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Generic Drug Repurposing: Exploring the Potential Role of the Regulator and Policy Solutions

Hybrid Public Workshop
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Speaker Biographies

Christine Colvis - For the past 13 years, Dr. Colvis has served as the director of the Office of Drug Development Partnership Programs at the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH), where she has been instrumental in collaborating with pharmaceutical companies and academic researchers to advance drug development. As the office's founding director, she provides a vision for and management of a diverse portfolio of projects focused on improving the efficiency of drug development by enhancing technologies such as computational tools, analytical instruments, and laboratory equipment to facilitate scientific progress toward the improvement of health for all people. In 2012, she led the launch of the NIH-Industry Pilot Program: Discovering New Therapeutic Uses for Existing Molecules (NTU), which matched phase II-ready drugs from pharmaceutical companies with academic researchers who had new ideas for the use of those drugs. In 2016, she assembled a team to assess the feasibility of developing a Biomedical Data Translator, a graph-based system that aggregates data from various knowledge sources and databases, encompassing a broad spectrum from clinical information to molecular-level genetic data. The system is designed to enable more informed biomedical research and study design by helping researchers find "knowable unknowns" including drug repurposing opportunities. The alpha version was made publicly available in 2023 at ui.transltr.io.

Devon Crittenden serves as Director of Strategy and Operations at Reboot Rx, a nonprofit dedicated to advancing affordable cancer treatments by repurposing generic drugs. Devon leads initiatives to identify promising drug candidates and increase clinical adoption of low-cost treatments for patients. She was the first author of a recent publication and policy memo with the Reboot Rx team focused on creating a regulatory pathway for nonprofits to drive labeling updates to include new uses of repurposed generic drugs.

David Fajgenbaum, MD, MBA, MSc, is co-Founder & President of Every Cure and a physician-scientist at the University of Pennsylvania where he is one of the youngest faculty members to receive tenure at Penn Medicine. He is also a patient battling a deadly disease who is alive thanks to a repurposed treatment he discovered and described in his national bestselling memoir 'Chasing My Cure'. He has advanced 13 more repurposed treatments for cancers and rare diseases and co-founded Every Cure to unlock more hidden cures, which has received over $100M from ARPA-H and TED's Audacious Project. He has been profiled by The New York Times, Good Morning America, TODAY, and Forbes 30 Under 30 and awarded the Atlas Award along with then VP Joe Biden, Philadelphia Citizen of the Year award, and named to 2025 TIME100 Health as one of the 100 most influential people in health. David earned a BS from Georgetown University, MSc from Oxford University, MD from the University of Pennsylvania, and MBA from Wharton.

Sara Wexler Koblitz is a Director at Hyman, Phelps & McNamara, P.C. in Washington D.C. Ms. Koblitz advises FDA-regulated clients on a range of issues with a particular focus on Hatch-Waxman patent and exclusivity, the Orange Book, the Biologics Price Competition and Innovation Act, biosimilars, and the Purple Book. She helps drug manufacturers in various stages of product development and guides clients through the applicable regulatory requirements with respect to applications and submissions, potential exclusivities, promotional issues, and post-marketing requirements. Ms. Koblitz has written and spoken widely on all aspects of Hatch-Waxman and the BPCIA. Ms. Koblitz graduated from Duke University School of Law in 2012 and from the Johns Hopkins University in 2006.

Heather Stone is a Health Science Policy Analyst at the U.S. Food and Drug Administration, in the Clinical Methodologies Group of the Office of Medical Policy, Center for Drug Evaluation and Research. Ms. Stone joined the FDA upon completing her Master's in Public Health (Concentration: Epidemiology) from the University of Maryland School of Public Health in 2012. She has led the CURE ID program since 2013, which is a joint FDA and NCATS/NIH drug repurposing initiative. Ms. Stone's research focus is on the creation of policies that will encourage drug development for infectious diseases and other diseases with high unmet medical need. She applies her policy expertise to issues related to drug repurposing and innovation in clinical trial design.

Janet Woodcock recently completed a long career at FDA. She served as Director of the Center for Drug Evaluation and Research for over twenty years in several stretches. Most recently she served as Principal Deputy Commissioner and prior to that as Acting FDA Commissioner. She held multiple other senior positions at FDA including at the Center for Biologics Evaluation and Research. She was the therapeutics lead for "Operation Warp Speed" during the COVID pandemic. Her most recent effort was spearheading a major reorganization of FDA's foods program and the Office of Regulatory Affairs. Dr. Woodcock completed many major regulatory initiatives during her FDA tenure. She was instrumental in getting the biosimilars legislation enacted and worked to ensure adoption in the clinical community. Additionally, she worked with industry and Congress to bring about the first GDUFA. After passage of the legislation, she oversaw an extensive reorganization of the generic drug review program at CDER, that successfully met the aggressive targets of the legislation and led to eventual reauthorizing, with elimination of backlogs and approval of thousands of generic drugs.

Moderators Biographies

Beth Boyer is a Policy Research Associate on the Biomedical Innovation team at the Duke-Margolis Institute for Health Policy. Beth primarily works on policy issues related to drug development and equitable global access to medicines, including topics such as the global response to COVID-19 and drug repurposing. Beth brings her background and expertise in global health and access to medicine challenges into her work at Duke-Margolis. Previously, she worked as a Senior Associate at Global Health Strategies providing strategic communications support to clients, primarily supporting the global health programs of a multinational pharmaceutical company. She also worked at the Access to Medicine Foundation as a Researcher for the 2018 Access to Medicine Index, analyzing and ranking the efforts of the world's largest pharmaceutical companies to improve access to medicine in low- and middle-income countries. Beth graduated from Messiah College with a Bachelor's degree in Biology and from Boston University with a Master's in Public Health with a concentration in Global Health.

Tanisha Carino is a senior corporate affairs and health policy expert with more than 20 years of experience providing strategic counsel in business strategy, government affairs and stakeholder management across the public and private sectors. Currently, Tanisha is a Partner at Brunswick Group and is also a Visting Fellow at the Duke-Margolis Insitute for Health Policy. Previously, she served as a Visiting Fellow in the White House Office of Science and Technology Policy, focused on pandemic preparedness. Prior to that, she was Executive Vice President and Chief Corporate Affairs Officer at Alexion Pharmaceuticals. Tanisha has also served as the Executive Director of FasterCures, a center of the Milken Institute, Vice President of U.S. Public

Policy at GlaxoSmithKline and Head of Life Sciences Strategic Advisory Services for Avalere Health. She began her career as an HIV case worker in Atlanta.

Gerrit Hamre is a Research Director in Biomedical Regulatory Policy at the Institute. Gerrit has worked for nearly 20 years in the pharmaceutical industry with a focus on clinical research, regulatory, and commercial roles. Central to much of his career work is extensive internal and external stakeholder engagement to advance innovative, evidence-based healthcare solutions. He has often worked in the drug development and approval environment. Highlights of Gerrit's career so far have included his work in the Food and Drug Administration's Office of Legislation and as a Peace Corps Volunteer in South Africa.