



## COVID-19 Lessons Learned: Clinical Evaluation of Therapeutics Virtual Public Workshop

September 28, 2021

### Speaker Bios

#### Keynote Speakers

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##### **Janet Woodcock, MD**

##### **Acting Commissioner, U.S. Food and Drug Administration (FDA)**



Dr. Janet Woodcock began her long and distinguished FDA career in 1986 with the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs. She also served as CBER's Acting Deputy Director, and later as Director of the Office of Therapeutics Research and Review.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. In that position, she has led many of the FDA's groundbreaking drug initiatives. She has also served in other leadership roles at the FDA, including as Deputy Commissioner and Chief Medical Officer.

With the onset of the COVID-19 public health emergency last year, Dr. Woodcock was asked to lend her expertise to "Operation Warp Speed" the initiative to develop therapeutics in response to the pandemic.

Dr. Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

Dr. Woodcock has received numerous honors during her distinguished public health career, including: a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute; and the 2020 Lifetime Achievement Award from NORD. She is also an avid and accomplished gardener.

##### **Francis Collins, MD, PhD**

##### **16th Director, National Institutes of Health (NIH)**



Dr. Francis S. Collins was appointed the 16th Director of the National Institutes of Health (NIH) by President Barack Obama and confirmed by the Senate. He was sworn in on August 17, 2009. In 2017, President Donald Trump asked Dr. Collins to continue to serve as the NIH Director. President Joe Biden did the same in 2021. Dr. Collins is the only Presidentially appointed NIH Director to serve more than one administration. In this role, Dr. Collins

oversees the work of the largest supporter of biomedical research in the world, spanning the spectrum from basic to clinical research.

Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the international Human Genome Project, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. He served as director of the National Human Genome Research Institute at NIH from 1993-2008.

Dr. Collins is an elected member of both the National Academy of Medicine and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in November 2007, and received the National Medal of Science in 2009. In 2020, he was elected as a Foreign Member of the Royal Society (UK) and was also named the 50th winner of the Templeton Prize, which celebrates scientific and spiritual curiosity.

## Panelists

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### **Stacey Adam, PhD**

#### **Associate Vice President, Research Partnerships, Foundation for the National Institutes of Health (FNIH)**



Dr. Stacey Adam plays a leadership role at the FNIH, helping to lead many public-private partnerships, such as Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), the PPP that evaluated hundreds of available therapeutic agents with potential application for COVID-19, prioritized them, and designed and launched multiple master protocols to test them. She oversees the Cancer, Metabolic Diseases and Clinical COVID Research portfolios at the Foundation for the National Institute of Health (FNIH). Beyond ACTIV other major partnerships under her guidance include the two steering committees of the Biomarkers Consortium and their projects, Partnership for Accelerating Cancer Therapies (PACT) and the Lung Master protocol (Lung-MAP) clinical trial. Prior to FNIH, she was a Manager at Deloitte Consulting within the Federal Life Sciences and Healthcare Strategy. She received her PhD at Duke and postdoctoral training at Stanford.

### **Phyllis Arthur, MBA**

#### **Vice President of Infectious Diseases and Emerging Science Policy, Biotechnology Innovation Organization (BIO)**



Phyllis Arthur is Vice President for Infectious Diseases and Diagnostics Policy at the Biotechnology Innovation Organization (BIO). In this role Ms. Arthur is responsible for working with member companies in vaccines, antimicrobial resistance, molecular diagnostics and biodefense on policy, legislative and regulatory issues. Ms. Arthur joined BIO in July 2009 as the Director of Healthcare Regulatory Affairs.

Prior to joining BIO, she worked in numerous marketing and sales positions for Merck & Co Inc in their Vaccine Division. Over her 16-year career at Merck, Ms. Arthur launched several exciting new vaccines in the United States and internationally, including the first HPV vaccine, GARDASIL. During her years in Marketing, she worked closely with clinical and academic thought

leaders in infectious diseases, oncology and public health. In addition, Ms. Arthur also led a large vaccine sales organization of over 75 representatives and managers covering 14 states.

Before graduate school, Ms. Arthur worked as a research assistant for two economists at the Brookings Institution in Washington, DC. There she conducted economic analyses related to savings and investment policies for the OECD countries.

Ms. Arthur received her B.A. in 1987 in Economics and International Politics from Goucher College and her M.B.A. in 1991 from the Wharton School of Business at the University of Pennsylvania.

### **Barbara Bierer, MD**

#### **Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital**



Dr. Barbara E. Bierer, a hematologist-oncologist, is Professor of Medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH). Dr. Bierer co-founded and now leads the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve standards for the planning and conduct of international clinical trials. In this capacity, she works with regulators, pharmaceutical companies, CROs, academia and patients/patient advocates to harmonize policies and approaches for multisite, transnational trials.

She is a co-founder of COVID-19 Collaboration Platform and of the non-profit Vivli, a global clinical research data sharing platform. She is also the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst, and Director of Regulatory Policy for SMART IRB. She serves as Faculty in the Center for Bioethics, HMS, and Affiliate Faculty in the Petrie-Flom Center for Health Law at Harvard Law School. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub. She is a past chair of SACHRP and has served or serves on the Board of Directors of AAHRPP, PRIMR, MSH, Vivli, North Star IRB, and the Edward P. Evans Foundation. She has authored over 250 publications.

### **Sam Brown, MD, MS**

#### **Professor of Research and Senior Medical Director for Clinical Trials, Intermountain Healthcare, and Professor of Medicine, University of Utah**



Dr. Samuel M. Brown is Professor of Research and Senior Medical Director for Clinical Trials at Intermountain Healthcare and Professor of Medicine at University of Utah, both in Salt Lake City. He is a practicing critical care physician at Intermountain Medical Center. Dr. Brown's scientific focus is on clinical trials and translational research in Acute Respiratory Distress Syndrome (ARDS) and sepsis, with special technical expertise and interest in echocardiography, machine learning, and long-term outcomes after critical illness. His research is supported by

National Institutes of Health, Department of Defense, and Centers for Disease Control and Prevention, and he has chaired or co-chaired multiple large interventional trials and cohorts in sepsis and ARDS, including chairing the ACTIV-3b trial of therapeutics for critically ill patients with COVID and co-chairing the ORCHID trial. He lives in Salt Lake City with his wife and three daughters and loves mountain biking, non-motorized water sports, and reading.

## **Janice Chang**

### **Chief Operating Officer, TransCelerate BioPharma Inc.**



Janice Chang is the Chief Operating Officer at TransCelerate BioPharma Inc. She has been involved with the organization since its inception. In her current position, Janice works closely with the CEO and the Board of Directors to shape the long-term strategic vision and priorities for the organization and its 30+ initiatives. Ms. Chang defines and guides TransCelerate's overall external engagement strategy with global health authorities, governmental agencies, industry groups, and TransCelerate's country network spanning across 30 countries. She has accountability overseeing TransCelerate's corporate operations and works closely with her team to drive strategic delivery of TransCelerate's portfolio.

Ms. Chang also actively participates in various cross-stakeholder global discussions to help evolve their R&D paradigm. Most recently she joined the Advisory Council for HL7 International's Vulcan Accelerator. Vulcan is a global strategic effort to bring together stakeholders across the translational and clinical research community to align on data exchange standards to bridge existing gaps between clinical care and clinical research, enabling more effective acquisition, exchange and use of healthcare data in translational and clinical research.

With a background of 20+ years of experience leading initiatives in large pharma and biotech companies, Janice has experience spanning across regulatory, clinical, and manufacturing. Janice is passionate in driving meaningful change across our ecosystem and not settling for the status quo. She believes in reimagining the way we advance innovative medicine and advocates for the power of open collaboration across stakeholder groups.

## **D. Clark Files, MD**

### **Associate Professor, Pulmonary and Critical Care Medicine, Wake Forest School of Medicine**



Dr. Clark Files is a critical care physician-scientist. He is an investigator in a number of COVID-19 clinical trials and is Co-Chair of Operations of the I-SPY COVID Clinical Trial.

## **Esther Krofah**

### **Executive Director, FasterCures and the Center for Public Health, Milken Institute**



Esther Krofah is the executive director of FasterCures and the Center for Public Health at the Milken Institute. She has deep experience in the government, nonprofit, and for-profit sectors, where she has led efforts to bring together diverse stakeholder groups to solve critical issues and achieve shared goals that improve the lives of patients. Most recently, Krofah was the director of public policy leading GlaxoSmithKline's engagement with the U.S. Department of Health and Human Services (HHS) and relevant Executive Branch agencies on broad healthcare policy issues, including leadership in improving vaccinations and care for people living with HIV. Prior to GSK, Krofah served as the deputy director of HHS' Office of Health Reform, where she led the development of policy positions for significant regulatory priorities, including the health insurance marketplaces. Prior to HHS, Krofah served as a program director at the National Governors

Association (NGA) health-care division, working directly with governors' health policy advisors, state Medicaid directors, and state health commissioners on health insurance, health workforce, and Medicaid coverage issues. Before joining the NGA, Krofah worked in consulting at Deloitte Consulting LLP, where she worked with public sector and commercial clients, including assisting states in developing state-based exchanges. Krofah received a BA from Duke University and a Master of Public Policy from the Harvard University John F. Kennedy School of Government.

**Michael Kurilla, MD, PhD**

**Director, Division of Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health**



Dr. Michael Kurilla is the director of the Division of Clinical Innovation at NCATS. In this capacity, he oversees the Clinical and Translational Science Awards (CTSA) Program, which supports innovative solutions to advance the efficiency, quality and impact of translational science, with the ultimate goal of getting more treatments to more patients more quickly. Prior to joining NCATS, Dr. Kurilla served as the director of the Office of Biodefense Research Resources and Translational Research within the National Institute of Allergy and Infectious Diseases (NIAID), where he focused on translational efforts toward infectious disease product development, including vaccines, therapeutics and diagnostics, with emphasis on biodefense and emerging infectious disease threats. Prior to joining NIAID in 2003, Dr. Kurilla was an associate director for infectious diseases at Wyeth. He also worked in antimicrobials at DuPont and on clinical microbiology and molecular pathology at the University of Virginia Health Sciences Center.

Dr. Kurilla received his MD and his PhD in microbiology and immunology from Duke University. He was a postdoctoral research fellow at Harvard Medical School and completed a residency in pathology at Brigham and Women's Hospital. He received a B.S. in chemistry from the California Institute of Technology.

Dr. Kurilla's research interests include all facets of translational science, especially innovative and novel interventional concepts requiring additional input from regulatory science to enable viable, robust developmental pathways.

**Elliott Levy, MD**

**COVID R&D Consortium and INTREPID**



Dr. Elliott Levy was formerly Senior Vice President, Global Development at Amgen where he was responsible for delivering the operational and transformational capabilities essential to executing Amgen's Research and Development strategy. Levy joined Amgen in 2014 as senior vice president, Global Development, where he was responsible for the clinical development of Amgen's pipeline.

Before joining Amgen, Levy served as senior vice president and head of Specialty Development at Bristol-Myers Squibb (BMS). Prior to that role, he held the position of senior vice president of Global Pharmacovigilance and Epidemiology. Levy joined BMS in 1997 and during his 17 years at the company, he held a range of senior positions in cardiovascular clinical development, immunoscience clinical research, and global clinical research operations.

**James Mayne, PhD**

**Vice President of Science Advocacy, *Pharmaceutical Research & Manufacturers of America***

Dr. James Mayne is Vice President, Science & Regulatory Advocacy at PhRMA, where he provides leadership for PhRMA involvement in a number of science-based public-private partnerships and works to support pharma industry efforts to evolve the contemporary R&D ecosystem and drug development pathways. Dr. Mayne has more than 30 years of pharmaceutical industry experience, including drug discovery research, individual product and portfolio planning and strategy, business development projects and partnerships, development program and clinical trial design, as well as frequent interactions with US and global regulatory agencies. He holds several international patents and is an author on over 50 research publications.

**Mark McClellan, MD, PhD**

**Director, Duke-Margolis Center for Health Policy, Duke University**



Dr. Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and Washington DC. The new Center supports and conducts research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors.

Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy.

Dr. McClellan is a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health Care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also previously served as a member of the President's Council of Economic Advisers and Senior Director for Health Care Policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an Associate Professor of Economics and Medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Dr. McClellan joined the Reagan-Udall Foundation for the FDA Board of Directors as a founding member in 2008 and currently serves as a Senior Advisor to the Board.

## **Doug Peddicord, PhD**

### **Executive Director, Association of Clinical Research Organizations (ACRO)**



Dr. Doug Peddicord came to Capitol Hill as an American Association for the Advancement of Science (AAAS) Congressional Fellow in 1994, following a career as a clinical psychologist. With policy expertise in the conduct and regulatory oversight of clinical trials, Dr. Peddicord serves as Executive Director of the Association of Clinical Research Organizations (ACRO). Founded in 2002 by leading clinical research organizations that provide a wide range of research and development support services to pharmaceutical, biotechnology and medical device companies, ACRO works to provide a heightened awareness of the critical role that CROs and technology companies play in the development of new drugs, new devices, and new treatments. ACRO is an active participant in policy discussions that may lead to regulations, legislation or other policy initiatives of importance to the clinical development industry, in the US, Europe and around the world.

## **Sarah Read, MD**

### **Deputy Director of the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID)**



Dr. Sarah Read serves as Deputy Director of the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID). The division supports a global HIV/AIDS research portfolio of more than \$1 billion in the areas of 1) fundamental basic laboratory research, 2) discovery and development of therapies for HIV infection, related co-infections, and non-infectious co-morbidities, and the complications associated with treated HIV disease through basic research and clinical trials, and 3) discovery and development of vaccines and other prevention strategies through basic research and clinical trials. Previously, Dr. Read served as Director of the Therapeutics Research Program in DAIDS. Prior to joining DAIDS, she was an Associate Clinical Investigator in the Laboratory of Immunoregulation at NIAID where her research focused on immune activation and inflammation in treated HIV infection as well as on immune based therapies for HIV.

Since April 2020 she has served as co-chair of the NIH-led Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Clinical Therapeutics working group. ACTIV is a public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. The Clinical Therapeutics working group has prioritized hundreds of compounds for evaluation in the treatment of COVID19 and has overseen and coordinated the development and launch of 10 master protocols for evaluating the prioritized compounds.

## **Kristin Schneeman**

### **Director, FasterCures, a Center of the Milken Institute**



Kristin Schneeman joined FasterCures in April 2005 as director of programs, with primary responsibility for its innovation portfolio of projects and activities, focused on best practices in the funding and conduct of medical research and innovative collaborations among players in the research enterprise. Among other initiatives, she runs the TRAIN (The Research Acceleration and Innovation Network) program, which provides a platform for knowledge sharing and

relationship building to support the growth of venture philanthropy in medical research.

Ms. Schneeman brings to FasterCures more than 25 years' experience in public policy, politics, academia, and the media. Schneeman served for three years as a senior adviser and policy director to a gubernatorial candidate in Massachusetts, as a policy aide to a U.S. Congressman, and for four years as the front-line manager and chief-of-staff for a senior adviser to Vice President Al Gore.

### **Michael Santos, PhD**

#### **Vice President of Science, Foundation for the National Institutes of Health (FNIH)**



Dr. Michael Santos is the Vice President, Science, at the Foundation for the National Institutes of Health (FNIH), which he joined in September 2019. He is responsible for a portfolio of health research programs studying new approaches to address the deadliest infectious diseases and to improve maternal and newborn health globally. He is also the FNIH lead on vaccines for the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

Dr. Santos previously worked at the Bill & Melinda Gates Foundation as a Deputy Director from 2013 to 2019. He led strategy and operations for the Discovery & Translational Sciences, HIV, and TB teams in the Global Health Program. His experiences included leading and supervising strategy development in areas including HIV cures, neonatal mortality reduction, and managing a portfolio of technical investments in genetically modifying mosquitoes to prevent malaria transmission. In his last role at the Gates Foundation he served as Strategy Advisor for the Strategy, Innovation, and Impact team, working on broader topics in the philanthropic sector.

Prior to joining the Gates Foundation Santos was a management consultant with the Boston Consulting Group for five years, working on strategic challenges in the corporate, public, and nonprofit sectors. His health projects as a consultant included vector control, HIV prevention with monoclonal antibodies, combining contraception and HIV prevention, global regulatory system

strategy, and pharmaceutical portfolio analysis. Michael's first career was astronomy: he received a Ph.D. from Caltech in 2003 for work on how galaxies are born and subsequently held research fellowships at the University of Cambridge and the Space Telescope Science Institute.

### **Sarah Sheehan, MPA**

#### **Assistant Research Director, Duke Margolis Center for Health Policy**



Sarah Sheehan is an Assistant Research Director at the Duke-Margolis Center for Health Policy working on biomedical innovation, medical product development, and regulatory science initiatives. At Duke, she oversees a portfolio of work related to clinical trial modernization and improved evidence generation, with core efforts on the integration of clinical research and clinical care using real world data, the engagement of community health systems in clinical research, and approaches to achieving representative clinical trial enrollment.

Before joining Duke, she was a Health Policy Analyst at the United States Government Accountability Office (GAO) and a Researcher at the Centers for Disease Control and Prevention (CDC). At GAO and CDC, her research covered policies related to incentivizing the development of new antimicrobials as well as approaches to antimicrobial stewardship and the prevention of healthcare-associated infections.

**Monica Webb Hooper, PhD**

**Deputy Director, National Institute on Minority Health and Health Disparities**



Dr. Monica Webb Hooper is Deputy Director of the National Institute on Minority Health and Health Disparities. She works closely with the Director, Dr. Pérez-Stable, and leadership, to oversee all aspects of the institute and to support the implementation of the science.

Dr. Webb Hooper is an internationally recognized translational behavioral scientist and licensed clinical health psychologist. She has dedicated her career to the scientific study of minority health and racial/ethnic disparities, focusing on chronic illness prevention and health behavior change. Her program of community engaged research focuses on understanding multilevel factors and biopsychosocial mechanisms underlying modifiable risk factors.

Before joining NIMHD, Dr. Webb Hooper was a Professor of Oncology, Family Medicine & Community Health and Psychological Sciences at Case Western Reserve University. She was also Associate Director for Cancer Disparities Research and Director of the Office of Cancer Disparities Research in the Case Comprehensive Cancer Center. During her time as a professor, Dr. Webb Hooper directed the Tobacco, Obesity, and Oncology Laboratory.

Dr. Webb Hooper completed her doctorate in clinical psychology from the University of South Florida, internship in medical psychology from the University of Florida Health Sciences Center, and her Bachelor of Science from the University of Miami.

**Kate Zenlea, MPH, CPH**

**Managing Director of The Global Health Initiative, Henry Ford Health System**



Ms. Kate Zenlea is the Managing Director for the Global Health Initiative at Henry Ford Health System in Detroit, Michigan. Her research is centered around advancing global health equity in resource-limited settings through evidence-based programmatic interventions. Currently, she is leading the Moderna and Johnson & Johnson Phase 3 COVID-19 clinical trials in Detroit where her site has performed amongst the highest for enrolled participants and diversity. Her

previous work includes using quality improvement methodologies to address health disparities amongst patients diagnosed with rheumatoid arthritis and diabetes. Ms. Zenlea received her Master of Public Health from New York University's College of Global Public Health, specializing in international and community health.

## Workshop Moderators

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### **Kevin Bugin, PhD**

**Acting Deputy Director of Operations, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) and formerly Therapeutics Chief of Staff, Federal COVID-19 Response (previously known as Operation Warp Speed)**



Dr. Kevin Bugin is the acting Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER). Prior to his current role, from May 2020 through May 2021, Dr. Bugin served as the Chief of Staff for the Therapeutics Response Efforts as part of the US Government's HHS and DOD operation formerly known as Operation Warp Speed. Dr. Bugin is adjunct faculty at the George Washington University in the Clinical Leadership Program, focusing on areas of clinical research and medicines development. Dr. Bugin joined the FDA in 2008 in the Office of Business Process Support, then joined the Division of Gastroenterology and Inborn Errors Products within OND as a Regulatory Health Project Manager in 2010, and as the Chief of Project Management from 2015 to 2017. From 2017 until 2020, he served as the Director of Special Programs and the lead of CDER's New Drugs Regulatory Program Modernization. Prior to joining the FDA, Dr. Bugin held roles in multiple areas and phases of drug development, including discovery (molecular biology) at the Virginia Bioinformatics Institute, translational research and technology transfer at the National Institute of Health's Office of Technology Transfer, safety and pharmacovigilance with NIH's National Cancer Institute's Cancer Therapy Evaluation Program, and regulatory affairs and quality assurance at Amarex Clinical Research. He received a BS in Biology and Chemistry from Virginia Tech in 2005, a MS in Biotechnology from American University in 2006, and a PhD in translational health science from George Washington University in 2020, with a focus on the Science of Team Science in drug development and regulatory science teams. He is certified in US regulatory affairs (RAC) and participates in numerous policy and regulatory science program working groups across the FDA.

### **Susan C. Winckler, RPh, Esq.**

**CEO, Reagan-Udall Foundation for the FDA**



Susan C. Winckler, is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she 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 in a series of positions of increasing responsibility.