The National Academies of
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VIRTUAL PUBLIC WORKSHOP FOR THE COMMITTEE ON IMPLICATIONS OF DISCARDED WEIGHT-BASED DRUGS

June 30, 2020
12:00PM – 2:15PM ET

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COMMITTEE ON IMPLICATIONS OF DISCARDED WEIGHT-BASED DRUGS

AGENDA

Workshop Objectives

Discuss the scope and overview of the study committee's task; understand the Medicare Part B drug payment system; explore measures to reduce waste from single dose vials and/or its associated cost in the biopharmaceutical chain; and examine the impact of revisions to current policies and practices to mitigate physician-administered drug waste and its associated costs.

12:00 pm **Welcome** **Edward (Ted) Shortliffe,** *Committee Chair*

12:10 pm **Scope of Problem, Potential Measures, and Potential Unintended Consequences**

Moderators: Ted Shortliffe / Deborah Schrag

Opportunities and Constraints

- **Donald M. Berwick, M.D., M.P.P.,** *President Emeritus and Senior Fellow, Institute for Healthcare Improvement; Former Administrator, Centers for Medicare & Medicaid Services*

Flow of Funding in Medicare Part B

- **Jay Crosson, M.D.,** *Immediate Past Chairman, Medicare Payment Advisory Commission; Senior Lecturer, Kaiser Permanente School of Medicine, California*

International Perspectives

- **Daniel Goldstein, M.D.**, *Senior Physician, Rabin Medical Center, Petach Tkvah, Israel*

- **Peter Gilbar**, **BPharm, MPallC, FISOPP, FSHP,** *Pharmacist Consultant, Toowoomba Hospital, Australia; Senior Lecturer, School of Medicine, University of Queensland*

Panel Discussion

2:15 pm **Adjourn Open Session**

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.

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Updated June 7, 2018

Speaker Biographical Information

Donald M. Berwick, M.D., MPP, FRCP, KBE
President Emeritus and Senior Fellow
Institute for Healthcare Improvement

Donald M. Berwick is President Emeritus and Senior Fellow at the Institute for Healthcare Improvement (IHI), an organization he co-founded and led as President and CEO for 18 years. He is one of the nation's leading authorities on health care quality and improvement. In July 2010, President Obama appointed Dr. Berwick to the position of Administrator of the Centers for Medicare and Medicaid Services (CMS), which he held until December 2011. As a trained pediatrician, Dr. Berwick has served as a Clinical Professor of Pediatrics and Health Care Policy at the Harvard Medical School, Professor of Health Policy and Management at the Harvard School of Public Health; a member of the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital; and the Brigham and Women's Hospital. He has also served as vice chair of the U.S. Preventive Services Task Force; the first "Independent Member" of the Board of Trustees of the American Hospital Association; and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He is an elected member of the American Philosophical Society, the American Academy of Arts and Sciences, and the National Academy of Medicine (formerly the Institute of Medicine [IOM]). Dr. Berwick served two terms on the IOM's governing Council and was a member of the IOM's Global Health Board. He served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry. He is a recipient of numerous awards; the author and co-author of over 160 scientific articles and six books. He currently serves as a Lecturer in the Department of Health Care Policy at Harvard Medical School.

Jay Crosson, M.D.
Immediate Past Chairman
Medicare Payment Advisory Commission
Senior Lecturer
Kaiser Permanente School of Medicine, California

Dr. Jay Crosson is the immediate past Chairman of the Congressional Medicare Payment Advisory Commission (MedPAC). MedPAC advises Congress on ways to promote high quality coordinated care for beneficiaries and preserve the fiscal integrity of the Medicare program. He was appointed by the U.S. Controller General to MedPAC from 2004 to 2010, 2014 to 2020, and as Chairman from 2015 to 2020.

Previously, Dr. Crosson was the founding Executive Director of The Permanente Federation, the national organization of the Permanente Medical Groups, and the physician component of Kaiser Permanente. He served in that role from 1997 to 2007. Subsequently, he was a Senior Fellow at the Kaiser Permanente Institute for Health Policy. He currently is Senior Lecturer at the Kaiser Permanente School of Medicine in Pasadena California.

Dr. Crosson is the former Chair of the Governing Board of the American Medical Group Association (AMGA). From 2012 to 2014, he was a Group Vice-President of the American Medical Association, where he founded a department dedicated to improving physician practices. He also served on the National Advisory Committee of the Agency for Healthcare Research and Quality (AHRQ) from 2012-2015.

Dr. Crosson received an undergraduate degree in Political Science and in a medical degree from Georgetown University. He completed a residency in Pediatrics at the New England Medical Center Hospitals and a fellowship in Infectious Diseases at the Johns Hopkins University Medical School. He is a graduate of the Kaiser Permanente Executive Program at Stanford Business School.

Peter Gilbar, BPharm, MPallC, FISOPP, FSHP
Pharmacist Consultant
Toowoomba Hospital, Australia
Senior Lecturer
University of Queensland, School of Medicine

Peter Gilbar is a Pharmacist Consultant and Team Leader for the Cancer Care Services Pharmacy at Toowoomba Hospital in Queensland, Australia and a Senior Lecturer at the Rural Clinical School, School of Medicine, University of Queensland. He is a foundation member of the International Society of Oncology Pharmacy Practitioners (ISOPP), whose aim is to promote and enhance oncology pharmacy practice worldwide through networking, education, research and advocacy in order to improve cancer patient care. He currently serves on the ISOPP Research Committee, instigated the ISOPP Virtual Journal Club, and is a long-time member of the Editorial Board of the Journal of Oncology Pharmacy Practice. He has 30 years of experience in clinical oncology pharmacy and is a former Chairperson of the Society of Hospital Pharmacists of Australia (SHPA) Committee of Specialty Practice in Cancer Services. He is a regular contributor to peer reviewed journals and presenter at oncology conferences. Areas of interest and research have included developing strategies to reduce expenditure associated with parenteral cancer drugs, the prevention of medication errors with intrathecal administration of chemotherapy, and rural oncology practice. He holds a Bachelor of Pharmacy from the University of Queensland, a Masters in Palliative Care from Flinders University, and Fellowships from both ISOPP and SHPA.

Daniel Goldstein, M.D.
Senior Physician
Rabin Medical Center, Petach Tkvah, Israel

Dr. Daniel Goldstein is a medical oncologist and internist at Rabin Medical Center in Israel, as well as a senior lecturer in Medical Oncology at Tel Aviv University. He received his medical training at Leeds University, UK, followed by a residency in internal medicine at Montefiore Medical Center in New York and a fellowship in hematology and medical oncology at Emory University, Atlanta. Over the past 5 years, he has published over 50 papers regarding the economics of cancer care both in the U.S. and around the world, focusing on cost-effectiveness,

budget impact, and affordability. This led to his appointment as an adjunct associate professor in the Department of Health Policy and Management, Gillings School of Public Health, University of North Carolina. More recently he has been focusing on opportunities to reduce cancer drug expenditure with dose adjustments, while maintaining health outcomes.

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., is the 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.

Harold Paz M.D., is Executive Vice President and chancellor for health affairs at The Ohio State University and chief executive officer of The Ohio State Wexner Medical Center. Before joining Ohio State in June 2019, he was executive vice president and chief medical officer at Aetna, where he led clinical strategy and policy at the intersection of all of Aetna's domestic and global businesses. He reported to Aetna's chairman and CEO, and was a member of its executive committee. Prior to joining Aetna, he served as president and CEO of the Penn State Hershey Health System, senior vice president for health affairs at the Pennsylvania State University and dean of its College of Medicine for eight years. Before his appointment at Penn State, he spent 11 years as dean of the Robert Wood Johnson Medical School and CEO of the Robert Wood Johnson University Medical Group. He is a fellow of the American College of Physicians and the American College of Chest Physicians. He is currently on the board of Research America. He is past chair of the board of directors of the Association of Academic Health Centers and a former board member of the Association of American Medical Colleges (AAMC) and chair of the AAMC Council of Deans. He has served on a number of corporate and scientific boards in the healthcare and biotechnology field. He received his bachelor's degree from the University of Rochester, a master of science in life science engineering from Tufts University and his medical degree from the University of Rochester School of Medicine and Dentistry. He completed his residency at Northwestern University, where he served as chief medical resident. He was a Eudowood Fellow in pulmonary and critical care medicine at Johns Hopkins Medical School. In addition, he was a postdoctoral fellow in environmental health science at Johns Hopkins School of Hygiene and Public Health.

Deborah Schrag, M.D., is a Medical Oncologist and a health services researcher at the Dana-Farber Cancer Institute. She is chief of the Division of Population Sciences and a professor at Harvard Medical School. She is a clinician with longstanding focus on gastrointestinal cancers, particularly colorectal cancer. She is currently the Principal Investigator of the PROSPECT trial, a National Cancer Institute phase III clinical trial in locally advanced rectal cancer. Prior, she practiced medical oncology in the Division of Gastrointestinal Oncology at Memorial Sloan-Kettering Cancer Center, where she was also an Associate Member and Associate Professor of Public Health and Medicine. Dr. Schrag is a fellow of the American Society of Clinical Oncology, an elected member of the Association of American Physicians and an Associate

Editor of the Journal of the *American Medical Association*. She received her M.D. from Columbia University and M.P.H. from the Harvard School of Public Health.

Ya Chen Tina Shih, Ph.D., is a Professor at the Department of Health Services Research at the University of Texas MD Anderson Cancer Center. She is also Chief, Section of Cancer Economics and Policy, Department of Health Services Research at the university. She applies methods of health economics, health services research, and pharmacoeconomics in medical research, in particular cancer research. She studies the diffusion of new medical technologies among various patients/provider subgroups and/or geographic areas, examines the impact of new technologies on the outcomes and costs of cancer care, and conducts methodological research on the analysis of medical cost data. She is currently working on several funded studies, including research that examines the costs, outcomes, and utilization patterns of new oncologic technology for cancer treatment, evaluates economic implications of targeted oral chemotherapy drugs, and develops novel statistical methods to estimate and project cost trajectories for cancer patients. Other ongoing research includes the assessment of the cost-effectiveness of cancer screening strategies and behavioral interventions. She is associate editor of *Journal of the National Cancer Institute*, and is on the editorial board of *Value in Health*, *PharmacoEconomics,* and *Journal of Oncology Practice*. She is a member of the American Cancer Society Guidelines Development Workgroup and was a member of the National Cancer Policy Forum at the National Academies of Sciences, Engineering, and Medicine.

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.

Holly Taylor, Ph.D., M.P.H., is a Research Bioethicist in the Department of Bioethics, Clinical Center, at the National Institutes of Health. She was formerly Associate Professor in the Department of Health Policy and Management at The Johns Hopkins Bloomberg School of

Public Health, and Core Faculty of the Berman Institute of Bioethics. She has served on the Institutional Review Boards of the Johns Hopkins Bloomberg School of Public Health, Johns Hopkins School of Medicine as well as IRBs in the government and private sector. Her primary interests are research ethics, local implementation of Federal policy relevant to human subject research, and qualitative research methods. She earned a Ph.D. in Bioethics and Health Policy from the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, a M.P.H., from the University of Michigan: School of Public Health, and a B.A. in Human Biology from Stanford University.

Jonathan Watanabe, Pharm D., Ph.D., is a Professor of Clinical Pharmacy and Associate Dean of Assessment and Quality at the University of California, Irvine. He was formerly an Associate Professor of Clinical Pharmacy in the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California San Diego. His research at UC San Diego focuses on pharmaceutical economic policy and health outcomes to improve health at the population level by examining how to improve medication-related health outcomes, particularly for the elderly and underserved populations. He served as an investigator and fellowship director for the San Diego Geriatrics Workforce Enhancement Program. He is a clinical consultant for the Program of All-inclusive Care for the Elderly (PACE) Clinic in San Diego, California. He was the inaugural recipient of the University of Washington/Allergan Global Health Economics and Outcomes Research Fellowship. He serves the California State Legislature as a faculty content expert for the California Health Benefits Review Program and was a member of the advisory group on pain assessment and management standards for long-term care organizations for The Joint Commission. He is a Board Certified Geriatric Pharmacist. He received a B.S. in Zoology from the University of Washington, a Pharm D. from the University of Southern California, a M.S. and Ph.D. from the University of Washington. He was the past recipient of the third NAM Fellowship in Pharmacy and is currently an inaugural Scholar in the NAM Emerging Leaders in Health and Medicine program.

Alastair Wood, M.D., is Emeritus Professor of Medicine and Emeritus Professor of Pharmacology at Vanderbilt University. Previously, he was assistant vice chancellor for Clinical Research and associate dean of Vanderbilt Medical School. He has served as professor of Medicine and professor of Pharmacology at Weill Cornell Medical College in New York and has served on a number of editorial boards. He was a member of the *New England Journal of Medicine* editorial board, served as the *Drug Therapy* Editor of the *New England Journal of Medicine,* and on the editorial board of the *British Journal of Clinical Pharmacology* and the Scientist. He has previously served on the editorial boards of *Clinical Pharmacology and Therapeutics* and *Biopharmaceutics and Drug Disposition*. He authored the chapter in *Harrison's Principles of Internal Medicine* on Adverse Drug Reactions from the 9th through the 15th edition. He received his medical degree from St Andrews University and Dundee Medical School in Scotland. He is a member of the National Academy of Medicine.

K. Robin Yabroff, Ph.D., is an Epidemiologist and Senior Scientific Director, Health Services Research at the American Cancer Society. She also serves as an Adjunct Associate Professor in the Department of Medicine, the Johns Hopkins University and Adjunct Professor in the Department of Health Policy and Management, Rollins School of Public Health, Emory University. Prior to joining the Surveillance and Health Services Research Program at the

American Cancer Society, she held positions within the Office of Health Policy, Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services, the Health Services and Economics Branch of the National Cancer Institute, and the faculty of the Lombardi Cancer Center, Georgetown University. She is an Associate Editor for the Journal of the National Cancer Institute, a founding member of the editorial board of the Journal of Cancer Survivorship, and a member of the editorial board of the Journal of Oncology Practice. She served as a guest editor for the Medical Care journal supplement, Health Care Costing: Data, Methods, Future Directions, and the Journal of the National Cancer Institute journal supplement, Comparing Cancer Care and Economic Outcomes Across Health Systems: Challenges and Opportunities. She holds a M.B.A. from the University of Rochester and her Ph.D. in epidemiology from the Johns Hopkins School of Public Health.

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.