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VIRTUAL PUBLIC WORKSHOP FOR THE COMMITTEE ON IMPLICATIONS OF DISCARDED WEIGHT-BASED DRUGS

April 29, 2020
10:30AM – 5:15PM ET

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COMMITTEE ON IMPLICATIONS OF DISCARDED WEIGHT-BASED DRUGS

VIRTUAL PUBLIC WORKSHOP

APRIL 29, 2020 **TIME: 10:30 AM - 5:15 PM ET**

Wednesday, April 29, 2020	
10:30 am	**Welcome and Workshop Overview** Edward Shortliffe, M.D., Ph.D., *(Chair), Committee on Implications of Discarded Weight-Based Drugs*
10:40 am	**SESSION 1: Federal Agencies Perspectives on Statement of Task** Session objective: To explore the intersection of research, policies, and programs of the various federal agencies pertinent to the study's statement of task Moderators: *Tracy Lieu / Alastair Wood* • **Centers for Medicare & Medicaid Services** o **Sarah Shirey-Losso,** *Director, Division of Ambulatory Services* • **Food and Drug Administration** o **Jacqueline Corrigan-Curay J.D., M.D.,** *Director, CDER's Office of Medical Policy* • **Department of Defense** o **Lieutenant Colonel Ronald Khoury, M.D., M.B.A.,** *Chief, Formulary Management Branch, Pharmacy Operations Division, DHA* Panel Discussion
11:30 am	**Break**
11:40 am	**SESSION 2: Regulatory Framework** Session objective: To explore the regulatory factors that influence drug packaging, quality, and safety distribution and delivery Moderator: *Kavita Patel / Jonathan Watanabe* • **Drug Stability and Safety** o **Brian Serumaga, Ph.D.,** *Science Program Manager, USP* • **Drug Dosing and Delivery** o **Michael Seiden, M.D., Ph.D.,** *President, The US Oncology Network* • **Pharmaceutical Compounding and Dispensing**

	○ **Michael Ganio, Pharm.D., FASHP,** *Director, Pharmacy Practice and Quality, ASHP Office of Practice Advancement* • **Rationale for vial-size choices in the pharmaceutical development process** ○ **Kedar Gokhale, Ph.D.,** *Associate Director, Janssen Research & Development Biotherapeutics on behalf of BioPhorum Fill Finish Group* Panel Discussion
1:15 pm	**Lunch Break**
2:00 pm	**SESSION 3: Payment Incentives and Reimbursements** Session objective: To discuss drug payment structures/models, policies, and beneficiary cost-sharing and the degree to which these policies may affect costs to federal programs and beneficiaries Moderator: *Robin Yabroff / Harold Paz* • **Payment and Reimbursement Models** ○ **Mireille Jacobson, Ph.D.,** *Associate Professor & Co-Director, USC Leonard Davis School of Gerontology & Aging and Cognition Program,Schaeffer Center for Health Policy & Economics* • **Patient Out-of-Pocket and Federal Spending** ○ **Stacie Dusetzina, Ph.D.**, *Associate Professor, Health Policy, Vanderbilt University Medical Center* • **Patient Cost Sharing** ○ **Gwen Darien,** E*xecutive Vice President, Patient Advocacy and Engagement, National Patient Advocate Foundation, Patient Advocate Foundation* • **Medicare Part B Drug Payment Policies and the JW Modifier** ○ **Prabath Malluwa-Wadu, Pharm.D.,** *Pharmacist, CMS* • **Determinants of Pharmaceutical Pricing** ○ **Alex Bastian, M.B.A.,** *Vice President, Value And Market Access Galapagos NV* Panel Discussion
3:45 pm	**Break**
4:00 pm	**SESSION 4: Stakeholder Perspectives and Potential Strategies** Session objective: To explore measures aimed at reducing waste from single dose vials and/or its associated cost in the biopharmaceutical chain and examining the impact of revisions to stakeholders Moderator: *Julie Donohue / Bapu Jena*

	• **Payer Perspective** o **Corbin Bennett, PharmD, MPH,** *Senior Director of Oncology and Outpatient Infusion Pharmacy Services , Kaiser Permanente* • **Clinician Perspective** o **Richard L. Schilsky, MD, FACP, FASCO,** *Executive Vice President and Chief Medical Officer, ASCO* • **Potential Unintended Consequences of Policy Changes** o **Amitabh Chandra, Ph.D.,** *Professor of Business Administration, Harvard Business School; Professor of Public Policy and Director of Health Policy Research, Harvard Kennedy School of Government* Panel Discussion
5:15 pm	**Adjourn Day**

NOTICE REGARDING OPEN SESSIONS

This workshop is being held in order to facilitate presentations and discussion among experts. The workshop is being recorded.

The conversations and information presented during this meeting will help to inform the study committee's work and may inform future Academies work and activities. Although opinions may be stated and lively discussion may ensue, no conclusions are being drawn and no recommendations will be made. Furthermore, individual participants may engage in discussion and questioning for the specific purpose of probing an issue and sharpening an argument.

The comments of any given participant should not be assumed to reflect the views of any organization with which the individual may be affiliated, including the study committee and the National Academies.

Questions about this meeting should be directed to Francis Amankwah (FAmankwah@nas.edu), program officer, Board on Health Care Services.

PREVENTING DISCRIMINATION, HARASSMENT, AND BULLYING
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Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

Bullying is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

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Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400, or
- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

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Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Updated June 7, 2018

Speaker Biographical Information

Alex Bastian, M.B.A.
Value & Market Access
Galapagos NV

Mr. Alex Bastian is Vice President of Value & Market Access at Galapagos NV, a Belgo-Dutch company that develops therapies with proprietary, novel modes-of-action. He leads the build-out of the value and access function, helps to shape the pipeline and ensures that value is captured for patients, Galapagos, and society. Prior to Galapagos, he was head of Global Value, Access, & Pricing at Incyte Corporation, an innovative biotechnology company focusing on oncology drug development. He was responsible for developing and implementing global market access, pricing, and reimbursement strategy, including health economics and outcomes research support for Incyte. Prior to Incyte, he led a biotech strategy market access consulting practice in San Francisco with Bridgehead International after having started his career with Pfizer (NYC) and Amgen (Switzerland). He has expertise in methodologies to drive commercial value of strategic and market access activities for biopharmaceuticals and companion diagnostics. He has published on various pricing, access, and health economic themes. He regularly speaks at conferences including those organized by the National Cancer Policy Forum of the National Academies of Sciences, Engineering and Medicine, Regional Medicare Caucuses, U.S. State Medical Society, the American Society of Hematology, ISPOR, the National Venture Capital Association, and the Association of Community Cancer Centers. He has served as a strategic advisor to the American Society of Clinical Oncology's taskforce to establish a value algorithm to assess new technologies in cancer care. He also served as an advisor to the Medication Education & Disposal Project for innovative risk-sharing models in the USA. He is currently on the Editorial Advisory Board for the *Journal of Comparative Effectiveness Research* and *the Journal of Clinical Pathways*. He holds a bachelor's degree with honors from the University of Minnesota and received his M.B.A. from the prestigious IESE Business School in Barcelona, Spain.

Corbin Bennett, PharmD, M.P.H.
Oncology and Outpatient Infusion Pharmacy Services
Kaiser Permanente

Dr. Corbin Bennett is the Senior Director of Oncology and Outpatient Infusion Pharmacy Services for Kaiser Permanente and has responsibility for oncology pharmacy and home infusion pharmacy services nationally. In this role, he has strategic oversight of 62 ambulatory oncology pharmacies, 13 outpatient and home infusion pharmacies and inpatient oncology services which includes policy development, facilities design, and standardization of work processes and systems. He also has direct oversight of the national Beacon (Epic) build and implementation teams. He has been with Kaiser Permanente since 2001. Prior to beginning his current role, he served as Clinical Operations Manager of the Fresno Medical Center. He directly oversaw drug use management and clinical pharmacy ambulatory care services and served as Pharmacy Residency Director. He received his M.P.H from University of California, Berkeley, PharmD and General Practice Residency from University of California, San Francisco.

Amitabh Chandra, Ph.D.
Business Administration at Harvard Business School;
Harvard Kennedy School of Government
Harvard University

Dr. Amitabh Chandra is the Henry and Allison McCance Professor of Business Administration at Harvard Business School and the Ethel Zimmerman Wiener Professor of Public Policy and Director of Health Policy Research at the Harvard Kennedy School of Government. He is also a member of the Congressional Budget Office's Panel of Health Advisors, a Research Associate at the National Bureau of Economic Research, and the Chair Editor of *the Review of Economics and Statistics*. His research focuses on innovation and pricing in the biopharmaceutical industry, value in health care, medical malpractice, and racial disparities in healthcare. He has been supported by the National Institute of Aging, the National Institute of Child Health and Development, the Robert Wood Johnson Foundation, and was published in the *American Economic Review*, the *Journal of Political Economy*, the *New England Journal of Medicine*, the *Journal of the American Medical Association*, and *Health Affairs*. He has testified to the United States Senate and the United States Commission on Civil Rights. His research was featured in the *New York Times*, the *Washington Post*, CNN, Newsweek, and on National Public Radio. He is the first-prize recipient of the Upjohn Institute's Dissertation Award, the NIHCM Foundation Health Care Research Award, the Kenneth Arrow Award for Best Paper in Health Economics, and the Eugene Garfield Award for the Impact of Medical Research. In 2012, he was awarded American Society of Health Economists (ASHE) medal. The ASHE Medal is awarded biennially to the economist age 40 or under who has made the most significant contributions to the field of health economics. He has a B.A. and Ph.D. in Economics from the University of Kentucky. He is a member of the National Academy of Medicine.

Gwen Darien
Patient Advocacy and Engagement
National Patient Advocate Foundation

Gwen Darien is a longtime patient advocate who has played leadership roles in some of the country's preeminent nonprofit organizations. As Executive Vice President for patient advocacy and engagement at the National Patient Advocate Foundation (NPAF) and the Patient Advocate Foundation (PAF), she leads programs that link PAF's patient service programs to NPAF initiatives, with the goal of improving access to equitable, affordable, quality health care. As a three-time cancer survivor herself, she came into cancer advocacy expressly to change the experiences and outcomes for the patients who came after her and to change the public dialogue about cancer and other life-threatening illnesses. She started the first stand-alone advocacy entity in a professional cancer research organization at the American Association for Cancer Research where she launched *CR magazine*. Later, she served as Executive Vice President of Programs and Services at the Cancer Support Community. In each role, she championed placing patients at the center of health system change, whether it is for research, public policy, or direct services. She serves on a wide range of program committees and workshop faculties. She is the Chair of Community Engagement in Genomics Working Group of the National Human Genome Research Institute and co-chair of Patient Centered-Outcomes Research Institute's Patient Engagement Advisory Panel. Additionally, she writes about her experiences as an advocate and cancer survivor. A recent piece, *Transformation: My Experience as a Patient and an Advocate in Three Chapters* appeared in the *National Academy of*

Medicine Perspectives. She is a graduate of Sarah Lawrence College, where she also served as an advisor for their Health Advocacy program.

Stacie Dusetzina, Ph.D.
School of Medicine
Vanderbilt University

Dr. Stacie Dusetzina is Associate Professor of Health Policy and Ingram Associate Professor of Cancer Research at Vanderbilt University School of Medicine. She is a Health Services Researcher focusing on the intersection between health policy, epidemiology, and economics related to prescription drugs. Her work focuses on prescription drug prices and affordability for consumers, with a special focus on high-priced or complex drugs. Her body of work has led to her participation in the President's Cancer Panel's workshops on Access to Cancer Drugs, her appointment to a National Academies of Sciences, Engineering, and Medicine committee on *Ensuring Patient Access to Affordable Drugs*, and testifying before the Senate Aging Committee on the same topic in 2019. She received her Ph.D. in Pharmaceutical Science from the University of North Carolina at Chapel Hill (UNC) and post-doctoral training at the Department of Health Care Policy at Harvard Medical School.

Michael Ganio Pharm.D., M.S., BCPS, FASHP
Pharmacy Practice and Quality
American Society of Health Pharmacists

Dr. Michael Ganio is Director of Pharmacy Practice and Quality at the American Society of Health Pharmacists (ASHP). As a member of the Center on Medication Safety and Quality team, his responsibilities span the practice of pharmacy and include drug shortages, pharmaceutical quality, sterile and non-sterile drug compounding practices, hazardous drug handling, and the ASHP Standardize 4 Safety initiative. He has over 18 years of hospital and health-system experience. His previous job roles have included clinical pharmacy practice, pharmacy informatics and technology, and operations management of outpatient oncology infusion pharmacies. He has extensive knowledge of pharmacy informatics and automation, medication billing and reimbursement, sterile compounding, and outpatient infusion and ambulatory care models. He earned his Pharm.D. from the Rutgers University Ernest Mario School of Pharmacy and his master's in Health-System Pharmacy Administration from The Ohio State University College of Pharmacy. He completed a PGY1 Pharmacy Practice residency at The Ohio State University Wexner Medical Center. He is a Board-Certified Pharmacotherapy Specialist and a Certified Professional in Healthcare Information and Management Systems.

Kedar S. Gokhale, Ph.D.
Drug Product Development
Janssen (Johnson & Johnson)

Dr. Kedar Gokhale has over 20 years of experience in biopharmaceutical industry spanning from early and late phase development to commercialization of drug products. He is currently an Associate Director in the Drug Product Development (DPD) department at Janssen (J&J) R&D in Malvern, Pennsylvania. His current focus is enabling the Janssen monoclonal antibody (mAB), oncolytic viruses, gene therapy and vaccine portfolio. He also has extensive experience in biosimilar

development from his previous role at Lupin Ltd. India, where he led the drug product process and formulation development group. He received his Ph.D. in Pharmaceutical Sciences from Philadelphia College of Pharmacy (University of the Sciences), and M.S. in Pharmaceutics from University of Mississippi.

Mireille Jacobson, Ph.D.
Davis School of Gerontology;
Schaeffer Center for Health Policy & Economics
University of Southern California

Dr. Mireille Jacobson is Associate Professor at the Davis School of Gerontology and Co-Director of the Aging and Cognition Program at the Schaeffer Center for Health Policy & Economics at University of Southern California (USC). She is also a Research Associate in the Health Care program at the National Bureau of Economic Research. Her research focuses on financial and non-financial barriers to timely and effective health care as well as the role of supply-side factors, such as the role of Medicare payment policy for cancer drugs on provider behaviors and patient outcomes. Prior to joining USC, she was a Professor at the Merage School of Business at UC-Irvine. Prior to this, she was a Senior Health Economist at the RAND Corporation and the Deputy Director of RAND Health's Economics, Finance, and Organization (EFO) Program. Her work has appeared in *Health Affairs, The New England Journal of Medicine, The Quarterly Journal of Economics*, among others. She has received grants from the Agency for the Healthcare Research and Quality, the National Institute on Aging, and the National Cancer Institute. She received her B.A. in Economics from the University of Chicago and her Ph.D. in Economics from Harvard University.

Lt. Col. Ronald J Khoury, M.D., M.B.A.
Pharmacy Operations Division
Defense Health Agency

Lieutenant Colonel Ronald Khoury serves as Chief, Formulary Management Branch, Pharmacy Operations Division, DHA. He leads a team responsible for reviewing individual drugs and drug classes for efficacy and safety to advise the Department of Defense Pharmacy and Therapeutics Function. He serves as a subject matter expert to the DoD on pharmacy benefits decisions affecting 9.5 million beneficiaries, 699 military treatment facilities, and a $7.4 billion budget. He is an active clinician with the Family Medicine Service Clinic at San Antonio Military Medical Center. He graduated from Duke University as an Angier B. Duke Merit Scholar, earning a Bachelor of Science in Biology. He was a direct commission to the Air Force in June 1998 and attended Commissioned Officer Training in July 1998. In 2003, he earned his M.D. from the Uniformed Services University of the Health Sciences. He completed his residency in Family Medicine at David Grant Medical Center, University of California Davis Network and is Board Certified with the American Board of Family Medicine. In addition, he completed his master's in Business Administration from the University of Tennessee, Knoxville. Lt. Col. Khoury is a Fellow of the American Academy of Family Physicians and has served as faculty at the Uniformed Services University and Touro University.

CDR Prabath Malluwa-Wadu, PharmD.
Part B Drug Payment Policy Group
Centers for Medicare & Medicaid Services

CDR Malluwa-Wadu is a pharmacist in the Medicare Part B drug payment policy group within the Centers for Medicare & Medicaid Services (CMS). His job responsibilities include calculating payment allowances for Part B drugs and vaccines, providing clinical advice to the Healthcare Common Procedure Coding (HCPCS) team about new coding applications, evaluating new drugs for proper assignment of coding and billing units for ASP pricing, and coordinating Sec 2008 of ACA fee calculation for Part B drugs with Internal Revenue Service. Prior to joining CMS, he worked at the Indian Health Service (IHS) for 2 years in Okanogan County, Washington State. At IHS, he managed an ambulatory satellite clinic in Colville Tribe in Omak. In addition to his IHS pharmacist duties, he worked as the clinical applications coordinator for two IHS sites. He received his first pharmacy license in 1988 in Sri Lanka and received his PharmD from University of Maryland.

Richard L. Schilsky, M.D., FACP, FSCT, FASCO
American Society of Clinical Oncology

Dr. Richard Schilsky is the Executive Vice President and Chief Medical Officer (CMO) of the American Society of Clinical Oncology (ASCO). He is a highly respected leader in the field of clinical oncology, specializing in new drug development and treatment of gastrointestinal cancers. He has spent the majority of his career at the University of Chicago where he joined the faculty in 1984, subsequently rising to the rank of Professor of Medicine and serving in many roles, including Associate Dean for Clinical Research in the Biological Sciences Division and Director of the University of Chicago Cancer Research Center. He is also formerly the Chief of Hematology/Oncology in the Department of Medicine and Deputy Director of the University of Chicago Comprehensive Cancer Center and past President of ASCO, having served in the role during 2008-2009. Additionally, he has extensive experience working with both the National Cancer Institute's (NCI) and the Food and Drug Administration (FDA), having served as past chair of one of the NCI's Cooperative Groups, Cancer and Leukemia Group B (CALGB), and was a member and chair of the Oncologic Drugs Advisory Committee of the FDA. His impressive experience and many accomplishments in both clinical medicine and research reflect his deep passion for cancer medicine. Presently, he serves as a member of the board of directors of Friends of Cancer Research and of the Reagan-Udall Foundation for the FDA. He has served on the editorial boards of many cancer journals, including the *Journal of Clinical Oncology* and currently serves on the editorial board of the *New England Journal of Medicine*. He is the author of nearly 400 original research articles, reviews and commentaries.

Michael V. Seiden, M.D., Ph.D.
The U.S. Oncology Network

Dr. Michael V. Seiden is the President of The U.S. Oncology Network, the largest collection of community-based oncology care practices in the United States. He is focused on leading The Network through the delivery of high value cancer care. Currently, The Network is the largest collection of practices participating in the Center for Medicare and Medicaid Innovation (CMMI) led Oncology Care Model (OCM) program with the majority of practices now participating in two-sided risk. Previously, he served as the Senior Vice President and Chief Medical Officer of the U.S. Oncology Network; the CEO and President of Fox Chase Cancer Center, a National Cancer Institute-designated Comprehensive Cancer Center research facility and hospital in Philadelphia. Prior to Fox Chase, he spent many years practicing oncology at Massachusetts General Hospital and Harvard

Medical School, where he served as Chief of the Clinical Research Unit, Cancer Science Division, and as Associate Professor in Medicine at Harvard University. He received his M.D. and Ph.D. from Washington University. He completed his residency at Massachusetts General Hospital, his fellowships in medical oncology and bone marrow transplant at Dana Farber Cancer Institute, and his post-doctoral fellowship at Brigham and Women's Hospital.

Brian Serumaga, Ph.D.
Healthcare Quality & Safety
U.S. Pharmacopeia Convention

Dr. Brian Serumaga is a Science Program Manager for the U.S. Pharmacopeia. His specialty areas are in health policy planning and implementation. He has over 10 years of experience working as a Pharmacist and Global Health professional. Prior to joining the U.S. Pharmacopeia, he was a technical advisor at John Snow Inc. He has served as a Pharmaceutical Policy Research Fellow at Harvard Medical School and a Research Fellow in Medicines Use and Patient Safety at the University of Nottingham. He is a member of the Cochrane Systematic Review Group on Patient Safety, the World Health Organization Access to Medicines Research Network, the International Society on Pharmacoepidemiology and Drug Safety and the Drug Utilization Research Group. He received his M.P.H. in International Public Health and Ph.D. in Primary Health Care from the University of Nottingham. He is a member of the Pharmaceutical Society of Uganda.

Sarah Shirey-Losso
Division of Ambulatory Services
Centers for Medicare & Medicaid Services

Ms. Sarah Shirey-Losso is currently the Director of the Division of Ambulatory Service within the Centers for Medicare & Medicaid Services (CMS). She joined CMS in 1998 and has had a variety of analyst roles in the agency including provider billing and education, inpatient hospital benefits, ICD-10 implementation, and most recently in payment policy, as the Director of the Division of Ambulatory Services. Prior to her current role, she worked in CMS' Provider Billing Group, developing inpatient hospital billing and claims processing guidance. She is a graduate of the University of Maryland and holds a B.A. in Art History.

Jacqueline Corrigan-Curay J.D., M.D.
Center for Drug Evaluation and Research
Office of Medical Policy

Dr. Jacqueline Corrigan-Curay, serves as director of the Office of Medical Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration. She leads the development, coordination, and implementation of medical policy programs and strategic initiatives, including policy development on real-world evidence, drug labeling, prescription drug promotion, clinical trial oversight, and innovative trial design. She works collaboratively with other Center program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Prior to joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute at the National Institutes of Health (NIH), where she focused on developing policies and procedures to enhance the clinical trial enterprise. She also served as the director of the Office of Biotechnology Activities, Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the Veterans Affairs Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington, DC.

Committee on Implications of Discarded Weight-Based Drugs

Biographical Information of Members

Edward Shortliffe, M.D., Ph.D., ***(Chair)*** is Adjunct Professor of Biomedical Informatics at Columbia University's College of Physicians and Surgeons and at the College of Health Solutions at Arizona State University. He is also Adjunct Professor of Healthcare Policy and Research (Health Informatics) at Weill Cornell Medical College. He has served as President and Chief Executive Officer of the American Medical Informatics Association, Professor in the School of Biomedical Informatics at the University of Texas Health Science Center in Houston, Professor of Biomedical Informatics at Arizona State University, Professor of Basic Medical Sciences and Professor of Medicine at the University of Arizona College of Medicine and founding dean of the Phoenix campus of the University of Arizona's College of Medicine. He was the Rolf A. Scholdager Professor and Chair of the Department of Biomedical Informatics at Columbia College of Physicians and Surgeons in New York City and Professor of Medicine and of Computer Science at Stanford University. He is a Master of the American College of Physicians and was a member of that organization's Board of Regents. He is Editor-in-Chief of the Journal of Biomedical Informatics. A recipient of several awards including a research career development award from the National Library of Medicine, the Grace Murray Hopper Award of the Association for Computing Machinery, and the Morris F. Collen Award of the American College of Medical Informatics, he was also appointed as a Henry J. Kaiser Family Foundation Faculty Scholar in General Internal Medicine. His research interests include the broad range of issues related to integrated decision-support systems, their effective implementation, and the role of the Internet in health care. He received an A.B. in Applied Mathematics from Harvard College, and both a Ph.D. in Medical Information Sciences and an M.D. from Stanford University. An elected member of the American Society for Clinical Investigation, the Association of American Physicians, and the American Clinical and Climatological Association, he has also been elected to fellowship in the American College of Medical Informatics and the American Association for Artificial Intelligence. He is a member of the National Academy of Medicine.

Julie Donohue, Ph.D., Vice Chair for Research, and Co-Director of the Ph.D. Program in the Department of Health Policy and Management, in the Graduate School of Public Health at the University of Pittsburgh. She directs the Medicaid Research Center, which provides analytic support to Pennsylvania's Medicaid program, and Co-Directs the Center for Pharmaceutical Policy and Prescribing (CP3). She conducts research on insurance coverage, financing, and delivery of health care with a focus on behavioral health care and pharmaceuticals. Her pharmaceutical policy work has informed both Medicare and Medicaid policy. Together with AcademyHealth, she recently launched the Medicaid Outcomes Distributed Research Network (MODRN) to support state Medicaid policy evaluations. She holds secondary appointments in the Clinical and Translational Science Institute and is a faculty affiliate in the Health Policy Institute. She earned a Ph.D. in health policy from Harvard University and completed a post-doctoral fellowship in pharmaceutical policy research at Harvard Medical School.

Anupam Jena, M.D., Ph.D., is the Ruth L. Newhouse Associate Professor of Health Care Policy at Harvard Medical School and a physician in the Department of Medicine at

Massachusetts General Hospital. He is also a faculty research fellow at the National Bureau of Economic Research. His research involves several areas of health economics and policy including the economics of physician behavior and the physician workforce, medical malpractice, the economics of health care productivity, and the economics of medical innovation. He is a recipient of the Eugene Garfield Award by Research America for his work demonstrating the economic value of medical innovation in HIV/AIDS. He is a recipient of the NIH Director's Early Independence Award to fund research on the physician determinants of health care spending, quality, and patient outcomes, and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) New Investigator Award. He received his M.D. and Ph.D. in Economics from the University of Chicago. He completed his residency in internal medicine at Massachusetts General Hospital. He served on the National Academies of Sciences, Engineering, and Medicine ad hoc Committee on Diagnostic Errors in Health Care.

Tracy Lieu, M.D., M.P.H., is the director of the Division of Research, Kaiser Permanente Northern California. She leads a department of 600 people who conduct studies in clinical effectiveness, delivery science, and epidemiology to benefit Kaiser Permanente members and society at large. She is also a practicing pediatrician who has led internationally recognized research in vaccine safety and policy and childhood asthma. Before her current role, she was a professor and center director in the Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School. Her national roles have included membership on the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices and the chair of the Health Services Organization and Delivery study section of the National Institutes of Health. She was elected to the National Academy of Medicine for her use of decision sciences and economic evaluation to inform health policy.

Gary Lyman, M.D. M.P.H., serves as a senior lead for health care quality and policy within the Hutchinson Institute for Cancer Outcomes Research, or HICOR, at the Fred Hutchinson Cancer Research Center and Professor of Medicine, Public Health and Pharmacy at the University of Washington. He is a board-certified medical oncologist, hematologist, and public health researcher who focuses on comparative effectiveness, health technology assessment, and health services and outcomes research. He has served as an advisor to the U.S. Food and Drug Administration's Oncologic Drug Advisory Committee, and has been active in the Alliance for Clinical Trials in Oncology (formerly Cancer and Leukemia Group B), the SWOG Cancer Research Network, and the Eastern Cooperative Oncology Group. He has served on the Breast Cancer Screening and Diagnosis Panel and the Growth Factors Panel for the National Comprehensive Cancer Network, and Chairs Clinical Practice Guidelines for the American Society of Clinical Oncology (ASCO) and the American Society of Hematology. He was Chief of Medicine at the Moffitt Cancer Center and Research Institute and Professor of Medicine at the University of South Florida, the University of Rochester, and Duke University. Additionally, he holds leadership positions within ASCO as well as the SWOG Cancer Research Network, for which he serves as executive officer for Cancer Care Delivery, Symptom Management and Quality of Life Research, and Immunotherapy. He earned his M.D. from the State University of New York and a Master of Public Health degree in Biostatistics from Harvard University School of Public Health and pursued postdoctoral training at the Roswell Park Cancer Center and Dana Farber Cancer Institute.

Kavita Patel, M.D., M.P.H., is a non-resident fellow at the Brookings Institution and a primary care physician in Washington, DC. She advises health care technology and services organizations through New Enterprise Associates and is an advisor to the Bipartisan Policy Center. She is a member of the Department of Health and Human Services Physician Focused Payment Model Technical Advisory Committee. Previously, she consulted for biopharmaceutical companies, directed the health policy program at the New America Foundation, and served in the Obama administration as director of policy for the Office of Intergovernmental Affairs and Public Engagement in the White House. She is a practicing physician with health care policy experience in the U.S. Senate Health, Education, Labor and Pensions Committee, where she was deputy staff director for health under Senator Edward Kennedy. She was selected as a Young Global Leader by the World Economic Forum and is a Society of General Internal Medicine Advisory Board Member for the National Commission on Physician Payment Reform. She received her M.P.H from the University of California, Los Angeles, and her M.D. from University of Texas Health Science Center.

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Kenneth Silverman, M.S., is the director of packaging technology, global technical operations at AstraZeneca. He manages a team of engineers responsible for commercializing innovative, standardized, sustainable commercial package systems for protein-based therapeutics including monoclonal antibodies, antibody drug conjugates, mRNA, DNA, Enzymes, Gene therapy and Cell therapy. He entered biopharmaceutical research and development over two decades ago as a lab manager for developing packaging systems for new protein-based therapeutics at Schering-Plough. He moved into medical device research and development at Merck Research Laboratories focusing on design control methodologies to assess and mitigate risk and ensure optimal device packaging system development from prototype to a commercially scalable device design for biologics. In 2012, he moved out of research and development into technical operations at Bristol Myers Squibb where he developed packaging, scaled up manufacturing and commercially launched Immuno-Oncology therapies including Opdivo, Yervoy and Empliciti. At Bristol Myers Squibb, he advanced from principal engineer to associate director where he harmonized and standardized Bristol Myers Squibb's global packaging footprint for biologics. Ken Joined AstraZeneca in January 2018 where he is responsible for all biological packaging from late stage new molecular entities to commercialized products including Imfinzi, Fasenra, and Lumoxiti. He is currently responsible for assuring uninterrupted supply of protein-based therapeutics with a focus on optimal package design, excellence in manufacturing, harmonization, interchangeability, sustainability and simplicity. He is the single patent holder for a senior friendly single dose dispensing package (WO2009149267). He received his Masters and Bachelor of Science in Packaging Science degrees from the Rochester Institute of Technology.

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Statement of Task

An ad hoc committee under the auspices of the National Academies of Sciences, Engineering, and Medicine will examine federal health care costs, safety, and quality concerns associated with discarded drugs resulting from weight-based dosing of medicines contained in single-dose vials. Based on that review, the committee will identify relevant drugs and examine:

- Current delivery practices, including manufacturing, storage, and transportation guidelines,
- Guidance from relevant federal agencies to biopharmaceutical manufacturers and distributors,
- Federal drug reimbursement and cost-sharing policies,
- Implications of current dosing practice to patients' safety and quality of care, and
- Financial consequences of discarded drugs.

The committee will issue a report with findings and recommendations to consider in order to reduce waste in the biopharmaceutical supply chain.