

The National Academies of
SCIENCES • ENGINEERING • MEDICINE
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., (<i>Chair</i>), <i>Committee on Implications of Discarded Weight-Based Drugs</i>
10:40 am	<p>SESSION 1: Federal Agencies Perspectives on Statement of Task</p> <p>Session objective: To explore the intersection of research, policies, and programs of the various federal agencies pertinent to the study’s statement of task</p> <p>Moderators: <i>Tracy Lieu / Alastair Wood</i></p> <ul style="list-style-type: none"> • Centers for Medicare & Medicaid Services <ul style="list-style-type: none"> ○ Sarah Shirey-Losso, Director, Division of Ambulatory Services • Food and Drug Administration <ul style="list-style-type: none"> ○ Jacqueline Corrigan-Curay J.D., M.D., Director, CDER’s Office of Medical Policy • Department of Defense <ul style="list-style-type: none"> ○ Lieutenant Colonel Ronald Khoury, M.D., M.B.A., Chief, Formulary Management Branch, Pharmacy Operations Division, DHA <p>Panel Discussion</p>
11:30 am	Break
11:40 am	<p>SESSION 2: Regulatory Framework</p> <p>Session objective: To explore the regulatory factors that influence drug packaging, quality, and safety distribution and delivery</p> <p>Moderator: <i>Kavita Patel / Jonathan Watanabe</i></p> <ul style="list-style-type: none"> • Drug Stability and Safety <ul style="list-style-type: none"> ○ Brian Serumaga, Ph.D., Science Program Manager, USP • Drug Dosing and Delivery <ul style="list-style-type: none"> ○ Michael Seiden, M.D., Ph.D., President, The US Oncology Network • Pharmaceutical Compounding and Dispensing

	<ul style="list-style-type: none"> ○ Michael Ganio, Pharm.D., FASHP, <i>Director, Pharmacy Practice and Quality, ASHP Office of Practice Advancement</i> ● Rationale for vial-size choices in the pharmaceutical development process <ul style="list-style-type: none"> ○ Kedar Gokhale, Ph.D., <i>Associate Director, Janssen Research & Development Biotherapeutics on behalf of BioPhorum Fill Finish Group</i> <p>Panel Discussion</p>
1:15 pm	Lunch Break
2:00 pm	<p>SESSION 3: Payment Incentives and Reimbursements</p> <p>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</p> <p>Moderator: <i>Robin Yabroff / Harold Paz</i></p> <ul style="list-style-type: none"> ● Payment and Reimbursement Models <ul style="list-style-type: none"> ○ Mireille Jacobson, Ph.D., <i>Associate Professor & Co-Director, USC Leonard Davis School of Gerontology & Aging and Cognition Program, Schaeffer Center for Health Policy & Economics</i> ● Patient Out-of-Pocket and Federal Spending <ul style="list-style-type: none"> ○ Stacie Dusetzina, Ph.D., <i>Associate Professor, Health Policy, Vanderbilt University Medical Center</i> ● Patient Cost Sharing <ul style="list-style-type: none"> ○ Gwen Darien, <i>Executive Vice President, Patient Advocacy and Engagement, National Patient Advocate Foundation, Patient Advocate Foundation</i> ● Medicare Part B Drug Payment Policies and the JW Modifier <ul style="list-style-type: none"> ○ Prabath Malluwa-Wadu, Pharm.D., <i>Pharmacist, CMS</i> ● Determinants of Pharmaceutical Pricing <ul style="list-style-type: none"> ○ Alex Bastian, M.B.A., <i>Vice President, Value And Market Access Galapagos NV</i> <p>Panel Discussion</p>
3:45 pm	Break
4:00 pm	<p>SESSION 4: Stakeholder Perspectives and Potential Strategies</p> <p>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</p> <p>Moderator: <i>Julie Donohue / Bapu Jena</i></p>

	<ul style="list-style-type: none"> • Payer Perspective <ul style="list-style-type: none"> ○ Corbin Bennett, PharmD, MPH, <i>Senior Director of Oncology and Outpatient Infusion Pharmacy Services , Kaiser Permanente</i> • Clinician Perspective <ul style="list-style-type: none"> ○ Richard L. Schilsky, MD, FACP, FASCO, <i>Executive Vice President and Chief Medical Officer, ASCO</i> • Potential Unintended Consequences of Policy Changes <ul style="list-style-type: none"> ○ Amitabh Chandra, Ph.D., <i>Professor of Business Administration, Harvard Business School; Professor of Public Policy and Director of Health Policy Research, Harvard Kennedy School of Government</i> <p>Panel Discussion</p>
5:15 pm	Adjourn Day