutgers University
Piscataway, NJ

VICE CHAIR

Michael D. Apley, DVM, PhD, DACVCP

Professor, Department of Clinical Sciences
College of Veterinary Medicine
Kansas State University
Manhattan, KS

Stephanie R. Black, MD, MSc

Medical Director, Communicable Disease
Program
Chicago Department of Public Health
Chicago, IL

Helen W. Boucher, MD, FIDSA, FACP

Director, Infectious Diseases Fellowship Program
Director, Heart Transplant and Ventricular Assist
Device Infectious Diseases Program
Professor of Medicine
Tufts University School of Medicine
Division of Geographic Medicine and Infectious
Diseases
Tufts Medical Center
Boston, MA

Virginia R. Fajt, DVM, PhD, DACVCP

Clinical Professor, School of Veterinary Medicine
and Biomedical Sciences
Texas A&M University
College Station, TX

Paula J. Fedorka Cray, PhD

Department Head, Population Health and
Pathobiology
College of Veterinary Medicine
North Carolina State University
Raleigh, NC

Christine Ginocchio, PhD, MT

Chief Scientific and Medical Officer
Quotient Limited
Newton, PA

Locke Karriker, DVM, MS, DACVPM

Professor and Interim Chair, Veterinary Diagnostic
and Production Animal Medicine
Director, Swine Medicine Education Center
Iowa State University
Ames, IA

Elaine L. Larson, PhD, RN

Anna C. Maxwell Professor Emerita and Special
Lecturer, School of Nursing
Professor Emerita of Epidemiology, Mailman
School of Public Health
Columbia University
Scholar in Residence, New York Academy of
Medicine
New York, NY

Ramanan Laxminarayan, PhD, MPH

Director and Senior Fellow
One Health Trust
Washington, DC

Armando Nahum

CEO, Safe Care Campaign
Principal, H2PI
Smyrna, GA

Payal K. Patel, MD, MPH

Assistant Professor
System-Wide Director of Antimicrobial
Stewardship
Intermountain Healthcare
Salt Lake City, UT

Paul Plummer, DVM, PhD, DACVIM, DECSRHM
Executive Director, National Institute of
Antimicrobial Resistance Research and Education
Professor, Anderson Chair of Veterinary Sciences
Iowa State University Research Park
Ames, IA

Julia E. Szymczak, PhD
Associate Professor
Division of Epidemiology
Department of Internal Medicine
University of Utah School of Medicine
Salt Lake City, UT

David White, PhD, MS
Associate Dean for Research
Professor of Food Science
Department of Agriculture Research
University of Tennessee
Knoxville, TN

REPRESENTATIVE MEMBERS – NON-VOTING MEMBERS

American Association of Extension Veterinarians
Carla L. Huston, DVM, PhD, Dipl. ACVPM
Mississippi State, MS

American Veterinary Medical Association
Joni Scheftel, DVM, MPH, Dipl. ACVPM
St. Paul, MN

Biotechnology Innovation Organization
Emily Wheeler
Washington, DC

Healthcare Infection Control Practices Advisory Committee
Lisa Maragakis, MD, MPH
Baltimore, MD

Minor Crop Farmer Alliance
James Adaskaveg, PhD
Riverside, CA

Pediatric Infectious Diseases Society
Jason Newland, MD, MEd
St. Louis, MO

Society of Infectious Disease Pharmacists
Elizabeth Dodds Ashley,
PharmD, MHS, FCCP, FIDP, BCIDP
Durham, NC

Wellcome Trust
Timothy Jinks, PhD
Cambridge, UK

REGULAR GOVERNMENT EMPLOYEES

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Jeffrey Silverstein, PhD
Deputy Administrator
Animal Production and Protection
Office of National Programs
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Animal and Plant Health Inspection Service
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Executive Director, Strategy and Policy
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U.S. Department of Defense

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U.S. Department of Health and Human Services

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Centers for Disease Control and Prevention

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Centers for Medicare & Medicaid Services

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National Institutes of Health

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Office of Global Affairs

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Administration for Strategic Preparedness & Response

Christopher Houchens, PhD
Director (Acting), Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority
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Food and Drug Administration

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U.S. Environmental Protection Agency

Office of Research and Development

Jay Garland, PhD
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DESIGNATED FEDERAL OFFICER

Jomana F. Musmar, MS, PhD

Executive Director and DFO
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
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ANNEX VII – PACCARB CHARTER AND AUTHORIZING LEGISLATION

CHARTER

PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Committee’s Official Designation

The committee shall be known as the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (“the Advisory Council”).

Authority

The Advisory Council was established initially under Executive Order 13676, dated September 18, 2014. Per the delegation of authority dated March 3, 2020, the President of the United States has delegated his authority to the Secretary of the U.S. Department of Health and Human Services under section 9(a)(1) of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), to re-establish the Advisory Council.

Pursuant to this delegation of authority, the Secretary is re-establishing the Advisory Council. Per the President’s delegation of authority the Secretary may direct the Advisory Council to perform duties consistent with those assigned to the Advisory Council in section 505(b) of Public Law 116-22 (June 24, 2019), the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), and may, in the Secretary’s discretion, specify the membership of the Advisory Council, consistent with the requirements of the FACA. The activities and duties of the Advisory Council are governed by the provisions of the FACA, which sets forth standards for the formation and use of federal advisory committees.

Objectives and Scope of Activities

The Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The Advisory Council shall function solely for advisory purposes.

Description of Duties

In carrying out its mission, the Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving:

1. The effectiveness of antibiotics;
2. Research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities;

3. Surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics;
4. Education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals;
5. Methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and
6. Coordination with respect to international efforts to inform and advance the United States capabilities to combat antibiotic resistance.

Agency or Official to Whom the Committee Reports

As stipulated in PAHPAIA, the Advisory Council provides advice, information, and recommendations to the Secretary.

Support

To the extent permitted by law and subject to the availability of appropriations, the Department of Health and Human Services (HHS or the Department) shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions. Management and support services provided to the Advisory Council will be the responsibility of the Office of the Assistant Secretary for Health (OASH), which is a coordinating and program office within the Office of the Secretary.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Advisory Council, including travel expenses for members, but excluding staff support, is \$582,622. The estimate for annual person years of staff support required is 3.0, at an estimated annual cost of \$542,378.

Pursuant to an advance written agreement, the SGE voting members shall receive no stipend from the federal government for the services they perform during their tenure on the Advisory Council. However, the SGE voting members are entitled to receive per diem and reimbursement for travel expenses incurred for attending meetings of the Advisory Council, as authorized by 5 U.S.C. Sec. 5703, as amended, for persons who are employed intermittently in the Government service. The non-voting liaison representative members may be allowed to receive per diem and any applicable expenses for travel that is performed to attend meetings of the Advisory Council in accordance with federal travel regulations, as determined by the DFO.

Designated Federal Officer

The Assistant Secretary for Health (ASH), in consultation with the Secretary, will select the Designated Federal Officer (DFO) from among full-time or permanent part-time staff within

OASH or another organizational component within the HHS, who have knowledge of the subject matter and skills and experience necessary to manage the Advisory Council. The ASH may appoint an Alternate DFO, who will carry out the assigned duties in the event that the DFO cannot fulfill the assigned responsibilities for the Advisory Council.

The DFO will schedule and approve all meetings of the Advisory Council and of its respective subcommittees. The DFO will prepare and approve all meeting agendas. The DFO may collaborate with the Advisory Council Chair in this activity, and when deemed appropriate, with chairs of any existing subcommittees that have been established by the Advisory Council. The DFO, and/or Alternate DFO, will attend all meetings of the Advisory Council and all meetings of any subcommittees/working groups that have been assembled to assist the Advisory Council. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and the DFO can be directed by the Secretary or designee to chair meetings of the Advisory Council.

Estimated Number and Frequency of Meetings

The Advisory Council shall meet not less than two times per year, and, to the extent practicable, in coordination with meetings of the Antimicrobial Resistance Task Force established in section 319E(a) of the Public Health Service Act (42 U.S.C. 247d-5(a)). Meetings will be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in accordance with guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings will be provided to the public in accordance with the FACA. Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies. A quorum is required for the Advisory Council to meet to conduct business. A quorum will consist of a majority of the Advisory Council's voting members.

When the Secretary or designee determines that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared by the DFO that includes, at a minimum, a list of the members and their business addresses, the Advisory Council's functions, date and place of the meeting, and a summary of the Advisory Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

Duration

Continuing.

Termination

Unless renewed by appropriate action, the charter for the Advisory Council will terminate two years from the date it is filed.

Membership and Designation

The Advisory Council will consist of at least 30 members, including the voting and non-voting members and the Chair and Vice Chair. The Secretary will designate the Chair and Vice Chair from among the voting, special government employee (SGE) members of the Advisory Council who have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with federal agencies and partner organizations.

Special Government Employees (voting members). All public voting members will be classified as special government employees (SGEs). SGE members will be selected from individuals who are engaged in a range of fields intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance in humans, animals, or its presence in the environment. Examples include research on, or implementation of, interventions regarding efforts to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The SGEs will represent balanced points of view from human biomedical, public health, environmental, and agricultural fields to include surveillance of antibiotic-resistant infections, prevention and/or interruption of the spread of antibiotic-resistant threats, or development of rapid diagnostics and novel treatments. These voting members may be physicians, veterinarians, epidemiologists, microbiologists, or other health care professionals (e.g., nurses, pharmacists, others); individuals who have expertise and experience as consumer or patient advocates concerned with antibiotic resistance, or in the fields of agriculture and pharmaceuticals; and they also may be from State or local health agencies or public health organizations. The SGEs will be appointed by the Secretary.

Regular Government Employee Members (non-voting). The Advisory Council will include members selected to represent various federal agencies that are involved in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research for human, animal, or environmental health. The federal *regular government employee (RGE)* members shall possess the knowledge, skills, experience, and expertise necessary to inform the Advisory Council in generating intelligent recommendations with respect to the issues mandated by Public Law No. 116-22, PAHPAIA. Federal agencies will be invited to participate as non-voting *RGE* members of the Advisory Council, as it is deemed necessary by the Secretary to accomplish the mission the Advisory Council.

Liaison Representative Members (non-voting). The Advisory Council structure also may include non-voting liaison representative members from organizations and/or interest groups that have involvement in the advocacy, education, development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Non-voting liaison representative members shall possess the knowledge, skills, experience, and expertise necessary to inform the Advisory Council in generating intelligent recommendations with respect to the issues mandated by

Public Law No. 116-22, PAHPAIA. Individuals from among the following sample sectors may be invited to serve as non-voting liaison representative members:

- Professional organizations or associations representing providers or professionals for human and/or animal health involved in infection control and prevention; this can include physicians, nurses, pharmacists, microbiologists, veterinarians.
- Public health, environmental health, and/or animal health organizations or associations (state/territorial, county, or local) representing laboratories, health officials, epidemiologists, agricultural state departments, or environmental associations.
- Other organizations representing patients and consumer advocates, hospitals, pharmaceutical industry, food producers and retailers, or other commodity groups.

Invitations may be extended to other organizations and/or interest groups to participate as non-voting liaison representative members, as it is deemed necessary by the Secretary or designee to accomplish the established mission of the Advisory Council.

Terms. The SGE voting members will be appointed to serve for terms of up to four years; newly appointed members will serve up to four years while renewed members may serve up to an additional three years. The non-voting liaison representative members will serve two-year terms. Any member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. A member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days.

Subcommittees

With approval or recommendation of the Secretary or designee, the Advisory Council may establish standing and *ad hoc* subcommittees to provide assistance for carrying out its function. The subcommittee shall consist of only members of the Advisory Council. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings. All reports and recommendations of a subcommittee must be reported back to the full Advisory Council for deliberation and action. No advice or work products of a subcommittee can be given directly to the Secretary.

Recordkeeping

Records of the Advisory Council and the respective subcommittees or working groups will be handled in accordance with General Schedule 6.2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date: September 2, 2022

Approved: September 1, 2022

September 1, 2022

Date


Xavier Becerra

Presidential Documents

Executive Order 13676 of September 18, 2014

Combating Antibiotic-Resistant Bacteria

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

Section 1. Policy. The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the United States and around the world. The rise of antibiotic-resistant bacteria, however, represents a serious threat to public health and the economy. The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) estimates that annually at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone.

Detecting, preventing, and controlling antibiotic resistance requires a strategic, coordinated, and sustained effort. It also depends on the engagement of governments, academia, industry, healthcare providers, the general public, and the agricultural community, as well as international partners. Success in this effort will require significant efforts to: minimize the emergence of antibiotic-resistant bacteria; preserve the efficacy of new and existing antibacterial drugs; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance efforts in public health and agriculture; develop and promote the use of new, rapid diagnostic technologies; accelerate scientific research and facilitate the development of new antibacterial drugs, vaccines, diagnostics, and other novel therapeutics; maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public and healthcare providers; work with the pharmaceutical industry to include information on the proper use of over-the-counter and prescription antibiotic medications for humans and animals; and improve international collaboration and capabilities for prevention, surveillance, stewardship, basic research, and drug and diagnostics development.

The Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.

Sec. 2. Oversight and Coordination. Combating antibiotic-resistant bacteria is a national security priority. The National Security Council staff, in collaboration with the Office of Science and Technology Policy, the Domestic Policy Council, and the Office of Management and Budget, shall coordinate the development and implementation of Federal Government policies to combat antibiotic-resistant bacteria, including the activities, reports, and recommendations of the Task Force for Combating Antibiotic-Resistant Bacteria established in section 3 of this order.

Sec. 3. Task Force for Combating Antibiotic-Resistant Bacteria. There is hereby established the Task Force for Combating Antibiotic-Resistant Bacteria (Task Force), to be co-chaired by the Secretaries of Defense, Agriculture, and HHS.

(a) Membership. In addition to the Co-Chairs, the Task Force shall consist of representatives from:

(i) the Department of State;

- (ii) the Department of Justice;
- (iii) the Department of Veterans Affairs;
- (iv) the Department of Homeland Security;
- (v) the Environmental Protection Agency;
- (vi) the United States Agency for International Development;
- (vii) the Office of Management and Budget;
- (viii) the Domestic Policy Council;
- (ix) the National Security Council staff;
- (x) the Office of Science and Technology Policy;
- (xi) the National Science Foundation; and
- (xii) such executive departments, agencies, or offices as the Co-Chairs may designate.

Each executive department, agency, or office represented on the Task Force (Task Force agency) shall designate an employee of the Federal Government to perform the functions of the Task Force. In performing its functions, the Task Force may make use of existing interagency task forces on antibiotic resistance.

(b) *Mission.* The Task Force shall identify actions that will provide for the facilitation and monitoring of implementation of this order and the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy).

(c) *Functions.*

(i) By February 15, 2015, the Task Force shall submit a 5-year National Action Plan (Action Plan) to the President that outlines specific actions to be taken to implement the Strategy. The Action Plan shall include goals, milestones, and metrics for measuring progress, as well as associated timelines for implementation. The Action Plan shall address recommendations made by the President's Council of Advisors on Science and Technology regarding combating antibiotic resistance.

(ii) Within 180 days of the release of the Action Plan and each year thereafter, the Task Force shall provide the President with an update on Federal Government actions to combat antibiotic resistance consistent with this order, including progress made in implementing the Strategy and Action Plan, plans for addressing any barriers preventing full implementation of the Strategy and Action Plan, and recommendations for new or modified actions. Annual updates shall include specific goals, milestones, and metrics for all proposed actions and recommendations. The Task Force shall take Federal Government resources into consideration when developing these proposed actions and recommendations.

(iii) In performing its functions, the Task Force shall review relevant statutes, regulations, policies, and programs, and shall consult with relevant domestic and international organizations and experts, as necessary.

(iv) The Task Force shall conduct an assessment of progress made towards achieving the milestones and goals outlined in the Strategy in conjunction with the Advisory Council established pursuant to section 4 of this order.

Sec. 4. Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (a) The Secretary of HHS (Secretary), in consultation with the Secretaries of Defense and Agriculture, shall establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council shall be composed of not more than 30 members to be appointed or designated by the Secretary.

(b) The Secretary shall designate a chairperson from among the members of the Advisory Council.

(c) The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to: preserve the effectiveness of antibiotics by optimizing their use; advance

research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance. The Secretary shall provide the President with all written reports created by the Advisory Council.

(d) Task Force agencies shall, to the extent permitted by law, provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

(e) To the extent permitted by law, and subject to the availability of appropriations, HHS shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions.

Sec. 5. *Improved Antibiotic Stewardship.* (a) By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs.

(b) Task Force agencies shall, as appropriate, define, promulgate, and implement stewardship programs in other healthcare settings, including office-based practices, outpatient settings, emergency departments, and institutional and long-term care facilities such as nursing homes, pharmacies, and correctional facilities.

(c) By the end of calendar year 2016, the Department of Defense (DoD) and the Department of Veterans Affairs (VA) shall review their existing regulations and, as appropriate, propose new regulations and other actions that require their hospitals and long-term care facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those defined by the CDC. DoD and the VA shall also take steps to encourage their other healthcare facilities, such as ambulatory surgery centers and outpatient clinics, to adopt antibiotic stewardship programs.

(d) Task Force agencies shall, as appropriate, monitor improvements in antibiotic use through the National Healthcare Safety Network and other systems.

(e) The Food and Drug Administration (FDA) in HHS, in coordination with the Department of Agriculture (USDA), shall continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.

(f) USDA, the Environmental Protection Agency (EPA), and FDA shall strengthen coordination in common program areas, such as surveillance of antibiotic use and resistance patterns in food-producing animals, inter-species disease transmissibility, and research findings.

(g) DoD, HHS, and the VA shall review existing regulations and propose new regulations and other actions, as appropriate, to standardize the collection and sharing of antibiotic resistance data across all their healthcare settings.

Sec. 6. *Strengthening National Surveillance Efforts for Resistant Bacteria.*

(a) The Task Force shall ensure that the Action Plan includes procedures for creating and integrating surveillance systems and laboratory networks to provide timely, high-quality data across healthcare and agricultural settings, including detailed genomic and other information, adequate to track resistant bacteria across diverse settings. The network-integrated surveillance

systems and laboratory networks shall include common information requirements, repositories for bacteria isolates and other samples, a curated genomic database, rules for access to samples and scientific data, standards for electronic health record-based reporting, data transparency, budget coordination, and international coordination.

(b) Task Force agencies shall, as appropriate, link data from Federal Government sample isolate repositories for bacteria strains to an integrated surveillance system, and, where feasible, the repositories shall enhance their sample collections and further interoperable data systems with national surveillance efforts.

(c) USDA, EPA, and FDA shall work together with stakeholders to monitor and report on changes in antibiotic use in agriculture and their impact on the environment.

(d) Task Force agencies shall, as appropriate, monitor antibiotic resistance in healthcare settings through the National Healthcare Safety Network and related systems.

Sec. 7. Preventing and Responding to Infections and Outbreaks with Antibiotic-Resistant Organisms. (a) Task Force agencies shall, as appropriate, utilize the enhanced surveillance activities described in section 6 of this order to prevent antibiotic-resistant infections by: actively identifying and responding to antibiotic-resistant outbreaks; preventing outbreaks and transmission of antibiotic-resistant infections in healthcare, community, and agricultural settings through early detection and tracking of resistant organisms; and identifying and evaluating additional strategies in the healthcare and community settings for the effective prevention and control of antibiotic-resistant infections.

(b) Task Force agencies shall take steps to implement the measures and achieve the milestones outlined in the Strategy and Action Plan.

(c) DoD, HHS, and the VA shall review and, as appropriate, update their hospital and long-term care infectious disease protocols for identifying, isolating, and treating antibiotic-resistant bacterial infection cases.

Sec. 8. Promoting New and Next Generation Antibiotics and Diagnostics. (a) As part of the Action Plan, the Task Force shall describe steps that agencies can take to encourage the development of new and next-generation antibacterial drugs, diagnostics, vaccines, and novel therapeutics for both the public and agricultural sectors, including steps to develop infrastructure for clinical trials and options for attracting greater private investment in the development of new antibiotics and rapid point-of-care diagnostics. Task Force agency efforts shall focus on addressing areas of unmet medical need for individuals, including those antibiotic-resistant bacteria CDC has identified as public and agricultural health threats.

(b) Together with the countermeasures it develops for biodefense threats, the Biomedical Advanced Research Development Authority in HHS shall develop new and next-generation countermeasures that target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

(c) The Public Health Emergency Medical Countermeasures Enterprise in HHS shall, as appropriate, coordinate with Task Force agencies' efforts to promote new and next-generation countermeasures to target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

Sec. 9. International Cooperation. Within 30 days of the date of this order, the Secretaries of State, USDA, and HHS shall designate representatives to engage in international action to combat antibiotic-resistant bacteria, including the development of the World Health Organization (WHO) Global Action Plan for Antimicrobial Resistance with the WHO, Member States, and other relevant organizations. The Secretaries of State, USDA, and HHS shall conduct a review of international collaboration activities and partnerships, and identify and pursue opportunities for enhanced prevention, surveillance, research and development, and policy engagement. All Task Force

agencies with research and development activities related to antibiotic resistance shall, as appropriate, expand existing bilateral and multilateral scientific cooperation and research pursuant to the Action Plan.

Sec. 10. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (the "Act"), may apply to the Advisory Council, any functions of the President under the Act, except for that of reporting to the Congress, shall be performed by the Secretary in accordance with the guidelines issued by the Administrator of General Services.



THE WHITE HOUSE,
September 18, 2014.