



PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

## **Meeting Summary**

### **Inaugural Public Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria Microbiome Subcommittee**

**September 2, 2026**

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## Meeting Proceedings

### Rules of Engagement and Participant Roll Call

*Sarah McClelland, M.P.H., Designated Federal Official*

Ms. McClelland welcomed participants to the inaugural public meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) microbiome subcommittee at 9:50 a.m. ET, and thanked attendees and stakeholders for joining. She described the purpose of the subcommittee as providing expertise and insights on the microbiome to the full council. She then conducted the roll call. (See the appendix for the list of subcommittee members and staff.)

### Introductory Remarks

*Tammy Huizenga, D.O., U.S. Department of Health and Human Services (HHS)*

Dr. Huizenga provided introductory remarks, framing the meeting as an opportunity to examine the role of the microbiome in maintaining health and preventing disease, rather than focusing solely on treating disease after it develops. She then introduced Admiral Brian Christine, M.D., Assistant Secretary for Health.

### Welcome Address

*Admiral Brian Christine, M.D., Assistant Secretary for Health*

Admiral Christine recognized Secretary Robert F. Kennedy Jr.'s leadership in shifting the nation's health care system from reacting to disease after it develops toward preventing disease and addressing its root causes. He also acknowledged National Institutes of Health (NIH) Director Jay Bhattacharya, M.D., Ph.D., for his leadership in advancing biomedical research; thanked Tammy Huizenga, D.O., for helping bring the idea for the microbiome subcommittee meeting to fruition; and recognized the subcommittee members, PACCARB staff, and others who made the meeting possible.

Admiral Christine described advances in sequencing and other technologies that have expanded the scientific community's understanding of the microbiome's relationship to metabolism, immune function, antimicrobial resistance, cancer, and other areas of health. While emphasizing the field's considerable promise, he cautioned that associations do not establish causation and called for research that produces reproducible findings, identifies which aspects of the microbiome can be modified safely, and translates scientific advances into improvements in human health. He framed microbiome research as an opportunity to understand and preserve the biological systems that protect health, including how diet affects the microbiome and treatment response, and when the microbiome can recover independently or may require intervention.

Admiral Christine charged the subcommittee with identifying where the scientific evidence is strong and where uncertainty remains; determining the research methods and infrastructure needed to establish causation and reproducibility; assessing where microbiome-based approaches hold the greatest potential for prevention and treatment; and identifying pathways to translate discoveries into clinical practice and public health. He emphasized that this work should be grounded in gold-standard science and that public trust must be earned through transparent standards, responsible communication, and acknowledgment of scientific uncertainty.

## Opening Statement

*Jay Bhattacharya, M.D., Ph.D., NIH Director*

Dr. Bhattacharya thanked the subcommittee members for contributing their expertise and shared that his own understanding of the microbiome had grown through conversations with NIH researchers working in the field. He described microbiome science as a potentially transformative area of research that could reshape biology and medicine and expressed NIH's support for the subcommittee's work.

Dr. Bhattacharya discussed the importance of understanding how microbial communities influence immune function and contribute to conditions such as autoimmune disorders and cancer, including melanoma. He emphasized the need to translate this knowledge into improved approaches to disease prevention, diagnosis, and treatment, consistent with NIH's core research priorities. He encouraged the subcommittee to assess what is known, identify critical evidence gaps, and determine which studies could provide greater scientific certainty and have the greatest impact.

Dr. Bhattacharya acknowledged that the subcommittee's expertise reflects the extent of the microbiome's potential influence across human health. He noted that its work could help sharpen research questions, clarify the current state of the science, identify promising directions for future research, and inform NIH's microbiome strategy going forward.

## Introduction to the Subcommittee

*Suchitra Hourigan, M.D., Chair of Subcommittee*

Dr. Hourigan expressed her honor in chairing the newly established HHS Microbiome Subcommittee of the PACCARB. She described the subcommittee as an international group of leading microbiome experts convened to assess the current state of the field, consider a strategic vision for future research priorities, and generate meaningful and actionable insights for the public and health care professionals. She pointed out that the subcommittee would identify the scientific, translational, and infrastructure advances needed to support microbiome-based prevention and treatment strategies, with a summary of the discussion to be presented to the full council.

Dr. Hourigan said the initiative reflects HHS's commitment to advancing microbiome science to improve public health and reduce chronic disease across the lifespan. She reintroduced the subcommittee members, highlighting their affiliations, accomplishments, and areas of expertise, and framed the meeting as an opportunity to begin with an honest assessment of the current state of microbiome science before determining where the field should go next.

## Current State of the Field

*Rob Knight, Ph.D.*

Dr. Knight thanked HHS for recognizing the importance of the microbiome and acknowledged the breadth of expertise represented on the subcommittee. He described how initiatives such as the Human Microbiome Project (an NIH initiative) and the National Microbiome Initiative (a federal and private-sector collaboration) helped advance understanding of microbial communities throughout the human body and expand microbiome research nationally and internationally. He emphasized that there is no single, universal microbiome and that microbial communities vary considerably across populations and regions of the world.

Dr. Knight noted that microbiome science has progressed rapidly over the past decade, moving beyond cataloging microbial communities toward investigating their roles in disease, treatment response, and potential interventions. Researchers have identified associations between the microbiome and conditions such as irritable bowel syndrome, neurological disorders, and cancer, and animal studies have provided evidence that modifying the microbiome can affect health outcomes. However, he remarked that findings from animal models do not always translate to humans. Dr. Knight identified establishing causality in humans, reproducing findings across cohorts, including diverse populations, standardizing research methods, and conducting sufficiently large studies as critical challenges that must be addressed to realize the field's potential.

During the discussion, Maria Gloria Dominguez-Bello, Ph.D., asked how artificial intelligence (AI) could help address limitations in microbiome methods and data. Dr. Knight said AI can accelerate software development and support the analysis of large data sets but cautioned against relying on it to interpret findings without appropriate safeguards. Nicola Segata, Ph.D., discussed AI's value in analyzing and integrating large quantities of microbiome data and emphasized the importance of open data, while acknowledging considerations related to patient privacy and the evolving nature of the science. Tim Spector, M.D., described the potential to build large, internationally coordinated data sets using information voluntarily contributed by individuals who receive microbiome testing, provided participants receive meaningful information in return.

Jennifer Wargo, M.D., M.M.Sc., discussed the microbiome as a potentially actionable area for people with cancer and highlighted the use of machine learning to study factors that may influence treatment response. She noted emerging evidence that diet and antibiotic exposure may affect the gut microbiome and cancer treatment outcomes and encouraged collaboration among NIH, the U.S. Food and Drug Administration (FDA), researchers, and other partners. Dr. Spector also highlighted the need for larger studies of probiotics, prebiotics, postbiotics, and food-based interventions, as earlier studies were often limited by small sample sizes. Martin Blaser, M.D., identified AI and the integration of sequencing, metabolomics, and other emerging technologies as important opportunities for understanding microbial function and supporting product development.

Subcommittee members also emphasized the importance of translating research into tangible benefits for patients and the public. Jennie H. Kwon, D.O., M.S.C.I., noted growing public and patient interest in the microbiome and encouraged researchers to keep clinical needs at the forefront. Dr. Knight agreed that maintaining public trust will require microbiome science to produce credible treatments, products, and other practical applications. Majdi Osman, M.D., M.P.H., cited the use of fecal microbiota transplantation (FMT) for recurrent *Clostridioides difficile* infection as an example of microbiome science reaching patients and described the OpenBiome Foundation's work to expand access to this investigational treatment.

## **Evidence-Based Recommendations for a Healthy Gut Microbiome**

*Tim Spector, M.D.*

Dr. Spector reviewed current evidence on how individuals may support a healthy gut microbiome. He described research demonstrating the importance of environmental influences and observed that microbial diversity, while frequently used as an indicator of gut health, has significant limitations when considered alone. He discussed large population studies examining associations among microbial species, nutrition, and health outcomes across diverse populations.

These studies are helping researchers develop more comprehensive measures of gut health and better understand how dietary interventions may meaningfully alter the microbiome.

Based on the available evidence, Dr. Spector outlined several practical dietary approaches, including consuming a wider variety of plant-based foods and fiber, incorporating fermented foods, reducing consumption of ultra-processed foods, and emphasizing overall food quality. He described consuming approximately 30 different plant foods each week as a practical way to encourage dietary diversity. He also encouraged greater consumption of beans, legumes, and foods rich in polyphenols, such as berries, nuts, seeds, and olive oil. Dr. Spector characterized these recommendations as a combination of emerging evidence and pragmatic guidance that can be communicated to the public while research continues to evolve.

During the discussion, Maria Gloria Dominguez-Bello, Ph.D., agreed on the value of greater plant diversity and reduced consumption of ultra-processed foods but emphasized the considerable influence of the food industry on consumer behavior. She asked how government and other stakeholders could encourage manufacturers to reformulate products, add beneficial fiber, and improve food quality. Dr. Spector expressed skepticism that voluntary industry agreements alone would result in meaningful change and called for clearer public guidance and policy action related to ultra-processed foods. Jennifer Wargo, M.D., M.M.Sc., emphasized that data and public knowledge are essential and recommended collaboration among consumers, food manufacturers, researchers, and policymakers. Rob Knight, Ph.D., added that clear regulatory guidance and government-supported research could help assess the effects of reformulated products and establish appropriate standards for health claims and marketing.

Sarkis Mazmanian, Ph.D., emphasized that recommendations must support sustainable, long-term changes in diet and lifestyle rather than rely solely on short-term interventions among highly motivated study participants. Dr. Spector noted that providing individuals with feedback about changes they experience—including improvements in energy, hunger, and mood—may help motivate them to sustain healthier dietary patterns. Dr. Mazmanian agreed that effective communication and appropriate incentives will be necessary to translate these findings into lasting changes at the population level.

## **Research Gaps and Strategic Priorities for Microbiome-Based Prevention and Treatment Strategies to Improve Health**

### **Challenges in Moving Toward Causation and Reproducible Microbiome Interventions**

*Nicola Segata, Ph.D.*

Dr. Segata discussed the challenges of moving microbiome science from identifying associations to establishing causation. He explained that the microbiome is a highly complex system that interacts with multifactorial diseases, making it difficult to isolate a single causal factor. Although observational studies remain valuable, he emphasized the importance of interventional research that deliberately modifies the microbiome and measures the resulting effects. Potential approaches include interventions involving patient-derived or synthetic microbial communities, probiotics, prebiotics, postbiotics, and synbiotics. Dr. Segata encouraged the field to focus on approaches that act directly on the microbiome and can generate actionable evidence.

During the discussion, Eran Elinav, M.D., Ph.D., agreed that establishing causality is one of the field's greatest challenges and opportunities. He cited FMT as evidence that modifying the microbiome can affect health outcomes and anticipated progress toward more precisely defined

microbiome interventions. The discussion also addressed whether synthetic microbial communities could reproduce the complexity and functions of naturally occurring microbiomes.

Rob Knight, Ph.D., noted that the regulatory pathway for live biotherapeutic products can be lengthy and encouraged complementary approaches that generate evidence from large, well-characterized, and appropriately stratified human populations. He emphasized the value of flexible study designs that can assess outcomes both across broad populations and within subgroups, while avoiding large investments in interventions unlikely to produce meaningful effects. He also identified limited access to individualized microbiome diagnostics outside academic medical centers as a barrier to broader research and clinical application.

Sarkis Mazmanian, Ph.D., raised questions about whether dietary and microbiome-based interventions can overcome the microbiome's resistance to change and whether interventions should be designed for broad populations or tailored to specific groups. Jennifer Wargo, M.D., M.M.Sc., emphasized that reliable measurement and diagnostic tools are essential for comparing findings across diseases and evaluating the microbiome from both genetic and functional perspectives. Jennie H. Kwon, D.O., M.S.C.I., added that studies must identify appropriate surrogate markers and clinically meaningful outcomes when evaluating microbiome interventions.

### **Early Life as a High Priority Window for Prevention and Women's Health and the Microbiome**

*Maria Gloria Dominguez-Bello, Ph.D.*

Dr. Dominguez-Bello discussed early life as a critical period for microbiome development and a significant opportunity for preventing chronic disease. She emphasized the central role of mothers in shaping an infant's early microbial environment through pregnancy, birth, breastfeeding, and the environment in which the child develops. Because disruptions during this rapidly changing developmental period may influence health later in life, she encouraged the subcommittee to consider how emerging microbiome research could be translated into preventive strategies.

Dr. Dominguez-Bello outlined two complementary approaches. The first is to minimize avoidable disruptions to the developing microbiome, including unnecessary exposure to antibiotics and cesarean delivery when it is not medically indicated, while developing strategies to restore the microbiome when such exposures are necessary. She emphasized the need for validated measures of a healthy microbiome to determine who may benefit from an intervention, what should be restored, and when an intervention should occur. The second approach is to preserve microbial diversity, including microbial communities found in humans and throughout the world, as changes in lifestyle and the environment may contribute to the loss of important microbes. She also raised the possibility of preserving an individual's healthy microbiome for future use and called for long-term clinical trials to determine whether microbiome-restoration strategies meaningfully reduce disease risk. Dr. Dominguez-Bello encouraged NIH to support bold, high-risk research capable of advancing the field.

During the discussion, Tim Spector, M.D., asked which maternal and early-life periods—including preconception, pregnancy, and breastfeeding—offer the greatest opportunities for intervention. He also raised questions about dietary guidance and antibiotic use during pregnancy and the potential value of preserving an individual's microbiome for future restoration. Dr.

Dominguez-Bello emphasized that interventions must be appropriately timed because the infant microbiome changes rapidly during development.

Nicola Segata, Ph.D., said infants acquire microbes from their mothers, other family members, and their broader environments, including food. He emphasized that preserving microbial diversity among parents, siblings, and communities may be important because microbes lost from a population may be difficult to restore. Dr. Dominguez-Bello further highlighted the need to understand how to restore an infant's microbiome following disruptions such as repeated courses of antibiotics.

Majdi Osman, M.D., M.P.H., discussed the urgency of studying maternal and infant microbiomes globally, including interventions addressing childhood malnutrition in Africa. He recommended continued surveillance to understand how nutrition, environmental exposures, and clinical care affect children's microbiomes and long-term health. He also emphasized the need to evaluate both microbiome-related and clinical outcomes when assessing interventions. Frederic Bushman, Ph.D., added that the virome remains an underexplored component of the microbiome and that further research is needed to understand how viral communities acquired early in life may affect health.

### **Neurological Disease and the Gut Brain Axis**

*Sarkis Mazmanian, Ph.D.*

Dr. Mazmanian discussed the gastrointestinal symptoms experienced by many people with neurological and neurodevelopmental conditions, noting that these symptoms can substantially affect the quality of life of patients and caregivers. He cited constipation in people with Parkinson's disease as one example. Research over the past decade has suggested that gut bacteria may influence behavior and neurological function, with potential connections to Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, and autism. However, Dr. Mazmanian emphasized that much of the current evidence is observational and that additional mechanistic research, animal models, and human interventional studies are needed to establish causality.

Dr. Mazmanian noted that genetics alone cannot fully explain the development of many neurological conditions and encouraged further study of environmental factors, including industrial chemicals and other exposures that may affect both the body and brain. Because many neurological conditions have limited treatment options and existing therapies often address symptoms without modifying the underlying disease, he identified the microbiome as a promising area for research on prevention and new therapeutic approaches.

During the discussion, Tim Spector, M.D., expanded the conversation to include depression and anxiety, noting emerging evidence that the microbiome may influence mood, energy, and other aspects of mental health. He emphasized the potential for larger studies to bring greater attention to the gut-brain connection, while Dr. Mazmanian explained the frequent overlap between anxiety and depressive disorders and the need to better understand the biological and chemical pathways involved.

Martin Blaser, M.D., raised questions about when chronic neurological diseases such as Parkinson's and Alzheimer's disease begin. Majdi Osman, M.D., M.P.H., pointed out that symptoms and related conditions may emerge many years before a neurological diagnosis, creating potential opportunities to study the sequence of disease development and identify

preventive interventions earlier in life or during midlife. Dr. Blaser agreed that recognizing that disease processes may begin decades before diagnosis could reshape the research agenda.

Rob Knight, Ph.D., emphasized the importance of long-term population studies for validating associations among the microbiome, neurological conditions, and related conditions such as depression, irritable bowel syndrome, and inflammatory bowel disease. Dr. Mazmanian added that researchers need more comprehensive longitudinal information that captures both patient symptoms and biological data. He also encouraged the development of models that more accurately reflect human biology and disease progression, which could help researchers evaluate potential interventions without waiting decades for results.

### **Cancer and the Microbiome**

*Jennifer Wargo, M.D., M.M.Sc.*

Dr. Wargo thanked HHS for the opportunity to participate and described cancer as a major public health concern, including the increasing incidence of certain cancers among young people. She noted that advances in understanding cancer genetics and how tumors evade the immune system have contributed to transformative treatments such as immunotherapy, although these treatments do not benefit every patient. Researchers are therefore examining how additional factors—including microbes, diet, lifestyle, and sleep—may influence tumor development and treatment response.

Dr. Wargo discussed evidence that microbes within tumors can affect cancer biology and, in some cases, metabolize chemotherapy drugs. She also said established connections between certain viruses and cancer, such as human papillomavirus, while emphasizing that researchers have only begun to understand how the broader tumor and gut microbiomes may be targeted. Studies in melanoma and other cancers suggest that the composition and function of the gut microbiome can influence immune activity and response to immunotherapy.

Dr. Wargo described early research investigating FMT among patients who did not initially respond to immunotherapy, as well as ongoing studies in melanoma, lung cancer, and other cancers. She also discussed research suggesting that higher dietary fiber intake may be associated with improved immunotherapy response, while over-the-counter probiotics may not provide the anticipated benefits. Broad-spectrum antibiotic exposure has also been associated with less favorable treatment outcomes in several studies. Dr. Wargo reported on a clinical trial evaluating higher-fiber diets among patients with metastatic melanoma receiving immunotherapy, noting encouraging preliminary findings related to treatment response and patient well-being. She emphasized that larger randomized studies will require significant time, resources, and collaboration.

Dr. Wargo identified three priorities for the field: (1) strengthening antibiotic stewardship in cancer care; (2) developing the gut microbiome as a potential biomarker and therapeutic target; and (3) studying how diet may be used to support cancer prevention, treatment, and overall health. She emphasized the need for national and international collaboration to answer these questions across different cancer types.

During the discussion, Eran Elinav, M.D., Ph.D., described the research on the relationship between cancer and the microbiome as promising but complex and observed its potential relevance to primary prevention, maintaining remission, and preventing recurrence. Sarkis Mazmanian, Ph.D., asked why cancer microbiome research has progressed more rapidly than

other areas of the field and whether cancer is particularly well suited to microbiome-focused research. Dr. Wargo explained that melanoma provided a valuable model due to the close relationship between immune function and immunotherapy response and noted that this research has since expanded to kidney, lung, and other cancers.

Jennie H. Kwon, D.O., M.S.C.I., raised the concept of microbiome stewardship as an extension of antibiotic stewardship. Dr. Wargo agreed that preserving healthy microbiomes requires consideration of multiple influences, not only antibiotics, and should include attention to children, pregnant women, and healthy populations.

## **The Virome**

*Frederic Bushman, Ph.D.*

Dr. Bushman discussed the virome, the collection of viruses found within the human body and its microbial communities. He explained that viruses are present at most body sites, including the gastrointestinal tract, and that approximately 8% of the human genome consists of endogenous retroviral sequences inherited from ancient retroviral infections. Viruses can directly cause disease, but their effects are broader and more complex. For example, viruses that integrate into bacteria can alter bacterial functions in ways that may benefit or harm the human host.

Dr. Bushman described the NIH Common Fund Human Virome Program, which aims to characterize the “healthy” virome and improve understanding of its role in human health. The program will study diverse populations across the lifespan, develop tools and methods for virome research, investigate interactions among viruses, the human host, and other components of the microbiome, and coordinate data for use by the broader research community.

During the discussion, Martin Blaser, M.D., asked how researchers should identify conditions most appropriate for virome studies. He suggested that conditions such as cancer and progressive chronic diseases may be particularly informative when they have clearly defined subtypes, measurable disease progression, and clinical outcomes that allow researchers to determine whether an intervention is effective. Dr. Bushman noted that although individual viruses are well established as causes of human disease, emerging animal research is beginning to examine the effects of transferring entire viral communities, similar to previous studies involving bacterial communities.

Nicola Segata, Ph.D., raised questions about how the virome should be defined, particularly given the similarities among viruses and other mobile genetic elements involved in transferring and replicating genetic material. Dr. Bushman suggested studying viruses and mobile DNA collectively to better understand their functions and movement within microbial ecosystems.

Sarkis Mazmanian, Ph.D., asked whether researchers could define a healthy virome and identify ways to support it. Dr. Bushman said the field is still at an early stage and cited emerging research on how the virome is acquired during infancy and may be influenced by factors such as breastfeeding. Rob Knight, Ph.D., emphasized the importance of studying both RNA and DNA viruses to understand their roles within gut ecosystems and asked how the federal government could help address current research barriers. Dr. Bushman identified improved methods for reconstructing viral genomes and emerging tools for predicting viral structures and functions as important priorities for advancing the field.

## **Functional Microbiomics: Moving Beyond Sequencing**

*Eran Elinav, M.D., Ph.D.*

Dr. Elinav discussed the need for microbiome research to move beyond DNA sequencing toward a more complete understanding of microbial function. He said genomic sequencing transformed the field by allowing researchers to characterize the structure and functional potential of microbial communities. However, the presence or identity of a microorganism does not necessarily reveal what it is doing within the body. Dr. Elinav suggested that microbial function may provide a more meaningful and transferable measure of health than taxonomic composition alone.

Dr. Elinav described how understanding microbial functions and the molecules microbes produce could help explain how the microbiome in one part of the body affects distant organs and physiological systems. This knowledge could support the development of new therapeutics and more personalized approaches to nutrition, complementing dietary recommendations designed for the general population.

During the discussion, Tim Spector, M.D., observed that many microbes potentially important to human health remain unnamed or poorly characterized and asked what is needed to accelerate functional research. Dr. Elinav identified both conceptual and technological challenges, including the difficulty of connecting metagenomic information with specific molecules and biological functions. Individual microbiome samples can generate thousands of potential signals, and he suggested that promising therapeutic candidates may be found within this largely uncharacterized “microbial dark matter.” In response to a question from Dr. Spector, Dr. Elinav said AI could help researchers analyze these complex data sets but cautioned that it must be applied carefully.

Suchitra Hourigan, M.D., asked about the potential for microbial metabolites to be developed as therapeutics. Dr. Elinav emphasized the need to identify and characterize these molecules and then demonstrate their safety and effectiveness. Martin Blaser, M.D., noted that research should begin with a clearly defined biological question rather than a predetermined molecule. Once a promising molecule is identified, existing methods may allow researchers to modify its structure and improve its safety, stability, or therapeutic properties.

Maria Gloria Dominguez-Bello, Ph.D., cautioned that humans and their microbial communities have evolved as interconnected, complex systems and questioned whether an individual metabolite could reproduce the multiple functions performed by a living microorganism. Dr. Elinav agreed that no single molecule is likely to replace the full complexity of a microbe or microbial community. However, he suggested that molecules naturally secreted by microbes may reproduce specific physiological functions and offer practical starting points for developing targeted therapies.

## **Scaling, Methods, and Infrastructure**

*Rob Knight, Ph.D.*

Dr. Knight discussed the infrastructure and methodological advances needed to conduct microbiome research at scale. Although advances in DNA sequencing have expanded the field’s capabilities, microbiome research generates exceptionally large and complex data sets and often requires repeated measurements over time. He emphasized the need for sustained resources to collect longitudinal samples, connect microbiome data with detailed health and phenotype

information, and provide researchers with the high-performance computing capacity needed for AI and other advanced analyses.

Dr. Knight identified data harmonization, bridge studies across research methods and disciplines, and microbiome quality-control studies as high-impact priorities. He remarked that the genomics community has made substantial progress in creating reusable sequencing databases and encouraged similar investments in standardized microbiome data, reference resources, and analytical workflows. These resources would allow researchers to compare findings across laboratories and studies, integrate evidence from scientific literature and large data sets, and generate more reproducible results.

Dr. Knight also discussed the challenges of sharing and analyzing data containing personally identifiable information and protected health information, particularly across institutions and national boundaries. He encouraged the development of approaches that enable researchers to reproduce analyses and compare findings without requiring sensitive individual-level health data to be transferred or disclosed.

During the discussion, Sangeeta Khare, Ph.D., asked how FDA and NIH recommendations could support microbiome research. Dr. Knight described a two-pronged approach that would establish common standards, reference samples, and biospecimens while preserving researchers' ability to evaluate new methods. He cited comparisons among genome-sequencing centers as a useful model for identifying methodological variation, developing shared quality standards, and applying validated approaches across future studies.

### **Personalized and Precision Approaches**

*Martin Blaser, M.D.*

Dr. Blaser discussed the potential to move beyond one-size-fits-all microbiome interventions toward approaches tailored to an individual and a specific health condition. He noted strong public interest in the microbiome and the growing use of probiotics and other microbiome-related products. However, he pointed out the composition and quality of these products can vary, and many have not been adequately tested. Because they are biologically active and interact with the host, Dr. Blaser emphasized the need to determine which products are effective, for which conditions, and in which patients.

Dr. Blaser predicted that microbiome testing could eventually become a routine component of medical care. Although current tests remain at an early stage of development, future tools could examine microbial communities at different body sites and help guide prevention, diagnosis, and treatment. He compared this evolution to advances in cancer care, where diseases once treated as a single condition are now divided into biologically distinct subtypes requiring different therapies. He encouraged researchers to similarly stratify heterogeneous conditions such as obesity and asthma using disease characteristics, microbiome features, and functional biomarkers. Dr. Blaser emphasized that clinical investigations and experimental models will be needed to identify microbial patterns associated with risk or protection and examine the early factors that contribute to disease development.

During the discussion, Frederic Bushman, Ph.D., expressed concern that the widespread availability of probiotics with limited evidence of effectiveness may create barriers to the development and adoption of well-supported products. Dr. Blaser agreed that the field must

provide consumers with better information and cautioned that poorly supported products can undermine investment in and recognition of effective interventions.

Sarkis Mazmanian, Ph.D., emphasized the need to connect microbial functions with human physiology and specific diseases. He recommended bringing disease-area experts together with microbiome researchers and providing them with the technologies needed to investigate these relationships. Dr. Blaser agreed that clinical investigation and metagenomic analysis could help identify the functional roles of microbial communities and determine their relevance to different patient populations.

Tim Spector, M.D., remarked that the inability to clearly distinguish evidence-based products from other commercially available probiotics may discourage companies from investing in rigorous research. He identified diabetes and prediabetes as examples of conditions in which microbiome-based stratification could potentially help define an appropriate target population. Jennifer Wargo, M.D., M.M.Sc., shared concerns about the risks and uncertain effects of commercially available probiotics, including their potential influence on inflammation.

### **Regulatory Science and Translation**

*Sangeeta Khare, Ph.D.*

Sangeeta Khare, Ph.D., discussed the role of regulatory science in translating microbiome discoveries into products, public health strategies, and evidence-based guidance. She emphasized the need for regulatory approaches that clearly assess the safety and potential benefits of microbiome-based products. She also highlighted emerging work to understand how FDA-regulated products—including drugs, food additives, pesticides, and other chemical exposures—may affect the microbiome and contribute to broader health outcomes, such as kidney and liver toxicity.

Dr. Khare identified several priorities for advancing the field, including determining which measures of microbial abundance and function are most meaningful, integrating microbiome data with other sources of evidence, examining interactions between the microbiome and regulated products, and harmonizing research and regulatory approaches internationally. The discussion also explored personalized approaches, including whether healthy microbiota could be preserved for future use and the regulatory considerations associated with microbiome banking and FMT. Participants emphasized that clear, evidence-based communication is essential to translating emerging science responsibly and maintaining public trust.

During the discussion, Maria Gloria Dominguez-Bello, Ph.D., built on earlier comments about personalized approaches, drug–microbiome interactions, and the effects of antibiotics on immunotherapy outcomes. She asked whether individuals could preserve a healthy microbiome for future use and what regulatory considerations would apply to microbiome banking, noting that FMT is highly regulated.

### **Clinical Translation, Physician Education, and Public Trust**

*Majdi Osman, M.D., M.P.H.*

Dr. Osman discussed the need to bridge the gap between emerging microbiome research, clinical practice, and public understanding. He cited FMT for *Clostridioides difficile* infection as an example of microbiome science reaching patients, while noting that families are also seeking the treatment for other conditions. As patients increasingly bring microbiome test results and related information to health care appointments, clinicians need evidence-based guidance to interpret the

information, explain its risks and benefits, and counsel patients in a manner that reflects the current state of science. Dr. Osman also emphasized incorporating microbiome and nutrition science into medical education and clearly communicating when claims are not supported by sufficient evidence.

During the discussion, Tim Spector, M.D., recommended extending microbiome education beyond physicians to nurses and other health professionals, as well as introducing the science earlier in schools. Martin Blaser, M.D., agreed that microbiome education should begin at the outset of professional training. Sarkis Mazmanian, Ph.D., emphasized the need to define concrete, evidence-based recommendations that clinicians can share with patients, such as maintaining a healthy diet and reducing unnecessary exposure to antimicrobials. Dr. Osman noted that clinicians need clearer guidance for counseling parents and other patients about microbiome information, including the strength of the evidence and potential risks and benefits. Jennifer Wargo, M.D., M.M.Sc., added that educational efforts should advance alongside continued research and the development of larger data sets, including the responsible use of AI to help address outstanding questions.

## **Wrap-Up and Closing Remarks**

*Suchitra Hourigan, M.D.*

Dr. Hourigan thanked the subcommittee members for their time, curiosity, and commitment and recognized the staff who organized the meeting. She added that a summary of the discussion and the subcommittee's findings would be reported to the full PACCARB.

## **Adjourn**

*Sarah McClelland, M.P.H., Designated Federal Official*

Ms. McClelland thanked participants for joining, encouraged them to tune in to the forthcoming report-out, and formally adjourned the meeting at 12:45 p.m. ET.

## **Appendix: Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) Microbiome Subcommittee Members**

**September 2, 2026**

### **CHAIR**

Suchitra Hourigan, M.D. | Chief, Clinical Microbiome Unit, NIAID, NIH | USA

### **PACCARB SPECIAL GOVERNMENT EMPLOYEE (SGE)**

Jennie H. Kwon, D.O., M.S.C.I. | Northwestern University | USA

### **SUBCOMMITTEE MEMBERS**

Martin Blaser, M.D. | Rutgers University | USA

Frederic Bushman, Ph.D. | University of Pennsylvania | USA

Maria Gloria Dominguez-Bello, Ph.D. | Rutgers University | USA

Eran Elinav, M.D., Ph.D. | Weizmann Institute of Science | Israel / German Cancer Research Center (DKFZ) | Germany

Sangeeta Khare, Ph.D. | U.S. Food and Drug Administration (FDA) | USA

Rob Knight, Ph.D. | UC San Diego | USA

Sarkis K. Mazmanian, Ph.D. | California Institute of Technology | USA

Majdi Osman, M.D., M.P.H. | Wellcome Sanger Institute and University of Cambridge | UK

Nicola Segata, Ph.D. | University of Trento | Italy

Tim Spector, M.D. | King's College London | UK

Jennifer Wargo, M.D., M.M.Sc. | UT MD Anderson Cancer Center | USA

### **Regular Government Employees Present**

*U.S. Department of Health and Human Services (HHS)*

Admiral Brian Christine, M.D., Assistant Secretary for Health

Jay Bhattacharya, M.D., Ph.D., National Institutes of Health Director

Tammy Born Huizenga, D.O., Office of the Assistant Secretary for Health (OASH)

### **Designated Federal Official**

Sarah McClelland, M.P.H., Designated Federal Officer, Public Health Advisor, U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health (OASH)

### **Advisory Council Staff**

Lauren Plaine, M.P.S., RN, CEN, Deloitte Consulting

## **Glossary of Abbreviations**

|         |                                                                          |
|---------|--------------------------------------------------------------------------|
| AI      | artificial intelligence                                                  |
| FDA     | U.S. Food and Drug Administration                                        |
| FMT     | fecal microbiota transplantation                                         |
| HHS     | U.S. Department of Health and Human Services                             |
| NIH     | National Institutes of Health                                            |
| OASH    | Office of the Assistant Secretary for Health                             |
| PACCARB | Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria |
| SGE     | Special Government Employee                                              |