REAGAN-UDALL FOUNDATION FOR THE FDA

Accelerated Approval Program

30 Years On - Insights and Experiences

Virtual Public Meeting

March 11, 2022

Speaker and Moderator Biographies

Panel Presentation: Accelerated Approval 1992–2022

Jacqueline Corrigan-Curay, JD, MD
Principal Deputy Center Director, Center for Drug Evaluation and Research, U.S. Food & Drug Administration

Dr. Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations.

Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes.

Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), 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 VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, DC.

Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's degree in history of science from Harvard/Radcliffe College in Cambridge, MA. She completed her training in internal medicine at Georgetown University Medical Center, where she also served as a clinical assistant professor of medicine. She has continued to practice internal medicine part-time at the Veterans Affairs Medical Center in Washington, DC.

Kevin Fain, JD, MPH, DrPH
Senior Policy Advisor, Office of New Drug Policy, Center for Drug Evaluation and Research, U.S. Food & Drug Administration

Dr. Kevin Fain is a senior policy advisor in the Office of New Drug Policy in the Center for Drug Evaluation and Research at FDA. He previously served as a senior advisor at the National Library of Medicine, where he helped lead quantitative research and develop policies for the ClinicalTrials.gov program. From 1995 until 2010 he worked as an attorney in the Office of Chief Counsel at

FDA, specializing in drug regulatory matters. He earned his master's degree in public health in 2011 and his doctoral degree in Epidemiology in 2015 from Johns Hopkins University, and his law degree from the University of Chicago.

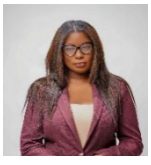
Gautam Mehta, MD
Clinical Reviewer and Medical Officer, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food & Drug Administration
Dr. Gautam Mehta received his medical degree from Georgetown University in 2010. He completed Neurosurgery residency at the NIH - University of Virginia joint program, followed by a Neurosurgical Oncology and Skull Base Surgery fellowship at M.D. Anderson Cancer Center. He was a member of the Neurosurgery faculty and Chair of the Research Committee at the House Ear Institute prior to joining FDA with the Division of Oncology 2 in 2020. He has published over 80 scientific papers and book chapters related to neuro-oncology and currently serves as the Scientific Liaison for Adult Neuro-Oncology at FDA's Oncology Center for Excellence. He is an Associate Editor for the Journal of Neuro-Oncology, Chair of the Endolymphatic Sac Tumors/Audiologic Screening Guidelines Subcommittee for the VHL Alliance, and a member of the Executive Committee for the American Association of Neurological Surgeons/Congress of Neurosurgeons Section on Tumors. At FDA, he leads the Oncology Center of Excellence's Project Confirm, an initiative to increase the transparency around the Accelerated Approval program for oncology indications.

Patient Perspective Panel

Katherine Couvillon, patient with cancer
Katherine Couvillon is a former data analyst for a large health system and is currently living with metastatic breast cancer. She writes about her life and health at www.lifecancergrace.com

Alberto Rubio, MBA, patient with HIV
Alberto Rubio was an ICU Respiratory Therapy Supervisor at Baylor Medical Center, Parkland, Children's Medical Center. He holds master's degrees in both business administration and in information systems from the University of Dallas. He was diagnosed with HIV in 1987.

Navdeep Singh, PhD, patient with beta-thalassemia
Navdeep Singh was born and raised in Detroit, MI. At 9 months of age, he was diagnosed with beta-thalassemia and has been receiving blood transfusions every 3-4 weeks. He was previously taking Desferal subcutaneously every night before Jadenu. Desferal was quite tough to administer especially when learning how to do it at the age of 10. Having an oral pill that chelated more effectively than IV subQ Desferal was lifechanging.



Teonna Woolford, patient with sickle cell disease
Teonna Woolford was born and raised in Baltimore, MD. She has always been talkative, friendly, and full of life. She has Sickle Cell Anemia SS and has faced numerous health complications as a result. A true fighter at heart, she has recovered from numerous complications including bilateral hip replacements, a failed bone marrow transplant, many pain crises, and

several other complications. She has a zeal for effecting change throughout the Sickle Cell community and understands the realities of those impacted by the disease. While sickle cell has been a huge part of her life, she does her best not to let sickle cell define who she is. Ms. Woolford has been blessed to sit at some incredible tables and contributed to publications and working committees with the American Society of Hematology and NHLBI. She is also the founder and CEO of a new nonprofit organization, The Sickle Cell Reproductive Health Education Directive.

Fireside Chat Panelists

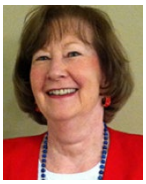
Julie R. Gralow, MD, FACP, FASCO
Chief Medical Officer, American Society of Clinical Oncology
Dr. Gralow is the Chief Medical Officer (CMO) and Executive Vice President of ASCO and brings to her role deep expertise in patient care, research, education, and global health.

Previously, she was the Jill Bennett Endowed Professor of Breast Cancer at the University of Washington School of Medicine, Professor in the Clinical Research division of the Fred Hutchinson Cancer Research Center, as well as Director of Breast Medical Oncology at the Seattle Cancer Care Alliance.

Dr. Gralow is strongly committed to advancing equity in cancer care. As founder of the Women's Empowerment Cancer Advocacy Network (WE CAN), she supports patient advocates in low- and middle-resource countries. In addition, she served as an adjunct professor in the University of Washington's Department of Global Health, as a member of the University of Washington's Breast Cancer Equity Initiative, as Medical Director for Women's Cancer-related Population Health at the University of Washington, and as an advisory council member for the Uganda Cancer Institute's adult Hematology/Oncology Fellowship Training Program. Dr. Gralow received the ASCO Humanitarian Award in 2018 for her work in empowering women cancer patients and survivors globally.

She is a recognized leader in breast cancer clinical research, and has conducted clinical trials in breast cancer prevention, treatment, and survivorship. Dr. Gralow served in leadership roles for the SWOG Cancer Research Network funded by the National Cancer Institute (NCI), including as Vice Chair of the Breast Cancer Committee and Executive Officer of Breast and Lung Cancer.

Dr. Gralow received her bachelor's degree from Stanford University and her medical degree from the University of Southern California School of Medicine. She trained in internal medicine at Brigham and Women's Hospital at Harvard Medical School and completed a medical oncology fellowship at University of Washington/Fred Hutchinson Cancer Research Center in Seattle.



Kay Holcombe, MS
Board Chair, National Organization for Rare Disorders
Kay Holcombe is Board Chair of the National Organization for Rare Disorders. She formerly served as Senior Vice President for Science Policy at BIO, the Biotechnology Innovation Organization. During her time at BIO, she worked with the BIO CEO and Board, BIO's health policy, reimbursement, government affairs, and alliance development staff to formulate, develop, and advance BIO principles, programs, and strategies relating to health policy matters that are of interest to and affect BIO member companies.

Prior to this, as Senior Policy Advisor and Vice President for Government Relations at Genzyme, a Sanofi Company, Ms. Holcombe worked to develop and implement corporate policies and appropriate responses to government initiatives in the regulatory and health policy arenas.

Before joining Genzyme in 2006, Ms. Holcombe spent 8 years as Executive Vice President of Policy Directions Inc., a government relations firm specializing in strategic planning and legislative and regulatory advocacy regarding health care and related issues.

She served as professional health legislative staff and senior health policy advisor for the House of Representatives Committee on Energy and Commerce; health legislative staff for the Senate Committee on Labor and Human Resources; Deputy Associate Commissioner for Legislative Affairs, U.S. Food and Drug Administration; Executive Vice President of the Foundation for Biomedical Research (advocating on behalf of the appropriate and necessary use of animals in research); Associate Director for Public Health Legislation, Office of the Assistant Secretary for Legislation, U.S. Department of Health and Human Services; Deputy Associate Administrator for Planning, Evaluation, and Legislation, Health Resources and Services Administration, U.S. Public Health Service; Special Assistant to the Director, Division of Legislative Affairs, National Institutes of Health; Executive Secretary, National Heart, Lung, and Blood Institute National Advisory Council; and researcher, National Heart, Lung, and Blood Institute, National Institutes of Health.

Ms. Holcombe is a member of the board of the National Capitol chapter of the National Multiple Sclerosis Society and of the National Blood Clot Alliance. She received her master's degree in chemistry from the University of Virginia.

Michelle McMurry-Heath, MD, PhD
President & CEO, Biotechnology Innovation Organization
Dr. Michelle McMurry-Heath assumed the leadership of the Biotechnology Innovation Organization (BIO) as President and CEO on June 1, 2020. A medical doctor and molecular immunologist by training, Dr. McMurry-Heath becomes just the third chief executive to steward the world's largest biotechnology advocacy group since BIO's founding in 1993.

BIO represents 1,000 life sciences companies and organizations from 30 countries. The organization's mission is to support companies that discover and deploy scientific breakthroughs that improve human health, environmental stewardship, and sustainable agriculture.

The common thread in McMurry-Heath's work across academia, government and industry has been her focus on broadening access to scientific progress so more patients from diverse backgrounds can benefit from cutting-edge innovation. Driven by her own past family experiences navigating clinical trials and funding uncertainties within the rare disease community, McMurry-Heath calls "the distribution of scientific progress the social justice issue of our age."

She comes to BIO from Johnson & Johnson where she served as Global Head of Evidence Generation for Medical Device Companies and then Vice President of Global External Innovation and Global Leader for Regulatory Sciences. She was also instrumental in bringing J&J's incubator, JLabs, to Washington, DC. She led a global team of 900 with responsibilities in 150 countries around the globe.

Prior to her time at J&J, Dr. McMurry-Heath was also a key science policy leader in government. The Obama-Biden transition team tapped her to conduct a comprehensive analysis of the National Science Foundation's policies, programs and personnel. President Obama then named her associate science director of the FDA's Center for Devices and Radiological Health under Commissioner Peggy Hamburg. In

that role, she championed clinical trial evolution, the use of real-world evidence in product evaluation, and an embrace of the patient's voice in health research so new medical products deliver outcomes that matter to them.

McMurry-Heath was the founding director of the Aspen Institute's Health, Biomedical Science, and Society Policy Program, where she promoted personalized medicine and bolstered international preparation for pandemic disease threats. She received her early training in science policy from the Robert Wood Johnson Foundation and later served as Senator Joe Lieberman's top legislative aide for science and health. In that role, she drafted legislation to protect the country from biological attacks.

McMurry-Heath received her medical and doctoral degrees from Duke's Medical Scientist Training Program, becoming the first African American to graduate from the prestigious program. She spent 12 years working at the research bench before taking policy and leadership roles in government and industry.

Michael Sherman, MD, MBA
Chief Medical Officer, Point32 Health

Dr. Michael Sherman is chief medical officer of Point32Health, providing clinical medical leadership to enhance quality of care and outcomes for health care consumers. He is responsible for medical trend management and assessing clinical partnerships, clinical innovations, and models of care. He also oversees medical policies and guidelines, including disease and care management services and wellness offerings that enhance the whole-person health care approach.

Michael was previously chief medical officer and senior vice president for health services at Harvard Pilgrim Health Care, which he joined in 2011. A pioneer in developing innovative, outcomes-based reimbursement models that engage providers and pharmaceutical and diagnostics companies, he is credited with cementing Harvard Pilgrim's position as a leader among insurers in crafting agreements that tie drug payments to performance.

Michael is responsible for overseeing the Harvard Pilgrim Health Care Institute, which encompasses the Department of Population Medicine at Harvard Medical School—the nation's only appointing medical school department based in a health plan. He is also a faculty member of the department and previously practiced as a cardiac anesthesiologist. He holds board appointments with several nonprofits, including the Institute for Clinical and Economic Review, the Personalized Medicine Coalition, the Harvard Business School Healthcare Initiative, the Center on Media and Child Health, the Museum of Science, and the Network for Excellence in Health Innovation.

His previous roles include corporate medical director for physician strategies at Humana, vice president for network and consumer solutions at UnitedHealth Group's subsidiary Ingenix (now part of Optum), and chief business development officer for United's Medicare Part D business.

He holds a medical degree. from Yale University, a master's degree in business administration from Harvard Business School, and master's and bachelor's degrees from the University of Pennsylvania.

Meeting 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. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA.

Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions, a national healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Ms. Winckler directly advised CEOs and C-suite executives of life-sciences and pharmaceutical companies, payers, health-care providers, government agencies, employers, and associations on international, federal and state public policy and regulation, business strategy, investments, M&A, and other major business matters. Ms. Winckler also served as Chief Risk Management Officer for the entire Leavitt Partners family of businesses. Before becoming President, her role leading the DC office for Leavitt Partners included serving as Interim Executive Director of the Health Care Transformation Task Force, an alliance of patients, payers, providers, and purchasers committed to moving 75% of their businesses to value-based payment by 2020.

A pharmacist and attorney by training, Ms. Winckler was CEO of the Food & Drug Law Institute, which serves nearly all major law firms' food and drug practices, government regulators, leaders of pharmaceutical, device, food and tobacco companies, and consumers with class-leading legal and regulatory resources, analyses, updates, journals, and conferences. She provided a neutral forum for these stakeholders to address domestic and global food and drug law issues. She also served on FDLI's board.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), Ms. 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 the White House, myriad government entities, and external stakeholders. She was unique among her predecessors in also simultaneously leading FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. In 2007, she led FDA's medical product negotiation with China's then-State Food and Drug Administration, resulting in the Product Safety Memorandum of Agreement between the two nations. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.

Ms. 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, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council. She previously served on the boards of the Partnership for Safe Medicines and the American Society of Pharmacy Law, and on the executive leadership board for the Univ. of Iowa College of Pharmacy.