

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Meeting Summary

**18th Public Virtual Meeting of the
Presidential Advisory Council on
Combating Antibiotic-Resistant Bacteria
October 6, 2021**

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Meeting Proceedings

Welcome and Overview

Martin Blaser, M.D., Chair, and Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair

Drs. Blaser and King opened the meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) at 10 a.m. ET and welcomed the participants. Dr. Blaser gave an overview of the agenda, which was primarily focused on a letter crafted by the Council's Immediate Action Subcommittee in support of pending legislation to address development of new methods for combating antimicrobial resistance (AMR) while supporting antimicrobial stewardship.

Roll Call

Jomana F. Musmar, M.S., Ph.D., Designated Federal Official, Advisory Council Committee Manager, Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS)

Dr. Musmar called the meeting to order and described the PACCARB's establishment and charter. She summarized the rules governing the PACCARB under the Federal Advisory Committee Act and conflict-of-interest guidelines and called the roll. (See Appendix for the list of participants.)

Patient Story

Ella Balasa, Cystic Fibrosis Foundation

Ms. Balasa was diagnosed with cystic fibrosis at age 18 months and has experienced the devastating effects of AMR throughout her life. Her condition makes her particularly susceptible to infections, and antibiotics have been her lifeline for years. However, over time, oral, inhaled, and even potent intravenous antibiotics have become ineffective. Two years ago, Ms. Balasa experienced a severe pseudomonas infection that crippled her lung capacity. Fortunately, experimental phage therapy halted the infection and restored lung function.

Ms. Balasa's experience ignited her passion for raising awareness about the need to support medical advances. She pointed out that, eventually, infection will destroy her lungs, and she will need a lung transplant to survive. Such a transplant will result in a compromised immune system, and Ms. Balasa will still be highly susceptible to infections. She noted that the risk of resistant infections affects everyone, not just those with conditions like cystic fibrosis.

Ms. Balasa urged consideration of novel approaches to address AMR, such as phage therapy, inhibiting bacterial cellular action, and breaking down biofilms. She advocated for passage of two pieces of legislation under consideration—the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act and the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act—which offer strategies for getting more alternative approaches to the market quickly. In conclusion, Ms. Balasa thanked the Council members for their work and expressed hopefulness for the future.

Public Comments

No public comments were provided.

Report of the Immediate Action Subcommittee

Martin Blaser, M.D., Co-Chair, and Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Co-Chair

Dr. Blaser explained that AMR is a major threat that requires a robust arsenal of new products to stop the spread of disease. The pipeline of new therapies is severely lacking, because the current payment system does not adequately cover the costs to private industry of developing and manufacturing new antibiotics. The DISARM Act would offer payment for the appropriate use of designated drugs, incentivizing hospitals to prescribe drugs based on their efficacy rather than cost. The act requires hospitals to participate in national monitoring systems to ensure good stewardship. The PASTEUR Act would create a subscription model for therapeutics that values new drugs on the basis of their potential public health impact rather than sales. It incentivizes industry to develop new therapies and also includes a public reporting requirement for hospitals to encourage good stewardship.

PACCARB strongly supports the passage of both proposals, as indicated by a letter crafted by the Immediate Action Subcommittee to the HHS Secretary. Dr. Blaser emphasized that the stewardship components of both acts are crucial to ensure responsible use of new antibiotic therapies. Combating AMR is critical for public health, pandemic preparedness, and global health security. Dr. King added enthusiastic support for the letter. He said the two bills would work together to ensure authorization and implementation of actions that are critical to resolving AMR. Dr. King said the urgent need for these bills cannot be overstated.

Council Discussion and Vote

Dr. Musmar described a last-minute change to the draft letter posted online, which clarified that decreased use of antibiotics is appropriate but also decreases the revenue that manufacturers receive from new antibiotics. No comments or additional changes were offered.

Vote: PACCARB members voted unanimously¹ to approve the letter of the Immediate Action Subcommittee to the HHS Secretary supporting passage of the DISARM Act and the PASTEUR Act.

Dr. Musmar said that PACCARB staff will post the final version of the letter online and submit it to the HHS Secretary.

Final Comments and Adjournment

Martin Blaser, M.D., Chair, and Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair

Dr. Blaser thanked the participants and presenters for their contributions and PACCARB staff for their excellent efforts. He said the letter to the Secretary epitomizes two issues that the PACCARB has been discussing for years: improving the pipeline for development of products to combat AMR and strengthening antimicrobial stewardship. Dr. King added his thanks and hoped the letter would be a catalyst for moving the proposed legislation forward. Dr. Blaser adjourned the meeting at 10:29 a.m.

¹ Paul Plummer, DVM, PhD, DACVIM, DECSRHM voted by proxy. Ramanan Laxminarayan, PhD, MPH was absent.

Appendix: Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) Members

October 6, 2021

PACCARB Voting Members Present

Martin J. Blaser, M.D., Chair
Lonnie J. King, D.V.M., M.S., M.P.A., ACVPM, Vice Chair
Michael D. Apley, D.V.M., Ph.D., DACVCP
Helen W. Boucher, M.D., FIDSA, FACP
Stephanie Black, M.D., M.Sc.
Sara E. Cosgrove, M.D., M.S.
Paula J. Fedorka Cray, Ph.D.
Christine Ginocchio, Ph.D., MT
Locke Karriker, D.V.M., M.S., DACVPM
Kent E. Kester, M.D., FACP, FIDSA, FASTMH
Elaine Larson, Ph.D., RN
Armando Nahum
David White, M.S., Ph.D.

Organizational Liaisons Present

American Association of Extension Veterinarians
Carla L. Huston, D.V.M., Ph.D., Dipl. ACVPM

American Veterinary Medical Association
Joni Scheftel, D.V.M., M.P.H., Dipl. ACVPM

Biotechnology Innovation Organization
Emily Wheeler

Healthcare Infection Control Practices Advisory Committee
Lisa Maragakis, M.D., M.P.H.

Pediatric Infectious Diseases Society
Jason Newland, M.D., M.Ed.

Society of Infectious Disease Pharmacists
Elizabeth Dodds Ashley, Pharm.D., M.H.S., FCCP, BCPS

Wellcome Trust
Timothy Jinks, Ph.D.

Regular Government Employees Present

U.S. Department of Health and Human Services
Marjory Cannon, M.D. (for Shari Ling, M.D.), Centers for Medicare & Medicaid Services
James Cleeman, M.D., Agency for Healthcare Research and Quality

Michael Craig, M.P.P. (for Rima Khabbaz, M.D.), National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention
Dennis M. Dixon, Ph.D., National Institute of Allergy and Infectious Diseases, National Institutes of Health
Lawrence Kerr, Ph.D., Office of Pandemics and Emerging Threats, Office of Global Affairs
William Flynn, D.V.M., Center for Veterinary Medicine, Food and Drug Administration
Christopher Houchens, Ph.D., Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response

U.S. Department of Agriculture

Emilio Esteban, D.V.M., M.B.A., M.P.V.M., Ph.D., Food Safety and Inspection Service
Jeffrey Silverstein, Ph.D., Agricultural Research Service
Chelsey Shivley, D.V.M., Ph.D., DACAW (for Sarah Tomlinson, D.V.M.), Animal and Plant Health Inspection Service

U.S. Environmental Protection Agency

Jay Garland, Ph.D., Center for Environmental Solutions and Emergency Response

Designated Federal Official

Jomana F. Musmar, M.S., Ph.D., Advisory Council Committee Manager, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services

Advisory Council Staff

Mark Kazmierczak, Ph.D., Gryphon Scientific
Sarah McClelland, M.P.H., Public Health Advisor, OASH, HHS
Taylor Simmons, M.P.H., ORISE Fellow, HHS
Chloe Loving, M.P.H., ORISE Fellow, HHS

Glossary of Abbreviations

AMR	antimicrobial resistance
COVID-19	coronavirus disease 2019
DISARM	Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (Act)
HHS	U.S. Department of Health and Human Services
OASH	Office of the Assistant Secretary for Health
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
PASTEUR	Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (Act)