# Annual Public Meeting of the Board of Directors

Hybrid Event | July 21, 2026
2:30pm *(eastern)*

## Agenda

### Welcome & Call to Order
**Adrian F. Hernandez, MD, MHS**
Board Chair, Reagan-Udall Foundation for the FDA

### Year in Review
**Adrian F. Hernandez, MD, MHS**

**Susan C. Winckler, RPh, Esq.**
Chief Executive Officer, Reagan-Udall Foundation for the FDA

### The Year Ahead: Strategic & Scientific Priorities
**Steven Kozlowski, MD**
Chief Scientist, Office of the Chief Scientist, U.S. Food and Drug Administration

**Lowell M. Zeta, JD**
Acting Chief of Staff, Deputy Commissioner for Strategic Initiatives, and Special Counsel, U.S. Food and Drug Administration

### Exploring the Foundation's Impact: A discussion with members of the Foundation's Board of Directors
**David C. Fajgenbaum, MD, MBA, MSc, FCPP**
**Adrian F. Hernandez, MD, MHS**
**Phuong Khanh (PK) Morrow, MD**
**Pietro Antonio Tataranni, MD**

### Remarks from the Acting Commissioner
**Kyle Diamantas, JD**
Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration

### Closing Remarks & Adjourn
Susan C. Winckler, RPh, Esq.

# Speaker Biographies

## FDA Leadership

### Kyle Diamantas, JD

**Acting Commissioner of Food and Drugs, FDA**

Kyle Diamantas, JD is the Acting Commissioner of Food and Drugs. Prior to becoming Acting Commissioner, as the FDA's Deputy Commissioner for Food, Mr. Diamantas lead the agency's Human Foods Program. In that role he oversaw all FDA nutrition and food safety activities, exercising authority over all Human Food Program entities and operations, including resource allocation, risk-prioritization strategy and decision making, policy initiatives, and major response activities involving human foods. Mr. Diamantas also oversaw food resources in the agency's Office of Inspections and Investigations. He also served since February 2026 as a Senior Counselor for the Food and Drug Administration in the U.S. Department of Health and Human Services.

As the FDA's top food executive, Mr. Diamantas set the strategic direction and operations for food policy in the U.S., while serving as a critical liaison between the agency, HHS, and The White House. He also represented the agency on food activities and matters in dealings with foreign governments and international organizations.

Mr. Diamantas has extensive experience working with various federal and state agencies and policy makers, scientific organizations, consumer advocacy groups, and industry stakeholders. He has wide-ranging experience on matters spanning regulatory, compliance, investigative, enforcement, rulemaking, and legislation. Mr. Diamantas holds a juris doctor from the University of Florida Levin College of Law and a bachelor's in pre-law political science from the University of Central Florida.

### Steven Kozlowski, MD

**Chief Scientist - Office of the Chief Scientist, FDA**

Steven Kozlowski, MD, is the FDA's Chief Scientist. The Chief Scientist promotes, leverages, and leads cross-cutting, collaborative activities and initiatives that catalyze FDA science, innovation, and research to help the agency address its most pressing regulatory and public health questions and respond to emerging issues. The Office of the Chief Scientist supports the research foundation, science, and innovation that underpins the FDA's regulatory mission. It does this through a broad framework that encompasses scientific collaborations, laboratory safety, the transfer of FDA inventions to the private sector, scientific integrity in FDA policy and decision-making, the professional development of regulatory scientists, and conducting applied research and testing at the FDA, including in its National Center for Toxicological Research, Office of Analytical and Regulatory Laboratories, and Office of Specialty Laboratories and Enforcement Support.

Dr. Kozlowski brings extensive scientific, regulatory and management experience to the Office of the Chief Scientist, including a breadth of knowledge in pharmaceutical quality, immunology and research.

Prior to assuming the role of Chief Scientist, Dr. Kozlowski served as Director of the Office of Product Quality Assessment III (OPQA III) in the Office of Pharmaceutical Quality (OPQ) in the FDA's Center for Drug Evaluation and Research (CDER). In that role he led a team responsible for ensuring the quality of all the active ingredients and substances in products overseen by CDER, which includes everything from over-the-counter analgesics to complex biological products. QPQA III was created as part of a major reorganization of the Office of Product Quality, an important initiative designed to support greater agility, connectedness and influence. Dr. Kozlowski was part of the strategic planning and change management involved in that effort.

Prior to the OPQ reorganization, Dr. Kozlowski served for 18 years as the Director of the Office of Biotechnology Products (OBP) in CDER's Office of Pharmaceutical Quality, overseeing the quality of therapeutic biological products and a laboratory program with research in manufacturing science, immunology and bioassays. His

tenure coincided with a phenomenal growth in the use and impact of biological products, including the development of a new regulatory pathway for biosimilar biological products.

Dr. Kozlowski holds a bachelor's in science from Northwestern University, as well as a Doctor of Medicine with distinction from their Medical School. He trained in pediatrics at the University of Illinois. He has published extensively in a wide range of scientific areas relevant to the FDA mission from in vivo models for drug development to vaccine safety and from biosimilar uptake to epidemiology.

## Lowell M. Zeta, JD

**Acting Chief of Staff, Deputy Commissioner for Strategic Initiatives, and Special Counsel, FDA**

Lowell M. Zeta, JD, is the Acting Chief of Staff at the U.S. Food and Drug Administration.

Mr. Zeta also serves as the FDA's Deputy Commissioner for Strategic Initiatives and as Special Counsel in the Office of the Chief Counsel (OCC), the Food and Drug Division of the U.S. Department of Health and Human Services' (HHS) Office of the General Counsel.

Mr. Zeta provides legal and strategic counsel to the FDA Commissioner and agency leadership to advance strategic regulatory initiatives, drive cross-agency innovation, and strengthen oversight across all FDA-regulated product areas. He leads a number of high-priority agency initiatives, including modernization of advanced and distributed manufacturing, transparency efforts, and innovation in FDA's investigation and inspection infrastructure and risk-prioritization strategies. Known for his deep experience in FDA regulatory law and pragmatic leadership style, Mr. Zeta brings together agency leadership, policymakers, counselors, and external stakeholders to navigate complex regulatory, compliance, and enforcement challenges.

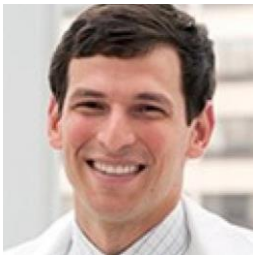
Previously serving at the FDA from 2020-2021 as a Senior Advisor to the Commissioner, he provided leadership on key public health initiatives, including the Pandemic Recovery and Preparedness Plan (PREPP) initiative to strengthen the FDA's response to public health emergencies. Prior to returning to the Agency, Mr. Zeta was a senior partner at a global law firm in Washington, D.C.

Mr. Zeta is a frequent speaker and published writer on FDA and healthcare policy issues. He previously served as a Food and Drug Law Journal advisory board member. Mr. Zeta completed his undergraduate studies at the University of Iowa and earned his juris doctor and postgraduate degree in law and health policy from Creighton University and Georgetown University.

# Foundation Leadership

## David C. Fajgenbaum, MD, MBA, MSc, FCPP

**Board Member, Reagan-Udall Foundation for the FDA**



David Fajgenbaum, MD, MBA, MSc, FCPP, is an Assistant Professor of Translational Medicine & Human Genetics at the Perelman School of Medicine at the University of Pennsylvania, Founding Director of the Center for Cytokine Storm Treatment & Laboratory (CSTL), Associate Director, Patient Impact of the Penn Orphan Disease Center, and Co-Founder/ President of the Castleman Disease Collaborative Network (CDCN). He is also the national bestselling author of 'Chasing My Cure: A Doctor's Race to Turn Hope Into Action' (http://www.ChasingMyCure.com) and a patient battling idiopathic multicentric Castleman disease (iMCD).

He is in his longest remission ever thanks to a precision treatment that he identified, which had never been used before for iMCD.

An authority on cytokine storms and their treatment, Fajgenbaum launched the CORONA project in March 2020 to identify and track treatments for COVID-19. Today, CORONA is the world's largest database of COVID-19 treatments, including more than 500 medications that have been administered to more than 400,000 patients, and a go-to resource for FDA, Google Health, and others. He serves on the treatment selection committee for the

NIH's ACTIV-6 trial as well as the Chair of the treatment selection committee for FDA/NIH/C-Path Institute's CURE Drug Repurposing Collaboratory (CDRC) COVID-19 inpatient trial.

One of the youngest individuals ever appointed to the faculty at Penn Medicine and in the top 1 percent youngest awardees of an NIH R01 grant, Dr. Fajgenbaum leads over 20 translational research studies, including the CORONA project and a clinical trial of the drug that is saving his life. He has published scientific papers in high-impact journals such as the New England Journal of Medicine, Blood, and Journal of Clinical Investigation, including one paper selected by STAT News in 2020 as one of the best innovations in science and medicine.

Dr. Fajgenbaum received a bachelor's degree in Human Sciences with Distinction from Georgetown University, where he was USA Today Academic All-USA First Team and a Quarterback on the Division I football team. Dr. Fajgenbaum earned his medical degree from the Raymond & Ruth Perelman School of Medicine at the University of Pennsylvania, where he was a 21st Century Gamble Scholar.

Dr. Fajgenbaum joined the Reagan-Udall Foundation for the FDA Board of Directors in 2022.

## Adrian F. Hernandez, MD, MHS

### Board Chair, Reagan-Udall Foundation for the FDA

Adrian F. Hernandez, MD, MHS, is a cardiologist who serves as the Vice Dean for Clinical Research at the Duke University School of Medicine. Dr. Hernandez has devoted his career to research in order to improve population health, focusing on understanding health outcomes, and closing the gap between clinical efficacy and effectiveness. An expert in trial design, use of electronic health data, health services, and regulatory science, Dr. Hernandez has led efforts to create more pragmatic clinical trials that get closer to what patients and clinicians experience every day.

Presently, he is the Coordinating Center Principal Investigator for PCORI's National Patient-Centered Clinical Research Network (PCORnet), NIH's Health System Collaboratory, and other pragmatic clinical trials to generate real world evidence. He is also the Coordinating Center Principal Investigator for the Baseline Health System Consortium which aims to change how clinical research is performed to integrate people in and outside of the health system, accelerate research, and improve efficiency.

Dr. Hernandez was previously the Director of Health Services and Outcomes Research at the Duke Clinical Research Institute (DCRI). Under his leadership at DCRI, he played a pivotal role in leading efforts to improve patient-centered outcomes through the creation of new therapies and enhanced delivery throughout the national health system. Dr. Hernandez has consistently provided significant contributions towards the fields of heart failure, outcomes research, population health, and clinical research methodology.

Dr. Hernandez earned a bachelor's degree from Rice University in Houston and his medical degree from University of Texas-Southwestern in Dallas. He finished his residency in internal medicine at the University of California, before completing his residency in cardiology at Duke University. He has over 500 published articles and is an elected member of the American Society of Clinical Investigation and Association of American Physicians. He is a member of the National Evaluation System for Health Technology Coordination Center (NEST) Governing Committee, associate editor for JAMA Cardiology, and professor of medicine with tenure at Duke University.

Dr. Hernandez joined the Reagan-Udall Foundation for the FDA Board of Directors in 2019.

## Phuong Khanh (PK) Morrow, MD

**Board Member, Reagan-Udall Foundation for the FDA**

PK Morrow is the Head of the Oncology Therapeutic Area Unit (OTAU). In this role, PK is responsible for Takeda's oncology R&D strategy and development portfolio.

Prior to joining Takeda, Dr. Morrow served as Chief Medical Officer at CRISPR Therapeutics, where she led a cross-functional team of physicians, scientists and support staff, overseeing end-to-end development of clinical programs spanning hematology, oncology, diabetes and cardiovascular disease states. She was responsible for the development of numerous drug candidates and for the implementation of strategic partnerships with academic institutions, key opinion leaders, regulatory agencies and biopharmaceutical collaborators to facilitate successful execution of clinical trials.

Before joining CRISPR, Dr. Morrow spent over a decade at Amgen, where she served as Vice President and Global Therapeutic Area Head of Hematology, GI Oncology, GU Oncology, and Bone Diseases. Before joining the industry, she held the role of Assistant Professor, Department of Breast Medical Oncology at the University of Texas MD Anderson Cancer Center.

Dr. Morrow received an M.D. from the University of Texas Medical School at Houston. She completed her internal medicine residency at Baylor College of Medicine and a Hematology/Oncology Fellowship at the University of Texas MD Anderson Cancer Center.

Dr. Morrow joined the Reagan-Udall Foundation for the FDA Board of Directors in 2023.

## Pietro Antonio Tataranni, MD

**Board Member, Reagan-Udall Foundation for the FDA**

Dr. Tataranni is currently the global Chief Medical Officer of PepsiCo. As Chief Medical Officer, Dr. Tataranni oversees all aspects of the company's efforts to protect its global workforce, products, and communities in the face of the COVID-19 pandemic and beyond. He also leads PepsiCo's Life Sciences strategy and the R&D Fellows Program as its Executive Sponsor. Dr. Tataranni joined PepsiCo in 2018 as the Senior Vice President of R&D Life Sciences, responsible for leading the development and execution of a nutrition and bio-sciences strategy in support of the company's portfolio transformation and Pep+ agenda. Dr. Tataranni serves on the Boards of several for-profit and non-profit organizations.

Prior to joining PepsiCo, Dr. Tataranni was Senior Vice President, Head of Global Medical Affairs, Diabetes & Cardiovascular Business Unit, in charge of medical strategy worldwide and operations for mature markets at Sanofi. Previous responsibilities within the group included the roles of Vice President Global Medical Affairs, Medical Director Europe, Vice President for the Metabolism Medical Unit in the US affiliate (2006-2008) and Medical Director for the Metabolism Franchise (2005-2006). Between 1999 and 2004 he was Head of the Obesity, Diabetes and Energy Metabolism Unit at the Phoenix Epidemiology and Clinical Research Branch of the National Institutes of Health in the U.S. and Director of the Clinical Research Center at the same institution from 2000 through 2004.

He is an avid researcher who has published and lectured extensively at national and international meetings on obesity, diabetes, and their cardio metabolic complications. Professional awards presented to Dr. Tataranni include the NIH Fellowship Award for Research Excellence (FARE) in 1998 and the North American Association for the Study of Obesity (NAASO)-Lilly Scientific Achievement Award in 2004.

Dr. Tataranni is a native of Italy. He graduated from Catholic University School of Medicine in Rome in 1990 and went on to receive a specialty diploma in Endocrinology, Metabolic Diseases and Diabetes at this University. He

has authored more than 100 original manuscripts, in addition to contributing to numerous review articles and book chapters.

Dr. Tataranni joined the Reagan-Udall Foundation for the FDA Board of Directors in 2024.

## Susan C. Winckler, RPh, Esq.

**Chief Executive Officer, Reagan-Udall Foundation for the FDA**

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