A UNITED FRONT: COLLABORATIVE GLOBAL LEADERSHIP TO COMBAT ANTIMICROBIAL RESISTANCE

A Report with Recommendations

May 2024

PACCARB

PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Management support and funding for activities of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria are provided by the U.S. Department of Health and Human Services. The findings of this report are those of the Advisory Council. They do not necessarily reflect the views of the Department.

[PAGE INTENTIONALLY LEFT BLANK]

TABLE OF CONTENTS

[PAGE INTENTIONALLY LEFT BLANK]

EXECUTIVE SUMMARY

Our ability to protect the world from infectious diseases is endangered by the rising threat of antimicrobial resistance (AMR), which spreads regardless of geographic boundaries, politics, or conflict. Antimicrobials are a foundation for the success of modern medicine—both in treating and preventing infections that may arise from lifesaving procedures such as surgery and cancer treatment. Agricultural and veterinary medicine also rely on effective antimicrobials to manage infections in plants and animals; biosecurity measures that protect animal health in turn help ensure food security. Global collaboration, leadership, and action are required to combat AMR, which is a fundamental threat to global health security, and the United States is positioned to be a leader of this effort worldwide.

To date, the United States has made progress toward reducing the burden of AMR. Released in its current iteration in 2020, the National Action Plan (NAP) for Combating Antibiotic-Resistant Bacteria (CARB) outlines five goals for federal U.S. departments and agencies to work toward collaboratively.[1] The first four goals address AMR domestically, while Goal 5 calls on the U.S. government (USG) to enhance international capacities to address the emergence, spread, and impact of AMR. The USG has advanced Goal 5 objectives by engaging the international community on several activities related to global health and AMR, including building surveillance and diagnostic capacity in low- and middle-income countries (LMICs) and promoting education and awareness. Despite these efforts, opportunities remain to collectively and collaboratively address global AMR at the intersection of the human, animal, and environmental sectors, otherwise described as the One Health approach.[2]

To capitalize on these opportunities, the Secretary of the Department of Health and Human Services, Xavier Becerra, tasked the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) with providing recommendations on advancing U.S. leadership in efforts to combat AMR in human, animal, and environmental health globally. The PACCARB convened the Global AMR Working Group to identify key priorities for global action on mitigating the threat of AMR in addition to opportunities for the United States to lead efforts for sustained action domestically and internationally. These recommendations are intended to provide guidance on how domestic U.S. policy can support global priorities during the 2024 United Nations General Assembly (UNGA) High Level Meeting (HLM) on AMR, and beyond. This report with recommendations is the result of the Council's conclusions informed by public meetings and Working Group discussions which took place from December 2023 – May 2024.[3]

---

[1] Federal Task Force on Combating Antibiotic-Resistant Bacteria. (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

[2] As defined by the World Health Organization, One Health is an "integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems," recognizing that the health of humans, domestic and wild animals, plants, and the environment are interconnected.

[3] Information on PACCARB public meetings is available at https://www.hhs.gov/ash/advisory-committees/paccarb/timeline-past-meetings/index.html.

Foundational Concepts

The PACCARB was guided by several foundational concepts critical to the interpretation and implementation of the recommendations in this report. The PACCARB recommends the adoption of these concepts during both the development of the U.S. position at the 2024 UNGA HLM and the implementation of the goals of the CARB NAP:

Defining AMR. Consistent with the 2014 USG CARB National Strategy and aligned with the World Health Organization's list of priority pathogens, the PACCARB considers AMR to include both bacteria and fungi. Implementation of the recommendations presented in this report should focus initially on high-consequence bacterial and fungal pathogens and then expand to other resistant pathogens.

Plain Language. Consistent, precise, and approachable language should be used when discussing AMR to facilitate understanding of the issue and thus community and political engagement and action.

Monitoring and Use of Metrics. The implementation of interventions should include the establishment of appropriate metrics, using the best available data, to enable leaders to monitor progress and identify areas for improvement.

Local Focus. Sustained change requires the engagement of local communities whose daily practices drive the success or failure of broader public health efforts. The PACCARB believes that it is critical to engage local community leaders and stakeholders when developing efforts to address AMR both in the global and local contexts.

Global Targets. The PACCARB does not prescribe global targets for AMR. Rather, targets should be crafted through international consensus that allows for localized implementation, as they are necessary to inform funding and interventions.[4]

Future Action

Given opportunity for action this year to make progress in the global fight against AMR, the PACCARB reemphasizes the need for consistent messaging and sustained advocacy for AMR issues. The U.S. can better coordinate and support ongoing efforts to address antibiotic resistance issues around the globe through the creation of a presidential initiative, led by a U.S. ambassador for AMR with subject matter expertise in One Health. Together, the initiative and ambassador will provide a singular, strong position

[4] The following two documents propose global targets to drive global and national action on AMR. See Global Leaders Group on Antimicrobial Resistance. (2024, April 4). *Towards specific commitments and action in the response to antimicrobial resistance.* https://www.amrleaders.org/docs/librariesprovider20/glg/glg-report-final.pdf?sfvrsn=1e2e2532_1&download=true; and Mendelson, M., et al. (2024). Ensuring progress on sustainable access to effective antibiotics at UNGA 2024: a target-based approach. *Lancet.* *https://doi.org/10.1016/S0140-6736(24)01019-5*

to represent U.S. AMR efforts and commitments that will further coordination and collaboration globally.

Global Priorities

The PACCARB identified four key, actionable priorities that the USG should consider for its global negotiations on collaboratively mitigating AMR. Each priority identifies opportunities to augment, expand, and renew current efforts to promote and strengthen global actions through coordinated collaboration. Each priority also acknowledges and addresses the diverse public health priorities and unique challenges facing LMICs.

The PACCARB proposes the following global priorities (depicted in Figure 1):

Preventing Infections. Preventing bacterial, fungal, and viral infections combats AMR on multiple fronts, reducing the need for antimicrobial treatment and reducing the transmission of antimicrobial-resistant pathogens. Interventions to reduce all infectious disease transmission are critical components of AMR prevention and include improved infection prevention and biosecurity; access to clean water, hygiene, and sanitation; and vaccination. This all-encompassing approach for prevention, agnostic of the pathogen, is necessary to achieve optimum results.

Awareness of AMR to Drive Global Action. Cultivating a basic understanding of the dire global threat posed by AMR in all One Health domains among political leaders, professionals, and the public is a necessary building block for meaningful action. To achieve this, communication should highlight the link between AMR and its negative impact on major health, social, and economic issues—such as cancer, maternal health, poverty, and food security. Further, awareness across One Health sectors should be fostered through multisectoral partnerships. Findings from the social and behavioral sciences should also be leveraged to create interventions that can be successfully implemented. Lastly, AMR must be communicated more simply in all global health conversations to drive political will toward action and influence change at the community and individual level.

Globally Responsive Development of Products and Solutions to Combat AMR. The discovery and development of new products to better diagnose, prevent, and treat resistant infections in humans and animals remains a challenge that is critical to reducing AMR. New mechanisms of support for developing antibiotics, vaccines, diagnostics, and other alternatives are urgently needed and should be centered around equity and access to these products to meet global needs, across all One Health domains. Public private partnerships and market-based incentives to reward innovation are crucial components to creating a truly sustainable pipeline.

Importantly, new innovations must be combined with stewardship programs to break the cycle of resistance.[5]

Equitable Access to Antimicrobials, Vaccines, and Diagnostics. Many places around the world, especially LMICs, suffer not only from the lack of access to basic needs, but also from limited access to medicines, poor diagnostic capacity,[6] fragmented surveillance data,[7] and insufficiency in other critical components of public health. Global access to antimicrobials, vaccines, and diagnostics is essential to curtail disease and should be facilitated through global procurement assistance programs. Improved system capacity is also necessary to better identify needs and facilitate the mechanisms of access.

Guided by the foundational concepts and the urgent need to combat AMR globally, the PACCARB provides these four main recommendations on global priorities and nine recommendations on specific U.S. actions to address this pressing global health threat. The global priorities are described in Figure 2. Figure 3 summarizes the U.S.-specific recommendations and their alignment with Goal 5 of the current 2020-2025 U.S. CARB NAP.

[5] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2021, October 6). Resolution: Support for legislation that promotes the production of new antimicrobial drugs. https://www.hhs.gov/sites/default/files/paccarb-incentives-leg-letter-oct-6-2021.pdf. An example of a U.S.-based mechanism for human health products is the re-introduced Pasteur Act, see: https://www.congress.gov/bill/118th-congress/senate-bill/1355.

[6] Fleming, K. A., et al. (2021). The *Lancet* Commission on diagnostics: Transforming access to diagnostics. *Lancet, 398*(10315), 1997–2050.

[7] Iskandar, K., et al. (2021). Surveillance of antimicrobial resistance in low- and middle-income countries: A scattered picture. *Antimicrobial Resistance & Infection Control, 10*(1), 63–82.

Figure 1. The PACCARB recommends actions to improve efforts to combat AMR globally in the following priorities: preventing infections; raising awareness of AMR; development of new products and solutions that address global needs; and equitable access to existing and new treatments, vaccines, and diagnostics. Furthermore, all of these priorities are prefaced by the need for: ensuring a collective understanding of AMR, using consistent and common language, implementing actions that address local needs and driven by local solutions, informing decision-making through use of monitoring and metrics, and setting global targets that are science driven.

***Recommendation**: AMR strategies (including NAPs) should include infection prevention as a core element and prioritize the challenges people face that contribute to infectious diseases and AMR — community prevention efforts; water, sanitation, and hygiene (WASH); infection prevention and control in healthcare; vaccine development, access, and uptake; and agricultural biosecurity.*

***Recommendation**: Raise awareness among the public and political leaders on AMR as a critical threat to public health, crop and animal health, the economy, and social issues to drive community, national, and global action.*

***Recommendation:** Advance market-based incentives to build and sustain development of new products that address AMR, including diagnostics and therapeutics, based on domestic and global need.*

***Recommendation**: Ensure equitable access to antimicrobials, vaccines, and diagnostics based on local and regional needs, while promoting stewardship and optimal use.*

Figure 2. Summary of Global Priorities.

Figure 3. Summary of U.S.-Specific Recommendations and their relation to U.S. CARB NAP Goal 5.

INTRODUCTION

Antimicrobial resistance (AMR) is associated with over 5 million deaths around the world each year, surpassing the annual mortality rate of people living with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and malaria.[8] AMR is anticipated to cause more than 10 million deaths annually by 2050, equaling and potentially surpassing the death rate of cancer.[9] The global economic cost of AMR as a result of increased healthcare expenditures and loss of productivity is estimated to total $855 billion U.S. dollars annually.[10] Low- and middle-income countries (LMICs), where the burden of AMR is the highest, are impacted the most.[11] It is estimated that an additional 24 million people will be forced into extreme poverty by 2030 in the absence of action to mitigate the threat of AMR.[12] The impacts of AMR are not restricted to human health; AMR also affects the health of animals, plants, and the environment. Growing rates of AMR coupled with limited novel treatment options creates an urgent crisis that must be addressed with global, coordinated multidisciplinary solutions and leadership.

The second iteration of the U.S. National Action Plan (NAP) for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025, outlines the U.S. response to address AMR through interagency coordination and action domestically and internationally.[13] The CARB NAP outlines five goals that work together to reduce the incidence and impact of drug-resistant infections. Goal 5 addresses the emergence, spread, and impact of AMR internationally through collaboration and capacity building. The U.S. government (USG) has made meaningful progress toward Goal 5 through efforts that bring countries together, promote awareness and capacity, and build global surveillance on AMR across the One Health spectrum. Examples of USG success are described below. The USG will soon begin the next iteration of the CARB NAP, expected to be completed by 2025.

The upcoming second United Nations General Assembly (UNGA) High-Level Meeting (HLM) on AMR in September 2024 provides an opportunity for renewed international commitment to combat AMR. Since the first HLM on AMR in 2016, more than 90 percent of countries have developed NAPs that focus on improving appropriate use of antimicrobials, strengthening AMR surveillance and laboratory capacity, and improving awareness and understanding of AMR. However, fewer than a third of countries that have NAPs are monitoring their implementation, and only 11 percent have allocated

---

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

[9] United Nations Environment Programme. (2023, February 7). *Bracing for superbugs: Strengthening environmental action in the One Health response to antimicrobial resistance.* https://www.unep.org/resources/superbugs/environmental-action

[10] Global Leaders Group on Antimicrobial Resistance. (2024, April 4). *Towards specific commitments and action in the response to antimicrobial resistance.* https://www.amrleaders.org/docs/librariesprovider20/glg/glg-report-final.pdf

[11] Ikhimiukor, O. O., Odih, E. E., Donado-Godoy, P., & Okeke, I. N. (2022). A bottom-up view of antimicrobial resistance transmission in developing countries. *Nature Microbiology, 7*(6), 757-765.

[12] Jonas, O. B., Irwin, A., Berthe, F. C. J., Le Gall, F. G., & Marquez, P. V. (2017). *Drug-resistant infections: A threat to our economic future (vol 2): Final report*. HNP/Agriculture Global Antimicrobial Resistance Initiative, World Bank Group. http://documents.worldbank.org/curated/en/323311493396993758/final-report

[13] 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

budgets to fund their NAPs.[14] Therefore, the UNGA HLM is an opportunity to build on the success of 2016, focus on implementation of NAPs, and identify additional practical and actionable solutions tailored to respective countries based on the challenges each faces. Although it is important to recognize and celebrate accomplishments, we must also move from plans to action to address multiple gaps and overall lack of progress.

As the USG prepares to update its CARB NAP, the UNGA HLM is a unique opportunity for the United States to identify new priorities and update existing efforts for advancing U.S. leadership in the global fight against AMR. The intent of this PACCARB report is to inform the U.S. priorities for the UNGA HLM and update of the CARB NAP to better position the USG as a leader in combating AMR beyond the events of 2024.

The PACCARB's Task and Approach

The PACCARB provides advice and recommendations to combat drug resistance for consideration by the Secretary of the U.S. Department of Health and Human Services (DHHS), along with other federal agencies. On August 13, 2023, DHHS Secretary Xavier Becerra tasked the PACCARB with providing recommendations on how USG agencies can lead global AMR efforts for sustained action domestically and internationally.[15] Ultimately, these recommendations are meant to give guidance on how domestic policy can support global priorities on combating AMR.

In response to the task, the PACCARB established the Global AMR Working Group, whose deliberations form the basis of this report.[16] The working group hosted six internal meetings in which subject matter experts across the One Health spectrum and USG representatives provided information on existing engagements and initiatives as well as challenges to global AMR prevention, surveillance, and control. At these meetings, working group members discussed the knowledge and infrastructure gaps in existing public health, environmental, and animal health practices 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.[17]

The December 20, 2023, PACCARB public meeting, held virtually, centered around ongoing USG efforts to combat AMR internationally. Representatives from the DHHS Office of Global Affairs (OGA), the U.S. Department of State Bureau of Global Health Security and Diplomacy, the U.S. Agency for International Development (USAID), the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service, the USDA Foreign Agricultural Services, and the Centers for Disease Control and Prevention (CDC) reviewed agency-specific progress to address AMR globally.

---

[14] Food and Agriculture Organization of the United Nations, United Nations Environment Programme, World Health Organization, & World Organisation for Animal Health. 2023. *Global database for tracking antimicrobial resistance country self-assessment survey.* https://amrcountryprogress.org/#/map-view

[15] See Annex II for Task Letter.

[16] See Annex III for WG Roster.

[17] Both meetings can be viewed at the PACCARB meeting, HHS.GOV/PACCARB

The February 22, 2024, PACCARB public meeting focused on international efforts to combat AMR through awareness and education, infection prevention, and data sharing. Representatives from international organizations, nongovernmental organizations, nonprofit organizations, and universities informed Council members of ongoing global AMR efforts. Discussions covered the successes of ongoing programs as well as the challenges and gaps that have prevented further progress.

Following the public meetings, the Global AMR Working Group drafted this report with recommendations, which was presented to the full PACCARB at the May 21–22, 2024, public meeting for further evaluation and discussion. The final version was approved unanimously on May 21, 2024, with no voting members absent/abstaining, for transmittal to the Secretary.

Examples of U.S. Government Successes and Existing Collaborative Efforts

Coordinating the USG's global activities—for AMR specifically and global health broadly—facilitates information sharing and accountability to maximize the USG impact on AMR. These activities are successfully coordinated under Goal 5 of the U.S. CARB NAP by the CARB Task Force.[18] Some of the ongoing efforts by federal agencies that align with the objectives in Goal 5 are highlighted below:

U.S. Department of Health and Human Services: DHHS encompasses many agencies, such as but not limited to Food and Drug Administration (FDA), Administration for Strategic Preparedness and Response (ASPR), Agency for Healthcare Research and Quality (AHRQ), and Assistant Secretary for Planning and Evaluation (ASPE), that coordinate and implement activities across the CARB NAP that support international efforts to combat AMR. Within the Office of the Secretary, OGA provides leadership and expertise in global health diplomacy and policy and is responsible for ensuring that U.S. priorities are addressed in international forums. OGA coordinates international engagement on human health issues with a One Health approach and provides leadership and policy expertise at the international level. OGA also engages with the Group of Seven (G7), the Group of Twenty (G20), the World Health Organization (WHO), the Pan American Health Organization, the Asia-Pacific Economic Cooperation Health Working Group, and the Association of Southeast Asian Nations on global health and AMR issues.

> **Centers for Disease Control and Prevention**: CDC leads USG public health efforts to combat AMR domestically and globally, guided by CDC's Antibiotic Resistance Threats Report,[19] to improve prevention, detection, and containment of AMR threats. CDC's Global Antimicrobial Resistance Laboratory and Response Network detects antimicrobial-resistant pathogens, prevents infections in healthcare and the community, and applies new and innovative ways to

[18] The CARB Task Force employs a One Health approach by engaging U.S. Government agencies that oversee human, animal, and environmental health and by promoting collaboration and communication to address antibiotic resistance in every relevant sector. The Task Force is co-chaired by the Secretaries of the U.S. Departments of Health and Human Services (DHHS), Agriculture (USDA), and Defense (DoD), and also includes the Departments of Interior (DoI), State (DoS), and Veterans Affairs (VA), the Environmental Protection Agency (EPA), the U.S. Agency for International Development (USAID), the National Science Foundation, and representatives from the Executive Office of the President.

[19] Centers for Disease Control and Prevention. (2019). *Antibiotic Resistance Threats in the United States, 2019*. Atlanta, GA, Centers for Disease Control and Prevention. https://www.cdc.gov/drugresistance/pdf/threatsreport/2019-ar-threats-report-508.pdf

respond to AMR threats. CDC serves as the secretariat of the Transatlantic Taskforce on Antimicrobial Resistance and is host to multiple WHO AMR collaborating centers.

National Institutes of Health (NIH): NIH established an international antibacterial resistance partnership among the National Institute of Allergy and Infectious Diseases' Antibacterial Resistance Leadership Group, the European Clinical Research Alliance on Infectious Diseases, and the Advancing Clinical Evidence in Infectious Diseases Network to overcome challenges in antibacterial resistance clinical trials. NIH participates in the Transatlantic Taskforce on Antimicrobial Resistance, the Global AMR Research and Development (R&D) Hub, and the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) to improve coordination and address challenges in global AMR R&D. NIH also supports and conducts AMR research in collaboration with international investigators and sites that correspond to other goals within the CARB NAP.

U.S. Department of State: The State Department's Bureau of Global Heath Security and Diplomacy houses USG efforts on disease outbreak response, health diplomacy, and global health security. It has identified AMR as a top threat to global security.

U.S. Agency for International Development: USAID provides catalytic investments, engages in advocacy, and fosters innovation and research to strengthen local, national, and global capacity for health security. USAID incorporates elements of AMR into many global health initiatives and supports building AMR surveillance capacity.

U.S. Department of Agriculture: The USDA Strategy to Address Antimicrobial Resistance[20] describes 10 priorities for the agency's efforts in combating AMR. USDA engages with the World Organization for Animal Health, the Food and Agriculture Organization, and the International Plant Protection Convention to promote U.S. leadership, support international collaboration, build surveillance capacity, and promote education and awareness on AMR. With the FDA, USDA led the U.S. delegation to the four-year Codex Alimentarius ad hoc Intergovernmental Task Force on Antimicrobial Resistance (2017–2021), which revised and updated the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance and drafted Guidelines for Integrated Monitoring and Surveillance for Foodborne Antimicrobial Resistance.

While these efforts continue to align global activities across traditional USG partners, there may be opportunities to foster stronger relationships on all One Health topics with a broader set of international partners and ensure fruitful collaborations. This report outlines several such opportunities identified by the PACCARB that, if incorporated into the existing efforts of federal agencies, would promote further U.S. global leadership on AMR.

[20] U.S. Department of Agriculture. (2023). *USDA Strategy to Address Antimicrobial Resistance* https://www.usda.gov/sites/default/files/documents/amr-2023-strategy.pdf

A decade has passed since the first National Strategy for CARB was written in 2014.[21] Since then, the rate of AMR across One Health domains has surpassed initial estimates. *The PACCARB proposes that the USG CARB Task Force conduct a thorough review and assessment of the 2014 CARB Strategy and determine whether the goals, as stated, remain appropriate to drive the milestones and objectives of the U.S. CARB NAP for 2025 to 2030. For example, the international collaboration described in Goal 5 could be integrated into the other four goals so that each goal includes both domestic and global objectives and targets.* This integration could potentially make available additional funding for international activities as appropriated by each agency and institute a more consistent process for action that includes our global partners.

Report Overview and Structure

To address the needed action to reduce the impact of AMR globally, this report summarizes the PACCARB's view of the global priorities in combatting AMR and U.S. recommendations that should be implemented to support them, recognizing that opportunities to drive improvement exist through the upcoming UNGA HLM and the forthcoming updated U.S. CARB NAP for 2025 to 2030.

The PACCARB identified four major priorities that encompass the critical aspects of leadership in combating AMR globally:

- Preventing Infections
- Awareness of AMR to Drive Global Action
- Globally Responsive Development of Products and Solutions to Combat AMR
- Equitable Access to Antimicrobials, Vaccines, and Diagnostics

Within each of these four priorities, global priorities for moving AMR solutions forward are presented first. Following the overview of global priorities, expanded descriptions highlight detailed approaches to how the priorities could be achieved, as well as the context and rationale behind them. The U.S.-specific recommendations follow and, where relevant, are associated with the CARB NAP Goal 5 objectives. The U.S. recommendations focus on what the United States can do to support action in the priority areas. Because of the difference in scope between the global and U.S. actions, the U.S. recommendations may not always align directly with the global priorities highlighted, specifically in areas in which the USG has had success.

Foundational Concepts

The PACCARB acknowledges several foundational concepts that must underpin all interventions. These broad, high-level principles are provided separately to highlight their importance and indicate that they

[21] The White House. (2014, September). *National strategy for combating antibiotic-resistant bacteria.* https://www.cdc.gov/drugresistance/pdf/carb_national_strategy.pdf

should be applied throughout all global AMR activities, including implementation of the more specific recommendations that follow.

Defining AMR

While AMR is rising in fungal, viral, and parasite populations, AMR in bacteria remains the highest concern for global health given inherent mechanisms of rapid spread. The WHO Bacterial Priority Pathogen List[22] provides an overview of drug-resistant bacterial pathogens of the highest consequence and should inform the development of U.S. CARB NAP international efforts. The PACCARB uses the term "AMR" in this report to include both antimicrobial-resistant bacterial and fungal pathogens, and, therefore, recommendations in this report primarily apply to bacterial and fungal resistance.

Plain Language

The current understanding of AMR is hindered by inconsistent and confusing language.[23] Many stakeholders do not understand AMR, which limits stewardship and funding worldwide. Buy-in at the community level requires an understanding of AMR and an ability to discuss how the different aspects of AMR affect individual communities and how local activities contribute to the global picture—either positively or negatively. To that end, consistent and common language should be used for all AMR communication.

Local Focus

The PACCARB affirms that sustainable, global action should be designed and implemented to address local needs and driven by local solutions. As the global health community advances the fight against AMR, the PACCARB believes that interventions proposed and instituted must primarily meet the specific needs of the communities where it is implemented and tailored to account for available resources and capabilities to drive long-term success and sustainability. Furthermore, local leaders should be involved in all processes and at every step, especially in the early stages, when needs are assessed and interventions first devised.

Monitoring and Use of Metrics

To ensure successful design and implementation of interventions, the PACCARB believes that appropriate metrics must be established and progress monitored and continually evaluated. Metrics based on health risks allow decision-makers to determine priorities in AMR prevention activities, continuously monitor the progress of interventions, and identify areas for improvement or revision. All interventions should be accompanied by appropriate risk-based metrics for AMR and prevention of infection, when feasible, and should leverage relevant available data to provide actionable insights for leaders.

---

[22] World Health Organization. (2024). WHO Bacterial Priority Pathogens List, 2024. https://iris.who.int/bitstream/handle/10665/376776/9789240093461-eng.pdf?sequence=1

[23] Karvanen, M., & Cars, O. (2024, March 23). The language of antimicrobial and antibiotic resistance is blocking global collective action. *Infectious Diseases, 56*(6), 487-495. https://doi.org/10.1080/23744235.2024.2332455

Global Targets

In this report, the PACCARB proposes four overarching global priorities to serve as common goals among all nations for the UNGA HLM on AMR and beyond. To achieve these goals, global targets to reduce the global burden of AMR are necessary and can help inform funding and interventions by identifying areas of greatest need. Global targets have been proposed by many organizations (e.g., the Global Leaders Group on Antimicrobial Resistance[24] and the AMR Industry Alliance[25]) as well as leading AMR researchers,[26] advocates, and stakeholders.

However, in alignment with the principle of local focus, the PACCARB does not propose or endorse specific targets under the priorities identified in this report. Targets must be developed through a process of international consensus-building that includes all of those affected, especially regions and countries with the greatest AMR burden and need for interventions. Targets should be crafted to be specific enough that all countries are working toward the same goals but broad enough that they may be implemented across countries and regions in accordance with local capacities and capabilities. Furthermore, experts and the Global Leaders Group have suggested that targets be crafted with the recommendation of an advisory panel that focuses on the science behind the metrics.[27]

Future Action

The PACCARB reaffirms the need for a Presidential AMR Initiative, led by an AMR ambassador, which would serve as a coordinating and motivating force. The initiative and ambassador were previously recommended by the PACCARB in the 2019 report, Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020–2025.[28] The Council acknowledges that this need remains unchanged and advises implementation to support the ongoing global conversations to combat AMR and address this urgent public health issue. The Presidential AMR Initiative would coordinate and support ongoing USG efforts to combat AMR globally while refocusing these efforts to align with those in this report. Furthermore, this initiative would provide a dedicated stream of funding at the executive level to accelerate progress toward achieving AMR-pandemic control in more than 50 countries around the world. Appointment of an Ambassador for AMR to lead the initiative would provide consistent representation and advocacy for global AMR efforts across the One Health spectrum. The ambassador would include support from a global collaborative team of experts from the U.S., preferably members of the Federal Interagency CARB Task Force, which inherently represents the U.S. on AMR issues across

---

[24] Global Leaders Group on Antimicrobial Resistance. (2024, April 4). *Towards specific commitments and action in the response to antimicrobial resistance*. https://www.amrleaders.org/docs/librariesprovider20/glg/glg-report-final.pdf?sfvrsn=1e2e2532_1&download=true

[25] AMR Industry Alliance. (2024, February). *Call-to-action in the fight against AMR*. https://www.amrindustryalliance.org/wp-content/uploads/2024/03/AMR-Industry-Alliance-2024-Call-to-Action.pdf

[26] Mendelson, M., et al. (2024). Ensuring progress on sustainable access to effective antibiotics at UNGA 2024: a target-based approach. *Lancet.* *https://doi.org/10.1016/S0140-6736(24)01019-5*

[27] Mendelson, M., et al. (2024). Ensuring progress on sustainable access to effective antibiotics at UNGA 2024: a target-based approach. *Lancet.* *https://doi.org/10.1016/S0140-6736(24)01019-5*

[28] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020–2025. https://www.hhs.gov/sites/default/files/PACCARB_NAP_Report.pdf

the One Health spectrum.[29] The appointment of an ambassador with credibility across all One Health sectors and subject matter expertise in AMR would not only serve as a symbol of dedication and commitment globally, but more importantly, domestically as well. Together, these entities will provide a strong, unified, and consistent approach and message to promoting U.S. AMR efforts worldwide that will further coordination, collaboration, and ultimately, motivate global action.

[29] The CARB Task Force employs a One Health approach by engaging U.S. Government agencies that oversee human, animal, and environmental health and by promoting collaboration and communication to address antibiotic resistance in every relevant sector. The Task Force is co-chaired by the Secretaries of the U.S. Departments of Health and Human Services (DHHS), Agriculture (USDA), and Defense (DoD), and also includes the Departments of Interior (DoI), State (DoS), and Veterans Affairs (VA), the Environmental Protection Agency (EPA), the U.S. Agency for International Development (USAID), the National Science Foundation, and representatives from the Executive Office of the President. Exec. Order No. 13676 3 C.F.R. 13676 (2014). https://obamawhitehouse.archives.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria

PRIORITY: Preventing Infections

Keeping humans, animals, and the environment healthy through the prevention of infections, including those caused by antimicrobial-resistant pathogens, is an essential component of the fight against AMR and must be a priority both for global and U.S. action. Prevention combats AMR on multiple fronts, reducing the need for antimicrobials by preventing the infection in the first place, and reducing the transmission of antimicrobial-resistant pathogens. Preventing infections also leads to a healthier population that may be generally less vulnerable to superinfections as well as opportunistic infections. Efforts to combat AMR should include infection prevention and control in healthcare; agricultural biosecurity; access to clean water, sanitation, and hygiene (WASH); and appropriate vaccination of humans and animals. Additionally, actions should be developed and implemented through a One Health approach, within the United States and globally. By mitigating causes of infectious diseases in healthcare settings, communities, and agricultural settings, we improve health globally and lessen the drivers of AMR.

Priorities for Global Action

***Recommendation**: AMR strategies (including NAPs) should include infection prevention as a core element and prioritize the challenges people face that contribute to infectious diseases and AMR—community prevention efforts; WASH; infection prevention and control in healthcare; vaccine development, access, and uptake; and agricultural biosecurity.*

Infection Prevention and Biosecurity

Infection prevention efforts in human healthcare and veterinary settings, in the community, and in the agricultural setting can help reduce disease burden and, subsequently, reduce the need for antimicrobials. For all infection prevention and biosecurity efforts, local communities and stakeholders must be central participants in intervention design and development to ensure that interventions are effective, address the needs of the community, and are sustainable. Infection prevention and control within the healthcare and veterinary setting includes many activities that have been explored by the PACCARB previously and are summarized in its 2018 report, Key Strategies to Enhance Infection Prevention and Antibiotic Stewardship.[30] These infection prevention and control strategies remain a critical component of AMR efforts across the One Health spectrum. Curbing infectious diseases in communities spans numerous actions that can lower the risk and prevalence of illness. Through education and community outreach, the public can learn about actions individuals can take to reduce infectious disease transmission, such as safe food handling, preparation, and cooking; safer sex

[30] 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

practices; proper wound care; containment of coughs and sneezes; hand hygiene; and safety when interacting with or caring for animals.

In agriculture, the promotion and support of husbandry and biosecurity best practices, coupled with vaccines and other prophylactic measures to reduce the spread of infection and AMR, must be prioritized. Addressing AMR on the farm, for both animals and crops, can be enhanced by leveraging global interest in the One Health approach and highlighting how vaccination, nutrition, and management practices can benefit animal, environmental, and human health. This step will encourage resources and new funding mechanisms to support and accelerate innovation, research, and development of biosecurity best practices in agriculture, as well as safe and efficacious alternatives to antimicrobial use.

Water, Sanitation, and Hygiene

WASH represents vital components of a safe and healthy infrastructure and a foundation of community and healthcare infection prevention. Clean water and adequate sanitation limit the spread of infectious diseases in communities, preventing the spread of AMR and reducing the need for antibiotic use.[31] Infection prevention and biosecurity rely on access to clean water and basic sanitation and hygiene for successful implementation. However, many LMICs do not have access to clean water, adequate sanitation, or resources for hand hygiene.[32] Global governments and partners have committed to ensuring WASH for all communities by 2030 as part of the United Nations' Sustainable Development Goals (SDGs).[33] To further accelerate these efforts, WASH should be a priority for development assistance efforts, especially those aimed at addressing AMR.

Vaccination

Vaccination of humans and animals is a critically important tool in the fight against AMR, and a variety of vaccines protect against bacterial or viral infections. Vaccines against bacterial pathogens (e.g., pneumococcus and typhoid) demonstrably reduce resistant strains of infection, in addition to reducing pathogen-related morbidity and mortality overall.[34,35] Expanded uptake of these vaccines would further increase this impact. Viral infections are frequently inappropriately treated with antibiotics because of diagnostic uncertainty, patient or family expectations, or concerns about secondary bacterial infections. Therefore, immunization strategies should be included in AMR NAPs, and a variety of approaches should be explored to improve vaccination rates and address the numerous challenges that exist in the delivery, access, and uptake of vaccines in LMICs.[36] Building on the successes of other

---

[31] Fuhrmeister, E.R., et al. (2023). Evaluating the relationship between community water and sanitation access and the global burden of antibiotic resistance: An ecological study. *Lancet Microbe, 4*(8), e591-e600.
[32] UNESCO World Water Assessment Programme. (2023). *The United Nations world water development report 2023: Partnerships and cooperation for water*. UNESCO. https://unesdoc.unesco.org/ark:/48223/pf0000384655
[33] United Nations. (2015). *Transforming our world: The 2030 agenda for sustainable development.* United Nations. https://sdgs.un.org/sites/default/files/publications/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf
[34] Birger, R., et al. (2022). Estimating the effect of vaccination on antimicrobial-resistant typhoid fever in 73 countries supported by Gavi: a mathematical modelling study. *The Lancet. Infectious diseases, 22*(5), 679–691. https://doi.org/10.1016/S1473-3099(21)00627-7
[35] Jansen, K. U., et al. (2018). The role of vaccines in preventing bacterial antimicrobial resistance. *Nature Medicine 24*(1): 10-19.
[36] Guignard, A., et al. (2019). Introducing new vaccines in low- and middle-income countries: Challenges and approaches. *Expert Review of Vaccines, 18*(2), 119-131.

global vaccination campaigns, such as those leading to the eradication of smallpox, to reduce the burden of poliovirus, and the global eradication of rinderpest, new pilot programs should be developed and implemented to test innovative delivery strategies to optimize acceptance and uptake.

Further research is needed on the cost of vaccination relative to the cost of infection treatment to demonstrate the economic value of vaccines;[37] the impact on AMR should be included as a key metric to assess the value of these products. For animal health, ensuring widely adopted prophylaxis for vaccine-preventable diseases in production and companion animals is critical to reduce the need for antimicrobial use worldwide. Many factors, including variable efficacy of some veterinary vaccines, economic drivers, and lack of incentives makes vaccine prophylaxis less desirable than antimicrobial treatment in some cases. There remains a need for efficacious animal vaccines to improve uptake at the local level for global vaccination policies. The nature of One Health and reducing AMR are complex and span not only health implications of vaccination and drug use, but also access and delivery of care. Addressing these issues globally while allowing for regional and local considerations is critically important to combating AMR.

United States-Specific Recommendations to Support Global Priorities

Infection Prevention and Biosecurity

***Recommendation**: Further support the implementation of prevention initiatives for decreasing infections in LMICs by developing guidance on program design and deployment that recognizes and considers local context.*

NAP Goal 5 Alignment: Objective 2.1

Numerous resources are available to support LMICs in designing and deploying programs aimed at reducing infections, such as the Core Elements of Human Antibiotic Stewardship Programs in Resource-Limited Settings guide developed by CDC[38] and the WHO Antimicrobial Stewardship Programs Practical Toolkit.[39] However, these guides often do not consider the differences in available resources, needs, and cultural norms between different regions and communities, making implementation challenging despite current efforts. Guidance that recognizes these differences between communities and provides recommendations to assist in implementing available tools and resources could be helpful to LMICs seeking to start or expand efforts to prevent infections within their borders. The United States can provide this assistance to ensure sustainable change and support global efforts toward reducing infectious disease and AMR.

---

[37] Kalanxhi, E., Roberts, N., Miller, L., Bahati, F., & Laxminarayan, R. (2023). *The value of vaccines to mitigate antimicrobial resistance—evidence from low- and middle-income countries.* One Health Trust. https://onehealthtrust.org/wp-content/uploads/2023/10/OHT-Report_Dec-8_final_Linked-1.pdf

[38] Centers for Disease Control and Prevention. (2018). *The core elements of human antibiotic stewardship programs in resource-limited settings: National and hospital levels*. https://www.cdc.gov/antibiotic-use/core-elements/resource-limited.html

[39] World Health Organization. (2019). *Antimicrobial stewardship programmes in health-care facilities in low- and middle-income countries: A WHO practical toolkit.* WHO. https://www.who.int/publications/i/item/9789241515481

***Recommendation**: Ensure a One Health approach is taken across the current and future U.S. international efforts in prevention of infectious diseases, biosecurity, and AMR reduction activities.*

NAP Goal 5 Alignment: All Objectives

Initiatives exist within the USG for both international and domestic strategies directed at prevention of infectious disease and AMR reduction. However, many current initiatives focus solely on human health, thereby excluding diseases in companion animals, agriculture, and the environment. Although the USG has successful programs aimed at capacity building and AMR education and awareness in the animal health sector, more such efforts should be instituted, along with initiatives that focus on AMR in the environment. These efforts are important to reduce the overall burden of infectious disease, particularly AMR, and should be expanded within the One Health framework for a more comprehensive approach to infectious disease prevention. A coordinated, One Health approach to the USG's international programs would allow agencies to provide support and expertise that is relevant to their mission space while expanding opportunities to ensure One Health is fully embraced across the spectrum of USG global support.

Vaccination

***Recommendation**: Incorporate veterinary vaccines into future development, distribution, and use domestically and globally.*

NAP Goal 5 Alignment: Objective 2.3

The United States has many programs to promote vaccination in LMICs, such as the Global Vaccine Access program led by USAID in partnership with CDC and other U.S. agencies,[40] although many focus on vaccines for human health. Vaccinating animals is important for reducing the transmission of bacterial and viral diseases, and global vaccination efforts should promote the use of existing and new vaccines. Increased vaccination uptake in animal populations has the benefit of combating zoonotic pathogens (including AMR zoonotic pathogens), reducing the need for antimicrobial use, promoting animal welfare, and preventing infectious disease spread into and from wildlife. Initiatives for vaccine promotion in LMICs must be expanded to include vaccination of animals in alignment with a One Health approach. Furthermore, uptake in veterinary vaccine use, especially in LMICs, is complicated by low efficacy rates and the cost of vaccines. Initiatives should promote the development and procurement of effective and inexpensive veterinary vaccines. If such vaccines do not exist, then research and funding should be prioritized to develop such vaccines.

[40] United States Agency for International Development. (2022). *Global VAX: A new 'initiative for global vaccine access' to accelerate U.S. vaccine delivery assistance around the world*. USAID. https://www.usaid.gov/coronavirus/fact-sheets/global-vax.

PRIORITY: Awareness of AMR to Drive Global Action

One of the largest challenges in combating AMR is increasing awareness and understanding of AMR among professionals, political leaders, and the public and turning that awareness and understanding into action. New approaches to build awareness of AMR and the impact it has on human, animal, and environmental health; economic security; and population wellbeing are needed to generate and sustain action to address this complex challenge. On the global scale, there is opportunity to increase awareness by highlighting the interconnectedness between AMR and other high-priority health and social issues, such as maternal and child health, progress in combatting other common diseases such as cancer, and food security. Multisectoral partnerships and community engagement are critical to U.S. efforts in combating AMR globally, including raising awareness of AMR issues among different stakeholder groups domestically and abroad. Research that leverages the social and behavioral sciences can help decision-makers identify points for intervention to change how antibiotics are used. Improving awareness and understanding of AMR is foundational to the success of interventions.

Priorities for Global Action

***Recommendation**: Raise awareness among the public and political leaders on AMR as a critical threat to public health, crop and animal health, the economy, and social issues to drive community, national, and global action.*

Connection with Health, Social, and Economic Priorities

Communication regarding the impact of AMR should not be siloed. Rather, it should demonstrate how AMR threatens numerous critical health issues, such as child and infant mortality[41] and cancer,[42] as well as social issues, such as food insecurity[43] and poverty.[44] Although AMR is directly linked to the issues of access to essential medicines and harm to patients from drug-resistant infections (as identified in the UN SDG framework), these two indicators do not capture the full crosscutting impacts of AMR. The PACCARB reinforces the need to connect AMR to other relevant public health issues, whether captured in the SDGs or otherwise recognized, to build and foster an understanding among international leaders of the wide-reaching consequences of AMR. The associations between AMR and critical health issues should be emphasized to raise the visibility of AMR and the urgency of action to address it among political leaders, health professionals, and the public.

---

[41] United Nations Children's Fund. (2023). *The urgent threat of drug-resistant infections: Protecting children worldwide*. UNICEF. https://www.unicef.org/media/144266/file/The-Urgent-Threat-of-Drug-Resistant-Infections:-A-UNICEF-Guidance-Note-on-Antimicrobial-Resistance-2023.pdf.

[42] Nanayakkara, A. K., et al. (2021). Antibiotic resistance in the patient with cancer: Escalating challenges and paths forward. *CA: A Cancer Journal for Clinicians, 71*(6), 488-504.

[43] George, A. (2017). Antimicrobial resistance, trade, food safety and security. *One Health, 5*, 6-8.

[44] Jonas, O. B., et al. (2017). *Drug-resistant infections: A threat to our economic future (vol 2): Final report*. HNP/Agriculture Global Antimicrobial Resistance Initiative, World Bank Group. http://documents.worldbank.org/curated/en/323311493396993758/final-report.

Community Engagement and Multisectoral Partnerships

Effectively solving complex AMR problems requires multisectoral partnerships that foster collaboration among disciplines and engage local communities with the goals of attaining trust and committed action. Efforts to engage partners across the One Health spectrum should build on existing work to bring in new ideas, learn from unique experiences, and disseminate knowledge on the broad-reaching impact of AMR. Lessons from these engagements should inform local initiatives that are adapted to the context in which they are implemented to build trust and ensure that efforts effectively disseminate information among community members. It is critical to identify and engage locally recognized and respected leaders in a particular setting before developing and implementing policies or interventions to address AMR. These individuals can come from varied backgrounds, including human and veterinary medicine, community health, agriculture, and education. Adopting plain language and a shared vocabulary can bolster grassroots efforts to educate and empower at the community level. Understanding settings and tailoring messages and initiatives accordingly will aid in promoting awareness and building trust among diverse community members whose engagement is necessary to address AMR.

Behavior Change

Crafting effective messages and interventions for sustained action within communities necessitates understanding the underlying motivations for behaviors that drive AMR. Acknowledging these drivers allows for improved communication and community action to create systemic change to reduce the incidence of AMR. However, there remains a need to understand the social and behavioral drivers of antibiotic use and misuse, the barriers to reliable adoption of infection prevention and stewardship techniques, and other drivers of AMR. Additional funding should be provided for the social sciences, such as sociology, anthropology, economics, psychology, and related disciplines, to bridge these gaps in our understanding and build initiatives that effectively inform people and change behavior around the prescription and use of antibiotics.[45] These initiatives, with input from trained social scientists, could include basic education on AMR, campaigns that use novel communication platforms to disseminate messages about AMR that are likely to influence behavior, and locally led initiatives that bring together community leaders and experts to develop and implement interventions.[46]

[45] Cuevas, C., et al. (2021). Improving antibiotic use through behavior change: A systematic review of interventions evaluated in low- and middle-income countries. *Health Policy and Planning, 36*(5), 594-605.
[46] Mendelson, M., et al. (2017). Antibiotic resistance has a language problem. *Nature, 545*(7652), 23-25.

United States-Specific Recommendations to Support Global Priorities

Connection with Health, Social, and Economic Priorities

***Recommendation**: Connect the issue and impact of AMR to key national priorities in human, animal, and environmental health; food security; and economic development.*

NAP Goal 5 Alignment: None

To increase awareness and drive global action, the USG should integrate AMR activities into existing global efforts to improve human, animal, and environmental health; food security; and economic development. For example, AMR could be connected to animal health initiatives through the inclusion of AMR considerations in biosecurity training programs. While many biosecurity training programs are intended to protect against viral diseases, such as avian influenza and African swine fever, the principle of keeping animals healthy reduces the need to use antimicrobials in animals. There are also opportunities to connect AMR with existing initiatives in human health, such as the CDC campaigns Preventing Infections in Cancer Patients and Get Ahead of Sepsis, which provide information and tools for patients, caregivers, and healthcare professionals to reduce the risk of life-threatening infections. Both programs, as well as many others in CDC, address issues in human health that are linked to AMR, a connection that should be emphasized and incorporated into other program initiatives.

Behavior Change

***Recommendation**: Support efforts to use social science to better understand and navigate the challenges of implementing AMR strategy and increase the effective implementation of country-specific AMR NAPs.*

NAP Goal 5 Alignment: None

In the global fight against drug resistance, the United States has led by example, navigating challenges in the implementation of its CARB NAP through a One Health framework. Many other countries that developed NAPs have also faced challenges in actualizing these commitments, despite the best intentions. Given our experience with navigating challenges that come when implementing NAP commitments and developing solutions, the United States can support the implementation of AMR NAPs in other countries and ensure global awareness of the burden of AMR by communicating what we have learned, partnering in research to identify barriers to enacting NAPs, and sharing novel implementation solutions as they are developed by ourselves or by others. The United States can also provide guidance to countries on the optimal way to identify barriers to enacting their own NAPs and invest in research to inform the identification of novel implementation strategies, with support from social scientists, that promote the success of sustainable interventions in a global context. In addition to providing support to other countries, the United States can continue to observe, listen, learn, and share with others as we all make strides toward addressing the AMR challenge.

PRIORITY: Globally Responsive Development of Products and Solutions to Combat AMR

Supporting the development of new products to better diagnose, prevent, and treat resistant infections in humans and animals is critical to reducing AMR. High-income countries (HICs) must bear the responsibility for the development and fair distribution of a sustainable pipeline that supports global antimicrobial product needs for human health, agriculture, and companion animals. As we continue to innovate and support development activities, the mechanisms created for development must be built on a foundation of equity and meet the greatest global needs, while remaining adaptive to different environments. U.S. global leadership must include exploration and implementation of market-based solutions that reward innovators for the development of new diagnostics and treatments for AMR pathogens and related diseases based on the greatest burden and not left solely to the current failing market.

Priorities for Global Action

***Recommendation**: Advance market-based incentives to build and sustain development of new products that address AMR, including diagnostics and therapeutics, based on domestic and global need.*

New Diagnostics and Therapeutics

As AMR continues to increase, so does the demand for new antimicrobial products for use in both human and animal health. On the diagnostics side, the ongoing technology revolution can be leveraged to enable accurate diagnosis of infectious diseases, informing appropriate and specific use of antibacterial or antifungal agents. In many cases, absent appropriate diagnostics, older antibiotics or antifungal agents that could work are being passed over because of concern for AMR; using new diagnostics could address this issue. On the therapeutic side, new therapies are needed to treat infections for which no or few therapies exist because of AMR, including vaccines and nontraditional antibacterial and antifungal therapies (e.g., decolonizing agents). Development of new therapies should focus on priority pathogens, based on existing literature and analysis of global impact.[47,48] Notably, the capacity to manage infectious complications plays a critical role in supporting advanced therapies in fields such as cancer care, transplantation, immunologically based treatments, routine or emergency surgeries, and childbirth.

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

[48] GBD 2019 Antimicrobial Resistance Collaborators. (2022). Global mortality associated with 33 bacterial pathogens in 2019: A systematic analysis for the Global Burden of Disease Study 2019. *Lancet, 400*(10369), 2221-2248. https://doi.org/10.1016/S0140-6736(22)02185-7

Sustainable Pipeline

Developing and maintaining a sustainable pipeline for diagnostics, vaccines, and therapeutics is crucial to meet the growing need and cannot be reliably achieved through public financing alone. Current pricing, sales, and marketing models provide insufficient revenue to innovator companies to encourage research and development for critically needed AMR therapeutics, diagnostics, and vaccines. As such, the investment community as well as the pharmaceutical industry have, in large part, abandoned the space. Market-based incentives that reward innovation are needed and must be commensurate with the positive health impacts afforded by new antimicrobial agents and other AMR-focused solutions. The market-based incentives should be adequate to draw innovators to market, while being cost-effective and sustainable for HICs. Product development activities in HICs should begin with evaluating how their own pricing and reimbursement strategies impact innovators domestically. In addition, HICs, international organizations, and nongovernmental organizations should support pilot programs to better understand market-based needs of countries with different economies. Support should include encouraging innovative product development partnerships that work to reduce barriers in the production and commercialization of novel therapeutics and diagnostics and facilitate access to these products in LMICs.

Supporting innovation incentives for the development of new therapeutics is not limited to the human health sector—introduction of new drugs and treatments to support the animal health sector is highly important to combating AMR. The market for pharmaceutical products for the animal and agricultural sectors is even less attractive than for human healthcare; therefore, development of new technologies to combat AMR in this space must also be incentivized. Creating new antimicrobials and novel treatments for the human sector without acknowledging the need for these products in animals limits therapeutic availability for treating companion and agriculture animals. This then contributes to increased impact and spread of disease among animals, which in turn increases the risk of disease for humans.

Stewardship

Notably, all development activities should be paired with diagnostic and antimicrobial stewardship efforts to ensure that new products are used optimally to treat disease effectively while minimizing emergence of resistance. The Stewardship and Access Guidelines produced by CARB-X provides a framework for incorporating antimicrobial stewardship and access into the drug development process; DHHS has endorsed the guideline, and the guideline could be incorporated in more efforts.[49] The use of diagnostics is a critical component of ensuring that stewardship practices support the appropriate use of novel antibiotics and other products.[50]

---

[49] *Stewardship & access plan development guide.* (2021). https://carb-x.org/wp-content/uploads/2021/03/Stewardship__Access_DevGuide_2021.pdf

[50] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2018, September). *Key strategies to enhance infection prevention and antibiotic stewardship: Report with recommendations for human and animal health*. https://www.hhs.gov/sites/default/files/final-ips-report-10-03-2018.pdf

United States-Specific Recommendations to Support Global Priorities

New Diagnostics and Therapeutics

***Recommendation**: Implement domestic policies that support market-based incentives for product development to demonstrate their effectiveness and reward innovation while supporting programs that pilot similar incentive models in partner countries.*

NAP Goal 5 Alignment: None

To stimulate and support a global pipeline, the United States should implement market-based incentives that promote R&D for innovative products and solutions. This approach includes funding the development of innovative products that help mitigate AMR, especially those that demonstrate a high potential for global utility. Incentives must be driven by research and data to elucidate the value of products. A key component of this data is comprehensive and actionable AMR surveillance, which provides valuable insight into diagnostics and antimicrobial therapeutics development needs and would help track the return on investments made through incentives. In addition, it is imperative that the United States lead by example, building on PACCARB's 2021 resolution[51] to implement policies that decouple reimbursement from volume of use for new diagnostics and therapeutics. The United States should also work collaboratively with partner countries to develop models that stimulate innovation through market-based incentives but are tailored to different economies. As a global leader, the United States should prioritize coordinating efforts through its G7 partner countries that incentivize long-term private-sector participation in the R&D ecosystem and that can be sustained with public and private funding.

***Recommendation**: Support research and development for animal- and crop-specific diagnostics, antimicrobials, and other products.*

NAP Goal 5 Alignment: Objective 4.2

Many new antimicrobial products are reserved for serious or life-threatening infections or resistant infections in humans; their use is restricted in veterinary medicine, specifically in production animals and the agriculture sector. To address the One Health nature of AMR and to ensure that the animal sector continues to have the tools needed to combat AMR, the United States should fund similar market-based incentive models that prioritize safe and efficacious alternative therapies specifically for use in animals. To ensure optimal use of antimicrobial products that support health in the agricultural sector, the United States should support research into and development and expansion of animal-specific culture and susceptibility use guidelines to better inform stewardship practice in animals.

[51] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2021, October 6). Resolution: Support for legislation that promotes the production of new antimicrobial drugs. https://www.hhs.gov/sites/default/files/paccarb-incentives-leg-letter-oct-6-2021.pdf.

Compared with food animal medicine, fewer regulations govern small and companion animal medicine within the United States and globally. Ensuring judicious use of critically important antimicrobials must be embraced to preserve these medications for future use in both human and animal health. The United States could look to the CARB-X program's innovative support mechanisms to spur R&D as a method to build alternatives within the animal health sector, such as better vaccines, precision agriculture approaches to identify and treat individual animals earlier, alternatives to antimicrobials, and nutritional approaches to mitigate disease.

PRIORITY: Equitable Access to Antimicrobials, Vaccines, and Diagnostics

Access to pharmaceuticals, diagnostics, and other public health interventions is essential for the treatment and prevention of drug-resistant infections. Many places around the world, especially LMICs, suffer not only from lack of access to medicines but also from poor diagnostic capacity,[52] fragmented surveillance data,[53] and other critical deficiencies in public and animal health infrastructure. Lack of access to standard treatments and testing is a major cause of negative health outcomes globally, and failure to properly diagnose and treat infections—including unnecessary antibiotic use—worsens the AMR burden. Developing new and novel AMR interventions may improve the ability to combat AMR, but without equitable access, we increase the burden on underserved global communities. To address the inequities in global access and reduce the burden of AMR, we must build system capacity to better facilitate the mechanisms of access.

Priorities for Global Action

***Recommendation**: Ensure equitable access to antimicrobials, vaccines, and diagnostics based on local and regional needs, while promoting stewardship and optimal use.*

Access to Antibiotics, Diagnostics, and Vaccines

Ensuring global access to existing antibiotics, diagnostics, and vaccines is critical for preventing and treating infectious diseases, including those caused by resistant pathogens. Global access requires products to be available, affordable, and effective.[54] In the animal health sector, nonantimicrobial therapeutics must also be safe, efficacious, and cost-effective to encourage uptake, and antimicrobials must remain available and effective to address bacterial infections in animals. Challenges in access to these products not only increase disease burden but also drive additional resistant infections. Funding to close the gaps in access and overcome these challenges remains essential. However, we must also look to innovation to help overcome the expanding resistance. For example, newer diagnostics can address operational challenges of implementing complex traditional microbiology diagnostic techniques in resource-limited settings, allowing for increased diagnostic use in areas where it was not previously available. Furthermore, access to antimicrobials, diagnostics, and vaccines should be prioritized based on epidemiological need. Prioritization will not only help minimize redundancy in resource-constrained regions but will help address suboptimal use of antimicrobials and other products.

---

[52]Fleming, K. A., et al. (2021). The *Lancet* Commission on diagnostics: Transforming access to diagnostics. *Lancet, 398*(10315), 1997–2050.
[53] Iskandar, K., et al. (2021). Surveillance of antimicrobial resistance in low- and middle-income countries: A scattered picture. *Antimicrobial Resistance & Infection Control, 10*(1), 63–82.
[54] Mendelson, M., et al. (2024). Ensuring progress on sustainable access to effective antibiotics at UNGA 2024: a target-based approach. *Lancet.* https://doi.org/10.1016/S0140-6736(24)01019-5.

Globally Relevant Procurement Systems

To facilitate access to the needed diagnostics and therapeutics that could help in the fight against AMR, the current, inequitable mechanisms of drug procurement must change. Currently, procurement systems rely on the purchase of these products on the global market for both LMICs and HICs, which does not promote innovation, facilitate access, or offer sustainability.[55] HICs should research, fund, and develop procurement assistance systems for LMICs. Such efforts can begin with funding research and pilot programs that support access while ensuring stewardship of antibiotics (e.g., AMR Access and Stewardship Initiative sponsored by USAID and SECURE sponsored by WHO and the Global Antibiotic Research and Development Partnership). Additional challenges exist in international harmonization of regulatory standards for diagnostics and therapeutics; streamlining standards could help to ensure access through product approval pathways in global markets and new drug registration across countries. Regulatory alignment could offer manufacturers the opportunity to launch a product in HICs and LMICs simultaneously. This approach could expand markets, drive production need and associated supply chain demand, and support equitable access for LMICs, which have the highest resistance rates and clinical needs but have historically been excluded from market access to novel therapeutics and diagnostics.[56, 57]

Building Laboratory Capacity

Interventions that build consistent, high-quality, sustainable laboratory capacity and infrastructure should be funded to better support regional and local surveillance and to understand disease burden and access needs. Such capacity is especially crucial for AMR laboratories, as they often require more resources than general laboratories to enable identification of multiple pathogen types and to determine the susceptibility of those pathogens to a range of antimicrobials. Therefore, there is a great need for sustainable support for interventions that assess the current regional availability of laboratory testing, provide the required support, and offer tailored solutions on how to build capacity. It is imperative that veterinary and environmental laboratory capacity are strengthened alongside human health laboratory capacity to improve surveillance of AMR pathogens. This would also allow for countries to perform research to support global recommendations about appropriate antimicrobial use in animals and better understand the persistence of AMR in soil, water, air, and wastewater.

Antimicrobial and Diagnostic Stewardship

Stewardship principles require equitable access to antimicrobials for their appropriate use in animal and human health, which subsequently minimizes the development of drug resistance. Furthermore, stewardship efforts should build on what is feasible at the community level, as stewardship is more than just limiting antimicrobial use. Antimicrobial stewardship programs include ensuring the optimal and judicious use of antimicrobial drugs to ultimately improve health outcomes—something that

---

[55] Berman, D., et al. (2022). Global access to existing and future antimicrobials and diagnostics: antimicrobial subscription and pooled procurement. *The Lancet. Global health, 10*(2), e293–e297. https://doi.org/10.1016/S2214-109X(21)00463-0.

[56] Mendelson, M., et al. (2024). Antimicrobial resistance and the great divide: Inequity in priorities and agendas between the Global North and the Global South threatens global mitigation of antimicrobial resistance. *Lancet Global Health, 12*(3): e516-e521.

[57] Cohn, J., et al. (2024). Accelerating antibiotic access and stewardship: A new model to safeguard public health. *Lancet Infectious Diseases*. Online ahead of print. https://doi.org/10.1016/S1473-3099(24)00070-7.

cannot be accomplished without access to needed drugs.[58] Stewardship guidelines for human health could provide a roadmap for priority areas based on local and regional need to help address the challenge of over-the-counter access to antibiotics in some sectors or countries, while balancing the lack of access to antimicrobials as a barrier in others. In animal health, stewardship guidelines should consider the interconnectedness of humans and animals and the economic considerations of stewardship programs, especially in LMICs. Another key aspect of antimicrobial stewardship is access to appropriate diagnostics, which enables use of the most appropriate treatments (i.e., the most narrow-spectrum product and optimal duration of use) when needed and restraint in the use of antibiotics when they are not needed. Diagnostics can partially mitigate AMR and should be a focus in human, animal, and agricultural health. Both increasing access to diagnostic testing and ensuring access to appropriate antimicrobials are critical to sustained judicious use.

United States-Specific Recommendations to Support Global Priorities

Access and Stewardship

***Recommendation**: Provide a sustainable funding mechanism that prioritizes reducing the global burden of AMR through access and stewardship.*

NAP Goal 5 Alignment: None

Many countries lack adequate, sustainable funding to dedicate scarce resources to address AMR—especially those with the highest burden of AMR[59]—but funding is a challenge even within the United States. The United States should target development assistance to support sustainable mechanisms for achieving equitable access domestically and enable LMICs to access products reliably and without facing detrimental tradeoffs. This assistance should also target equity in data collection and surveillance.

***Recommendation**: Promote access and stewardship for global animal health and the agricultural sector through enhanced international engagement.*

NAP Goal 5 Alignment: Objective 1

AMR presents a threat to humans and animals alike; however, the scientific support and tools to combat this threat often fail to address the needs of companion and agricultural animals. The adoption of stewardship programs in both companion and agricultural animals domestically still faces challenges in several areas: the lack of evidence supporting judicious and appropriate use of diagnostics and

[58] Patel, T. S., et al. (2024). Defining access without excess: Expanding appropriate use of antibiotics targeting multidrug-resistant organisms. *Lancet Microbe, 5*(1), e93-e98.
[59] The Lancet Regional Health–Americas. (2023). Antimicrobial resistance in the Americas: A tale of multiple realities. *Lancet Regional Health–Americas, 25*(100594). https://doi.org/10.1016/j.lana.2023.100594.

therapeutics; restrictions for use of new antibiotics in animals; and lack of cost-effective diagnostics, vaccines, and nonantimicrobial options for animal diseases. While the United States has maintained strong leadership in food safety and animal welfare, there is a need for more evidence-based guidance for antimicrobial use in the animal sector. In addition to championing optimal use of antimicrobials, ensuring continued development, implementation, and regulatory support of alternative approaches—such as biosecurity strategies and vaccination—is critical to improving judicious use of antimicrobials in animals.

CONCLUSION

The United States has made strides in engaging with the global community to address AMR, yet there remain ample opportunities for continued action, which is the focus of this report. As the United States prepares to revise the CARB NAP for the next five years, the PACCARB provides this report to advise the development of new goals and commitments for action on a global scale.

The PACCARB has identified four global priorities that should be central to global AMR actions: preventing infections; raising awareness of AMR; R&D to produce new products and solutions that address domestic and global needs; and equitable access to existing and new treatments, vaccines, and diagnostics. The global priorities and U.S.-specific recommendations within this report highlight critical aspects of how we can combat AMR on a global scale and how the United States can better lead this fight. However, the global priorities must be interconnected in development and execution, as implementation of one without another will not drive sustainable change. The ability to prevent infections through WASH, vaccination, and infection prevention and biosecurity practices relies on the community's awareness of the problem and access to efficacious products and solutions. Awareness of AMR relies heavily on understanding how to prevent infections and having the necessary access to products and solutions. While preventing infections would significantly reduce the need for antimicrobials, it is not enough to address the current global health threat of resistance; action must also be taken to develop new diagnostics and therapeutics through a sustainable pipeline. Lastly, the world's ability to treat drug-resistant infections must be coupled with efforts to ensure equitable access to antimicrobials, vaccines, and diagnostics. The priorities in this report serve to guide the United States as it prepares to collaborate with the international community at the UNGA HLM on AMR, which will set the stage for the next several years of combatting AMR globally.

To drive this collaboration, the PACCARB reiterates the need for a Presidential AMR Initiative, led by an AMR ambassador. Together, the initiative and ambassador would serve as a coordinating and motivating force that will provide a strong, unified, and consistent message to promote U.S. AMR efforts worldwide. The Presidential AMR Initiative and AMR ambassador were previously recommended by the PACCARB in the 2019 report, Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020–2025,[60] and the Council re-emphasizes that this need remains.

To be truly effective, action toward addressing these priorities and any global AMR activities must follow several foundational concepts: defining AMR and using plain, common language to ensure a collective understanding; designing solutions that address local needs and are developed with local leaders; facilitating informed decision-making through use of monitoring and metrics; and setting global targets that are driven by science, based on consensus, and actionable at the local level. Together, these principles help ensure that commitments made as part of the U.S. CARB NAP and the UNGA HLM on AMR are effective in reducing the burden of AMR globally. Ultimately, action to combat AMR on a global scale must also be firmly rooted at the local level, even in our own communities. This connection with our communities for the prevention and treatment of infections in the human, animal,

[60] Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (2019). Priorities for the National Action Plan on Combating Antibiotic-Resistant Bacteria: 2020–2025. https://www.hhs.gov/sites/default/files/PACCARB_NAP_Report.pdf.

and environmental heath settings, including infections caused by resistant pathogens, is central to the global priorities and USG recommendations brought forward by the PACCARB. The USG cannot be complacent in the fight against global AMR and must continue to act through sustained funding, collaboration, and leadership, as will be represented at the UNGA HLM, and beyond.

ANNEX I – ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
AMR	antimicrobial resistance
AS	antimicrobial stewardship
CARB	Combating Antibiotic-Resistant Bacteria
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
G7	Group of Seven
G20	The Group of Twenty
HAI	Healthcare-associated infection
DHHS	U.S. Department of Health and Human Services
HICs	High income countries
HIV	human immunodeficiency virus
HLM	High level meeting
ID	infectious diseases
IPC	infection prevention and control
LMICs	Low- or Middle-Income Countries
MCMs	medical countermeasures
NAP	National action plan
NIH	National Institutes of Health
OGA	Office of Global Affairs
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
PHE	Public Health Emergency
SDG	Sustainable Development Goals
UNGA	UN General Assembly
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USG	United States Government
WASH	Water, sanitation, and hygiene
WHO	World Health Organization

ANNEX II – TASK LETTER FROM THE SECRETARY

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

August 14, 2023

Paul Plummer, DVM, PhD, DACVIM, DECSRHM
Chair
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Dear Dr. Plummer:

Thank you for your commitment to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) as a member, and now, as Chair. The PACCARB's most recent report highlighted the critical need to incorporate antimicrobial resistance (AMR) into pandemic preparedness and our nation's biodefense plans. As we move forward, we must continue to broaden the ways in which we address AMR, looking not just through a U.S.-centric public health lens, but more broadly to understand AMR through a global One Health lens.

While the U.S. government has made meaningful progress as a leader for global health security, many challenges remain to be addressed to minimize global AMR rates and secondary impacts at the intersection of the human, animal, and environmental sectors. The National Action Plan (NAP) for Combating Antibiotic-Resistant Bacteria (CARB) seeks to enhance international capacities to address the emergence, spread, and impact of antibiotic resistance in Goal 5. A key part of this goal, as described in Objective 1, is to "enhance U.S. leadership in the global fight against antibiotic resistance." As we begin to envision the vital next steps of our NAP, we must review the progress made, as well as identify new methods and priorities for advancing U.S. leadership in the global exchange of ideas to achieve sustainable change. This is especially important in the context of supporting all partner nations, particularly low- and middle-income countries.

Therefore, I hereby request the PACCARB provide recommendations on how U.S. government agencies can lead global AMR efforts for sustained action domestically and internationally. The Council should examine the NAP objectives described in Goal 5 and recommend ways in which they can be updated to best position the U.S. as a global leader for CARB. The Council should ensure a One Health approach to this task, identifying opportunities for all three domains. To inform your recommendations, the Council should hold a public meeting in 2023 and invite stakeholders and experts in AMR and global health security to provide insight on the issue. Please prepare a report to present your findings and recommendations no later than May 2024.

It is my hope for the U.S. to be a global leader in reducing AMR and to champion global collaboration on this topic. I look forward to reviewing your recommendations that will inform our work and engagement moving forward.

Sincerely,

Xavier Becerra

ANNEX III – GLOBAL AMR WORKING GROUP ROSTER

SPECIAL GOVERNMENT EMPLOYEES – VOTING MEMBERS

CHAIR

Paul Plummer, DVM, PhD, DACVIM, DECSRHM
Executive Director, National Institute of Antimicrobial Resistance Research and Education
Associate Professor, Veterinary Diagnostic and Production Animal Medicine Department and Veterinary Microbiology and Preventative Medicine
Iowa State University Research Park
Ames, IA

VICE CHAIR

Jason Newland, MD, MEd, FPIDS
Professor of Pediatrics, Infectious Diseases
Washington University School of Medicine in St. Louis
Washington University in St. Louis,
St. Louis, MO

Stephanie R. Black, MD, MSc
Medical Director, Communicable Disease Program
Chicago Department of Public Health
Chicago, IL

Claire Burbick, DVM, PhD Diplomate, ACVM
Clinical Associate Professor, Department of Veterinary Microbiology and Pathology
Director of Infection Control and Antimicrobial Stewardship, Veterinary Teaching Hospital
Washington State University
Pullman, WA

Jennie Kwon, DO, MSCI, FSHEA, FIDSA
Associate Professor, Division of Infectious Diseases
Section Head, Hospital Epidemiology & Antimicrobial Stewardship
Medical Director, Infection Prevention
Washington University
St. Louis, MO

Brian Lubbers, DVM, PhD, DACVCP
Associate Professor, Food Animal Therapeutics Outreach
Department of Clinical Sciences,
Kansas State University
Manhattan, KS

Lynn Marks, MD
Owner, DDLC Solutions, LLC
Board Member, AN2 Therapeutics (ANTX)
Cape May, NJ

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

Robin Patel, MD
Elizabeth P. and Robert E. Allen Professor of Individualized Medicine
Mayo Clinic College of Medicine and Science
Mayo Clinic
Rochester, MN

Joni Scheftel, DVM, MPH, ACVPM
State Public Health Veterinarian, Supervisor, Zoonotic Diseases Unit
Minnesota Department of Health
St. Paul, MN

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

Thomas Wittum, PhD
Professor and Chair
Veterinary Preventive Medicine

College of Veterinary Medicine
The Ohio State University
Columbus, OH

REPRESENTATIVES – NON-VOTING MEMBERS

Bill & Melinda Gates Foundation
Designated Representative:
Padmini Srikantiah, MD, MPH
Seattle, WA

Biotechnology Innovation Organization
Designated Representative:
Emily Wheeler
Washington, DC

EpiX Analytics
Designated Representative:
Francisco Zagmutt, DVM, MPVM, PhD
Fort Collins, CO

National Institute for Animal Agriculture
Designated Representative:
Lucas Pantaleon, DVM, MS, DACVIM, MBA
Versailles, KY

Society of Infectious Disease Pharmacists
Designated Representative:
Elizabeth Dodds Ashley,
PharmD, MHS, FCCP, BCPS
Durham, NC

Wellcome Trust
Designated Representative:
Tim Jinks, PhD, MA
Cambridge, UK

REGULAR GOVERNMENT EMPLOYEES – NON-VOTING MEMBERS

U.S. Department of Agriculture

Animal and Plant Health Inspection Service
Chelsey Shivley, DVM, PhD, DACAW
Veterinary Medical Officer
Antimicrobial Resistance Coordinator
Office of Interagency Coordination
Veterinary Services, Strategy & Policy
Portland, ME

Food Safety Inspection Service
Neena Anandaraman, DVM, MPH, DACVPM
Veterinary Science Policy Officer,
Office of the Chief Scientist
Washington, DC

U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality
Susan Henderson, MD, MPH
Medical Officer
Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Rockville, MD

Centers for Disease Control and Prevention
Michael Craig
Director
Antibiotic Resistance and Coordination and Strategy Unit
Atlanta, GA

Stefanie Bumpus McBride, PhD
Associate Director for AR Policy and Partnerships
Antimicrobial Resistance Coordination & Strategy Unit
Atlanta, GA

Dawn M. Sievert, PhD, MS
Senior Science Advisor
Antimicrobial Resistance Coordination and Strategy
Atlanta, GA

National Institutes of Health
Dennis M. Dixon, PhD
Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Rockville, MD

Kyung Moon, PhD
Program Officer
Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Rockville, MD

Office of Global Affairs
Patrick McDermott
Senior Advisor, Office of Pandemics and Emerging Threats
Washington, DC

Office of the Assistant Secretary for Preparedness and Response
Christopher Houchens, PhD
Director (Acting), Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority
Washington, DC

U.S. Environmental Protection Agency

Office of Research and Development
Jay Garland, PhD
Senior Research Scientist
Center for Environmental Solutions and Emergency Response
Cincinnati, OH

DESIGNATED FEDERAL OFFICER

Jomana F. Musmar, MS, PhD
Public Health Advisor and Committee Manager
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Sarah McClelland, MPH
Public Health Advisor
Alternate Designated Federal Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Denver, CO

ADVISORY COUNCIL STAFF

Zanah Francis, PhD
ORISE Fellow
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Haley Krem
Committee Management Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Michael Haverkate, DVM
Consultant
Deloitte Consulting, LLP
Arlington, VA

Bryn O'Meara, MS
Consultant
Deloitte Consulting, LLP
Arlington, VA

Mark Kazmierczak, PhD
Consultant
Deloitte Consulting, LLP
Arlington, VA

Lauren Plaine, MPS, RN, CEN
Consultant
Deloitte Consulting, LLP
Arlington, VA

ANNEX IV – PACCARB MEMBERSHIP

SPECIAL GOVERNMENT EMPLOYEES – VOTING MEMBERS

CHAIR
Paul Plummer, DVM, PhD, DACVIM, DECSRHM
Executive Director, National Institute of Antimicrobial Resistance Research and Education
Associate Professor, Veterinary Diagnostic and Production Animal Medicine Department and Veterinary Microbiology and Preventative Medicine
Iowa State University Research Park
Ames, IA

VICE CHAIR
Jason Newland, MD, MEd, FPIDS
Professor of Pediatrics, Infectious Diseases
Washington University School of Medicine in St. Louis
Washington University in St. Louis,
St. Louis, MO

Stephanie R. Black, MD, MSc
Medical Director, Communicable Disease Program
Chicago Department of Public Health
Chicago, IL

Claire Burbick, DVM, PhD Diplomate, ACVM
Clinical Associate Professor, Department of Veterinary Microbiology and Pathology
Director of Infection Control and Antimicrobial Stewardship, Veterinary Teaching Hospital
Washington State University
Pullman, WA

Virginia R. Fajt, DVM, PhD, DACVCP
Clinical Professor
Department of Physiology and Pharmacology
College of Veterinary Medicine and Biomedical Sciences
Texas A&M University
College Station, TX

Susan Huang, MD, MPH
Professor, Infectious Diseases
Medical Director, Epidemiology and Infection Prevention
UC Irvine School of Medicine
Irvine, CA

Jennie Kwon, DO, MSCI, FSHEA, FIDSA
Associate Professor, Division of Infectious Diseases
Section Head, Hospital Epidemiology & Antimicrobial Stewardship
Medical Director, Infection Prevention
Washington University
St. Louis, MO

Brian Lubbers, DVM, PhD, DACVCP
Associate Professor, Food Animal Therapeutics Outreach
Department of Clinical Sciences,
Kansas State University
Manhattan, KS

Lynn Marks, MD
Owner, DDLC Solutions, LLC
Board Member, AN2 Therapeutics (ANTX)
Cape May, NJ

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

Robin Patel, MD
Elizabeth P. and Robert E. Allen Professor of Individualized Medicine
Mayo Clinic College of Medicine and Science
Mayo Clinic
Rochester, MN

Joni Scheftel DVM, MPH, DACVPM
Consultant, Veterinary Public Health
St. Paul, MN

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

Thomas Wittum, PhD
Professor and Chair
Veterinary Preventive Medicine
College of Veterinary Medicine
The Ohio State University
Columbus, OH

REPRESENTATIVE MEMBERS – NON-VOTING MEMBERS

American Association of Extension Veterinarians
Designated Representative:
Carla Huston, DVM, PhD, ACVPM
Cedar Bluff, MS

Bill & Melinda Gates Foundation
Designated Representative:
Padmini Srikantiah, MD, MPH
Seattle, WA

Biotechnology Innovation Organization
Designated Representative:
Emily Wheeler
Washington, DC

EpiX Analytics
Designated Representative:
Francisco Zagmutt, DVM, MPVM, PhD
Fort Collins, CO

Minor Crop Farmer Alliance
Designated Representative:
James Adaskaveg, PhD
Riverside, CA

National Institute for Animal Agriculture
Designated Representative:
Lucas Pantaleon, DVM, MS, DACVIM, MBA
Versailles, KY

Society of Infectious Disease Pharmacists
Designated Representative:
Elizabeth Dodds Ashley,
PharmD, MHS, FCCP, BCPS
Durham, NC

Wellcome Trust
Designated Representative:
Tim Jinks, PhD, MA
Cambridge, UK

REGULAR GOVERNMENT EMPLOYEES

U.S. Department of Agriculture

Agricultural Research Service
Jeffrey Silverstein, PhD
Deputy Administrator
Animal Production and Protection
Office of National Programs
Washington, DC

Animal and Plant Health Inspection Service
Sarah M. Tomlinson, DVM
Executive Director, Strategy and Policy
Veterinary Services
Fort Collins, CO

Food Safety Inspection Service
Kis Robertson-Hale, DVM, MPH, RADM
Deputy Assistant Administrator
Chief Public Health Veterinarian Office of Public Health Science
Washington, D.C.

U.S. Department of Defense

Uniformed Services University
Paige Waterman, MD, FACP, FIDSA COL, MC
Professor of Medicine
Bethesda, MD

U.S. Department of Health and Human Services

Administration for Strategic Preparedness and Response
Christopher Houchens, PhD
Director, Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority
Washington, DC

Agency for Healthcare Research and Quality
Melissa Miller, MD, MS, FCCM
Medical Officer, Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Rockville, MD

Centers for Disease Control and Prevention
Michael Craig
Director
Antibiotic Resistance and Coordination and Strategy Unit
Atlanta, GA

Centers for Medicare & Medicaid Services
Shari Ling, MD
Deputy Chief Medical Officer
Center for Clinical Standards and Quality
Baltimore, MD

National Institutes of Health
Dennis M. Dixon, PhD
Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Rockville, MD

Office of Global Affairs
Patrick McDermott
Senior Advisor, Office of Pandemics and Emerging Threats
Washington, DC

Food and Drug Administration
William Flynn, DVM
Deputy Director Science and Policy Center for Veterinary Medicine
Rockville, MD

U.S. Environmental Protection Agency

Office of Research and Development
Jay Garland, PhD
Senior Research Scientist
Center for Environmental Solutions and Emergency Response
Cincinnati, OH

DESIGNATED FEDERAL OFFICER

Jomana F. Musmar, MS, PhD
Public Health Advisor and Committee Manager
Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Sarah McClelland, MPH
Public Health Advisor
Alternate Designated Federal Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

ADVISORY COUNCIL STAFF

Zanah Francis, PhD
ORISE Fellow
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Michael Haverkate, DVM
Consultant
Deloitte Consulting, LLP
Arlington, VA

Mark Kazmierczak, PhD
Consultant
Deloitte Consulting, LLP
Arlington, VA

Haley Krem
Committee Management Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Bryn O'Meara, MS
Consultant
Deloitte Consulting, LLP
Arlington, VA

Lauren Plaine, MPS, RN, CEN
Consultant
Deloitte Consulting, LLP
Arlington, VA

ANNEX V – 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.

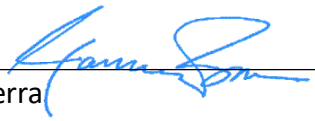
Recordkeeping

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, interspecies 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.

[FR Doc. 2014–22805
Filed 9–22–14; 11:15 am]
Billing code 3295–F4