Drug Repurposing: Considerations for Selection Criteria and Prioritization

Hybrid Public Meeting
Wednesday, August 5, 2026
10:30 am – 5 pm ET

Speaker Biographies

Amy Abernethy, MD
CEO, Highlander Health

Dr. Amy Abernethy is cofounder of Highlander Health, with a healthcare career marked by changemaking in organizations ranging from Flatiron Health to Duke University School of Medicine and Verily. Prior to Verily, Amy served as the principal deputy commissioner of the U.S. Food and Drug Administration from 2019–2021. Her board roles span public companies such as athenahealth and CareDx to private firms including insitro and Georgiamune. In addition to her standard setting and innovation work, Amy is a hematologist/oncologist, palliative medicine physician, and author of over 500 publications and counting.

Sundeep Agrawal, MD
Associate Director of Clinical Programs, Oncology Center of Excellence, FDA

Dr. Sundeep Agrawal is a board-certified medical oncologist and currently serves as the Associate Director for Oncology Clinical Programs in the FDA's Oncology Center of Excellence (OCE). He is also the clinical lead for Project Renewal within the OCE, evaluating evidence and providing clinical input for this public health initiative that aims to update the safety and efficacy labeling information for oncology products.

Dr. Agrawal completed his internal medicine residency training at Drexel University College of Medicine and completed fellowship in hematology and oncology at Washington Hospital Center/Georgetown University Hospital. His research interests include novel clinical trial designs and methods to expedite drug development, the treatment of genitourinary malignancies, cell and gene therapies for the treatment of solid tumors, and the application of technology to promote advances in oncology clinical trials.

Mitra Ahadpour, MD
Deputy Director, Office of Translational Sciences, CDER, FDA

Dr. Mitra Ahadpour is a primary care physician and Principal Deputy Director of the Office of Translational Sciences (OTS) at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). She leads scientific collaboration across drug regulatory review, advances the validity of clinical trial design, and promotes the use of quantitative and data-driven approaches in regulatory decision-making. Her work spans OTS's multidisciplinary scientific programs, including biostatistics, clinical pharmacology, pharmacogenomics, and artificial intelligence.

Prior to joining the FDA, Dr. Ahadpour served as Director of the Division of Pharmacologic Therapies at the Substance Abuse and Mental Health Services Administration, where she oversaw opioid treatment program accreditation and national provider training in pain management and substance use disorder treatment. Earlier in her career, while in private practice, she partnered with grassroots community organizations to advance tobacco prevention initiatives that contributed to smoke-free policies across Montgomery County and the state of Maryland. She also serves as an Adjunct Assistant Professor at the Georgetown University School of Medicine, where she develops and teaches curricula on addiction medicine and mental illness.

Dr. Ahadpour has received numerous honors for her leadership and innovation in public health, including the HHS Hubert H. Humphrey Award for Service to America, the HHS Ignite Accelerator Award for the nationwide Rapid Opioid Alert and Response Project—which became the framework for the Overdose Detection Mapping Application Program (ODMAP)—and the Federal Health IT Innovation Award for the Medication-Assisted Treatment (MATx) mobile application.

Dr. Ahadpour earned her Doctor of Medicine degree from the University of Maryland School of Medicine and completed her residency training at The George Washington University Hospital.

Andrew Brack, PhD
Program Manager – Proactive Health Office, ARPA-H

Dr. Andrew Brack joined ARPA-H as a Program Manager in April 2024, where he developed the PROSPR Program: A $144M effort to develop novel clinical endpoints for aging and to test therapeutics that target the aging process directly. For 16 years, his lab (University of California San Francisco and Harvard University), studied the cellular and molecular mechanisms that regulate skeletal muscle repair during aging. He was the co-founder of Arrive Bio, a longevity company that uses machine learning to identify drugs to treat age-related diseases.

Brack received a Ph.D. in molecular biology and biophysics from King's College London and completed two postdoctoral fellowships, one at King's College London and the second at Stanford University. Throughout his career Brack has led multidisciplinary teams with the goal of restoring healthy function during aging.

Marie Bradley, PhD
Senior Advisor RWE, Office of Medical Policy, CDER, FDA

Dr. Marie Bradley is a Senior Advisor for RWE in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER). Her responsibilities related to real-world evidence (RWE) include serving as lead for the Advancing Real-World Evidence Program, the Real-World Evidence Subcommittee, and a portfolio of RWE demonstration projects. She also evaluates complex real-world evidence related study protocols submitted to FDA. Recently, she has been helping to drive Agency level RWE initiatives in the Office of the Commissioner and is co-chair of FDA-RWE-ACCELERATE. Dr Bradley is an established advocate, speaker, and panelist across national and international platforms on RWE related topics and participates extensively in external engagement. She is a pharmacoepidemiologist and a pharmacist with over 16 years of experience working in regulatory, government, and academic sectors in US and the UK, including 12 years at the FDA. Dr. Bradley has a PhD in Pharmacoepidemiology and a Masters in Pharmacy degree from Queen's University Belfast as well as an MSc.PH degree from London School of Hygiene and Tropical Medicine.

Susan Cantrell, RPh, MHL, **CAE**
CEO, Academy of Managed Care Pharmacy

Susan Cantrell is Chief Executive Officer of the Academy of Managed Care Pharmacy (AMCP), the national professional association representing pharmacists and other professionals who manage medication therapy benefits for more than 300 million Americans. A registered pharmacist, she brings a clinical and policy perspective to discussions about how evidence, access, and payer decision-making intersect to support appropriate medication use.

Since joining AMCP in 2016, Susan has led the organization in advancing patient access to high-quality, cost-effective medications, improving health outcomes, and promoting wise stewardship of health care resources. Under her leadership, AMCP has strengthened its role as a voice for managed care pharmacy, expanded its influence in policy and thought leadership, and advanced initiatives addressing affordability, value-based care, real-world evidence, and population health.

Prior to AMCP, Susan held senior leadership roles at the Drug Information Association (DIA) and the American Society of Health-System Pharmacists (ASHP), experience that informs her understanding of the broader drug development, evidence generation, and health-system landscape. She is a frequent speaker on medication access, affordability, and the evolving role of managed care pharmacy. Susan earned her pharmacy degree from the University of Mississippi and completed a postgraduate residency at the University of Mississippi Medical Center. She also holds a master's degree in healthcare leadership, a Certificate in Public Health, and is a Certified Association Executive (CAE).

Christine Colvis, PhD
Director of Drug Development Partnership Programs, NCATS

Dr. Christine Colvis is the Director of the Office of Drug Development Partnership Programs (ODDPP) for the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health. ODDPP promotes innovations that improve efficiency of the discovery and development of or improve quality or accessibility of treatments for patients. Programs range from very early preclinical discovery and exploration of new treatment modalities with the potential to expand the target landscape to the development of therapeutics through early-stage clinical trials. Programs in ODDPP often involve partnerships with the private sector, other parts of the NIH or US Government, or NCATS' own intramural scientists.

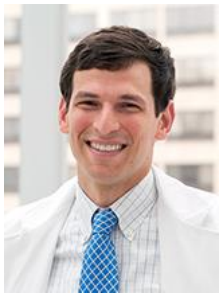
Emily Einstein, PhD
Senior Director, Quality and Science, American Society of Addiction Medicine

Dr. Emily Einstein is Senior Director of Quality and Science at American Society of Addiction Medicine (ASAM), where she supports strategic priorities to improve addiction treatment quality and works on initiatives to improve the adoption of national standards in addiction medicine. Prior to joining ASAM, Dr. Einstein was Chief of Science Policy at the National Institute on Drug Abuse (NIDA), where she led a team that: developed materials to communicate the science of addictive drugs and substance use disorders to members of the public, the scientific community, the media, and the government. Dr. Einstein was also an American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellow in the Office of Autism Research Coordination at the National Institute of Mental Health (NIMH). Dr. Einstein completed her Ph.D. in neuroscience at Yale University, where her research was focused on the molecular and cellular mechanisms of opioid reward.

Brian Fahey
Senior Advisor, Immediate Office of the Commissioner, FDA

Brian Fahey serves as the Senior Advisor to the Commissioner in the Immediate Office at the U.S. Food and Drug Administration (FDA). In his prior role, he led an office charged with being the Agency's leading voice to Congress to advance FDA's top legislative priorities. He joined the FDA in July 2025 as a Senior Advisor before assuming his role as Associate Commissioner for Legislation. Prior to joining the FDA, Brian built nearly a decade long career working as a Congressional staffer for senior Members of Congress. Most recently, he served as a Professional Staff Member on the Health Subcommittee of the House Energy and Commerce Committee under Chairman Brett Guthrie (R-KY), focusing on policies to promote innovation in health care and lower costs for everyday Americans. Before that, he served as Legislative Director for Representative Guthrie, the then-Chairman of the Energy and Commerce Health Subcommittee – work that gave him deep expertise in the American health care system, and specifically the breadth and depth of U.S. Food and Drug Administration policy. Brian holds a Bachelor of Arts in Political Science and Spanish from the University of Delaware, where he was recognized on the University Dean's List and was a member of the National Society of Leadership and Success.

David Fajgenbaum, MD, MBA, MSc
Co-Founder and President, Every Cure



Dr. David Fajgenbaum is co-Founder & President of Every Cure and one of the youngest faculty members ever to receive tenure at the University of Pennsylvania School of Medicine. A physician-scientist and patient battling a deadly disease, he discovered and repurposed a treatment that saved his own life—a story he chronicled in his national bestselling memoir 'Chasing My Cure', which is being adapted into a film by Forrest Gump producer Wendy Finerman. Dr. Fajgenbaum has since advanced 13 more repurposed treatments for cancers and rare diseases and co-founded Every Cure to unlock more hidden cures from existing medicines. Every Cure 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 honored with awards including the Atlas Award alongside then VP Joe Biden, Philadelphia Citizen of the Year Award, and named to the 2025 TIME100 Health list of the world's most influential people in health. Dr. Fajgenbaum earned a BS from Georgetown University, MSc from the University of Oxford, MD from the University of Pennsylvania, and MBA from Wharton.

Emily Freilich, MD
Director, Division of Neurology, Office of New Drugs, CDER, FDA

Dr. Emily Freilich is the Director of the Division of Neurology 1 within the Office of New Drugs in FDA's Center for Drug Evaluation and Research. Dr. Freilich is a board-certified pediatric neurologist. Dr. Freilich graduated from Duke University with a Bachelor of Science degree in biology and received her medical degree from Rutgers-New Jersey Medical School. She completed her pediatric residency and child neurology training at Children's National Health System in Washington, D.C. Prior to joining FDA, Dr. Freilich worked at Children's National and the Pediatric Specialists of Virginia, where she was a general child neurologist with special interest in rare pediatric epilepsies, served as co-director of the Tuberous Sclerosis Clinic, and was an Assistant Professor of Pediatrics and Neurology at George Washington University School of Medicine. She joined the Division of Neurology Products at FDA in 2016 as a clinical reviewer and subsequently transitioned to a team leader in the Division of Neurology 1 for review of treatments for neuromuscular and rare neurologic disorders. She subsequently served as Acting Deputy Director in the Division of Neurology 1 prior to her current role.

Pamela Gavin, MBA
CEO, National Organization for Rare Disorders

As Chief Executive Officer of the National Organization for Rare Disorders (NORD®), Pamela Gavin, MBA, leads the nation's longest-standing rare disease advocacy organization. Pam is a seasoned health care executive and passionate advocate who unites stakeholders to drive innovation to improve the lives of the 30 million-plus Americans living with rare diseases. Since joining NORD in 2012, Pam has spearheaded groundbreaking initiatives, including the NORD® Rare Disease Centers of Excellence, a first-of-its-kind, nationwide network dedicated to diagnosing, treating, and researching rare diseases. She also led the

development of IAMRARE®, the first natural history patient registry platform for the rare disease community, and expanded NORD's RareCare® program, which has provided nearly $175 million in financial assistance to patients and caregivers over the past five years. As a trusted leader in the rare disease community, Pam is committed to strengthening the systems that support people living with rare diseases.

Matt Hall, PhD
Scientific Director, National Center for Advancing Translational Sciences

Dr. Matt Hall is the Director of the Early Translation Branch (ETB) within the Division of Preclinical Innovation, where he oversees the activities of the branch's early discovery efforts. As Director of ETB, Hall has worked to build partnerships with other institutes at NIH to address unmet medical needs. He is currently co-chair of the NCI Chemical Biology Consortium (of which ETB is a member), co-chair of the NIH ACTIV TRACE group addressing COVID variants and therapeutics, oversees an ETB collaborative program for the NIH HEAL Initiative, created a discovery partnership with the NCI Natural Products Program, and established the Antiviral Program for Pandemics with NIAID and Biomedical Advanced Research and Development Authority (BARDA).

Hall joined NCATS in 2015 as a Biology Group Lead in the NCATS Chemical Genomics Center. Prior to joining NCATS, Hall worked as a staff scientist and postdoctoral fellow at NCI in the Laboratory of Cell Biology with Dr. Michael M. Gottesman, was an American Australian Association Sir Keith Murdoch Fellow at Johns Hopkins Bloomberg School of Public Health, and was trained at the University of Sydney, Australia. He has published more than 160 peer-reviewed papers and is on the editorial boards of Drugs of the Future and ACS Pharmacology & Translational Science.

Caroline Huang, PhD
Supervisory General Health Scientist, Controlled Substances Initiatives, CDER, FDA

Dr. Caroline J. Huang, is a Supervisory General Health Scientist at FDA, where she leads the Controlled Substances Initiatives team in the Center for Drug Evaluation and Research (CDER). In this role, she works to prevent overdoses and reduce deaths through evidence-based policy on opioids, psychedelics, ketamine, stimulants, benzodiazepines, cannabis, and other substances. Prior to joining CDER in August 2020, Dr. Huang spent a year as a Staff Fellow in FDA's Office of Women's Health, where she covered issues related to COVID19 and managed the team's social science portfolio. She also completed a Bioethics Fellowship with the NIH Clinical Center, where she researched chronic pain and opioid use disorders and served as a bioethics consultant. She holds an SB in Brain and Cognitive Sciences from the Massachusetts Institute of Technology and a PhD (DPhil) in Public Health from the University of Oxford, where she was a Rhodes Scholar.

Huong Huynh, PhD
Director of Regulatory Science, Critical Path Institute

Dr. Huong Huynh is the Director of Regulatory Science at Critical Path Institute (C-Path) and Professor of Practice at The University of Arizona James E. Rogers College of Law. At C-Path, Huong leads the development of regulatory strategies for the organization and bridges communication with regulatory authorities (FDA and EMA). Prior to joining C-Path, Huong was a review pharmacologist at FDA. At The University of Arizona, Huong serves as instructor for LAW 576A: Drug Discovery, Development, and in the Market and LAW589A Regulatory Science Case Study Project courses as part of the Graduate Certificate in Regulatory Science program. Huong earned her PhD in pharmacology and completed postdoctoral training under an NIH T32 training grant.

Shari Ling, MD
Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services

Dr. Shari M. Ling is currently the Centers for Medicare and Medicaid Services (CMS), Deputy Chief Medical Officer serving CMS and the Center for Clinical Standards and Quality (CCSQ), in the Agency's pursuit of optimizing health outcomes. Her committed focus is on the achievement of meaningful health outcomes for patients and families through the delivery of high quality, person-centered care, across all care settings. Her clinical focus and scientific interest are in the care of persons with dementia, multiple chronic conditions, and functional limitations. In addition to a clinician leadership role across CMS, Dr. Ling has represented CMS on several HHS committees and workgroups including the National Alzheimer's Project Act FACA, Behavioral and Mental Health, Interagency Coordinating Committee on Healthy Aging and Age-Friendly Communities, The Advisory Council on Parkinson's Research, Care, and Services (ACPRCS) and the Scientific Integrity Council. Dr. Ling received her medical training at Georgetown University School of Medicine where she graduated as a member of the Alpha Omega Alpha Honor Society. Dr. Ling received her clinical training in Internal Medicine and Rheumatology at Georgetown University Medical Center and completed Geriatric Medicine fellowship at Johns Hopkins University. She joined the Johns Hopkins University faculty for 5 years, after which she joined the Intramural Research Program of the National Institutes of Health at the National Institute on Aging as a Staff Clinician for 8 years studying human aging and age-associated chronic diseases with attention to musculoskeletal conditions and mobility function. She has authored over 100 publications over her career. Dr. Ling continues to serve as a part-time faculty member in the Division of Geriatric Medicine and Gerontology at Johns Hopkins University School of Medicine and serves as volunteer faculty for the dementia clinic with the Baltimore VA Medical Center - VA Maryland Health Care System in Baltimore. Prior to her medical training, she earned her Masters' Degree in Gerontology, from the Leonard Davis school of University of Southern California and subsequently served as the co-director of clinical services with the Andrus Older Adult Counseling Center.

Donald Lo, PhD
Director of Medicines Development and Scientific Lead, REMEDi4ALL

Dr. Donald Lo is the Director for Medicines Development at the European Infrastructure for Translational Medicine (EATRIS) and Scientific Lead of the REMEDi4ALL European Platform for Medicines Repurposing. Don previously headed the Therapeutic Development Branch at the National Center for Advancing Translational Sciences (NCATS) at the US NIH which has brought over 50 new and repurposed drugs into clinical trials with 5 drug approvals to date. Don joined the NIH following a 27-year academic career at Duke University Medical Center, during which time he also co-founded and led 2 biotechnology companies and a non-profit patient care organization for Huntington's disease, and served as a lead science advisor for Accelerate Brain Cancer Cure (ABC2). Don is a graduate of the California Institute of Technology, received his PhD from Yale University, and conducted postdoctoral research at the Ludwig Institute for Cancer Research at University College London.

Marta Sokolowska, PhD
Deputy Center Director for Substance Use and Behavioral Health, CDER, FDA

Dr. Marta Sokolowska is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs.

Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use.

Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Heather Stone, MPH
Health Science Policy Analyst, Office of Medical Policy, CDER, FDA

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.

Danielle Turley, PhD
Acting Director, Division of Regulatory and Quality Affairs, Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services

Dr. Danielle Turley currently serves as Acting Director of the Division of Regulatory and Quality Affairs (RQA) within BARDA, where she leads a team of 28 professionals overseeing regulatory affairs, regulatory operations, and quality affairs in support of medical countermeasure development. In this role, she serves as the primary point of contact for the ASPR/FDA Memorandum of Understanding and as Sponsor's Representative for BARDA-sponsored regulatory submissions, working closely with FDA to ensure that products developed through BARDA's programs meet all applicable regulatory requirements.

Dr. Turley brings more than 18 years of experience spanning government contracting, regulatory science, and product development. Prior to her current role, she spent five years as Branch Chief for BARDA's Regulatory Affairs Branch, leading regulatory coordination for the Mpox and COVID-19 public health emergency responses, and five years as a Contracting Officer Representative in BARDA's Chemical, Biological, Radiological and Nuclear (CBRN) Countermeasures Division, where she provided technical and regulatory oversight for advanced development programs spanning drugs, biologics, vaccines, devices, and diagnostics.

Before joining BARDA, Dr. Turley spent seven years as a scientific reviewer at the FDA, first as a Commissioner's Fellow and CMC reviewer in the Center for Biologics Evaluation and Research (CBER) working on stem cell and cellular therapeutics, and later as a regulatory reviewer in the Center for Devices and Radiological Health (CDRH), where she evaluated premarket submissions for in vitro diagnostic devices. This combination of FDA review experience and BARDA program leadership has given her a comprehensive perspective on the regulatory pathways available for advancing medical products—including opportunities to identify new uses for already-approved therapies to meet urgent and emerging public health needs.

Dr. Turley holds a Ph.D. in Microbiology-Immunology from Northwestern University and a B.S. in Biology from James Madison University.

Janet Woodcock, MD
Former FDA Acting Commissioner

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.

Moderator

Susan C. Winckler, RPh, Esq
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, and other stakeholders with a neutral forum to address domestic and global issues. As Chief of Staff for the FDA (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow, served as an elected member of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025) and Chair of that Board from 2019 to mid-2025. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of Pharmacy.