REAGAN-UDALL FOUNDATION FOR THE FDA

Annual Public Meeting of the Foundation Board of Directors

Hybrid Public Meeting

July 17, 2025 | 9–10:30am (eastern)

FDA Leadership

Martin Makary, MD, MPH
Commissioner of Food and Drugs, FDA

Dr. Marty Makary was confirmed on March 25, 2025 by a bipartisan vote of the U.S. Senate as the 27th Commissioner of Food and Drugs.

Prior to joining the FDA, Dr. Makary worked at Johns Hopkins University School of Medicine, where he was a surgical oncologist and chief of Islet Transplant Surgery. After six years on the faculty at JHU, Dr. Makary was named an endowed chair in gastrointestinal surgery, and subsequently promoted to full professor with tenure. He also served as a professor at the Johns Hopkins Carey Business School and founded the Johns Hopkins Center for Surgical Trials and Outcomes Research.

Dr. Makary is a widely published writer, having authored more than 300 peer-reviewed articles in medical journals. He is the author of three New York Times bestselling books on health care, including: "Unaccountable – What Hospitals Tell You and How Transparency Can Revolutionize Health Care;" "The Price We Pay," which examined health care costs; and which was named 2020 Business Book of the Year by the Association of Business Journalists; and "Blind Spots -- When Medicine Gets It Wrong, and What It Means for Our Health," which presents the latest scientific research on the microbiome, food and other health topics.

Dr. Makary has led cross-disciplinary research on a range of subjects, including cancer care, obesity, frailty and psychologic reserve in older patients, adverse event monitoring, the Orphan Drug Act, antimicrobial resistance, and Alzheimer's. Of particular note, he is the co-developer of the Surgery Checklist used in many operating rooms around the world today.

Dr. Makary was the first to perform several novel surgical operations, including the first-in-the-world series of laparoscopic pancreas islet transplant operations. For his pioneering work, Dr. Makary was awarded the Nobility in Science Award from the National Pancreas Foundation. For the last 22 years, he has had an active clinical practice.

During the COVID pandemic, he and his Johns Hopkins colleagues conducted landmark antibody studies on natural immunity published in JAMA. Most recently, his research has focused on vulnerable populations in health care.

Dr. Makary has led national quality collaboratives, served on several editorial boards, and was the first editor-in-chief of MedPage Today. He has served in a leadership position at the World Health Organization Patient Safety Program, and in 2018 was elected to the National Academy of Medicine.

Dr. Makary graduated from Bucknell University and earned an M.P.H. from the Harvard T.H. Chan School of Public Health. He received his M.D. from Thomas Jefferson University and did his surgical residency at Georgetown University, completing sub-specialty surgery training at Johns Hopkins University.

Grace Graham, MPP
Deputy Commissioner for Policy, Legislation, and International Affairs, FDA

Grace Graham is the Deputy Commissioner for Policy, Legislation, and International Affairs. In this role, she leads the Office of Policy, Legislation, and International Affairs (OPLIA), which serves as the FDA's focal point for engagement with the U.S. Congress, the Administration, global counterparts and partners, and state, local, territorial, and tribal policymakers.

Immediately before coming to the FDA, Grace served as Chief Health Counsel for the Energy and Commerce Committee (E&C) in the U.S. House of Representatives, where she worked on the 2022 User Fee Reauthorization and other health care matters under the scope of the committee. Prior to that, Mrs. Graham served as Health Policy Director for the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP), working on User Fee Legislation, 21st Century Cures laws, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, and other health care legislation.

Grace has a Master of Public Policy and Health Policy, as well as a Bachelor of Science in Biomedical Engineering from the University of Virginia.

Lowell Zeta, JD
Deputy Commissioner for Strategic Initiatives and Special Counsel, FDA

Lowell M. Zeta, JD, is the Deputy Commissioner for Strategic Initiatives at the U.S. Food and Drug Administration and serves as Special Counsel for FDA in the Office of the Chief Counsel (OCC), which is the Food and Drug Division of the U.S. Department of Health and Human Services' (HHS) Office of the General Counsel. In this dual role, 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-related product areas including drugs, biologics, food, medical devices, cosmetics, veterinary products, and tobacco products. He serves as the point-person ensuring that strategic initiatives and priorities, at all levels of the organization, are authorized under the Federal Food, Drug, and Cosmetic Act (FDCA) and other applicable laws and regulations and are in line with the FDA Commissioner's priorities and the broader goals of HHS and the Administration.

Mr. Zeta is responsible for collaborating with the FDA Commissioner to identify opportunities to improve regulatory programs, to develop innovative strategies for emerging and ongoing issues, and to implement new programs and solutions to achieve the FDA's mission objectives. He works closely with FDA leadership and provides executive oversight for operations and regulatory process improvements. His responsibilities include providing analyses and recommendations on innovative regulatory initiatives and programs, ensuring the alignment of the key functions of strategy planning, and driving change and overseeing change management during implementation to maximize efficiency and public health benefit.

As Special Counsel for FDA, Mr. Zeta provides legal counsel and strategic counsel on high-priority regulatory and administrative actions and cross-cutting legal issues involving emerging technologies such as artificial intelligence, domestic manufacturing and foreign inspections, and risk management for regulations, guidance, and policy development, which often involves complex legal analyses of intricate statutory provisions. He works closely with OCC litigators and counselors to advise FDA officials on strategy planning and risk mitigation approaches, new and pending regulations and draft legislation, and complex compliance and enforcement matters to advance FDA's mission of promoting and protecting public health.

Mr. Zeta was previously with the FDA (2020-2021), serving as a Senior Advisor to the Commissioner, and 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 his return, Mr. Zeta

was a senior partner at a global law firm in Washington, D.C., focusing on regulatory and commercial strategies, enforcement and administrative matters, compliance and investigations involving the pharmaceutical and biotech industries. In addition, he has extensive experience and is a frequent speaker and published writer on FDA and healthcare priorities. Mr. Zeta previously served as a Food and Drug Law Journal advisory board member where he was responsible for peer-review of publications in the Food and Drug Law Journal, covering scholarly work on legislation, regulations, court decisions, and public policies affecting FDA regulated industries. 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, respectively.

Foundation Board Members

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Foundation Board Chair, Reagan-Udall Foundation for the FDA

Richard Schilsky, MD, FACP, FSCT, FASCO, is the former Chief Medical Officer with the American Society of Clinical Oncology and Professor emeritus at University of Chicago. Dr. Schilsky earned his medical degree at the University Of Chicago Pritzker School Of Medicine in 1975. Following a residency in Internal Medicine at the University of Texas Southwestern Medical Center and Parkland Memorial Hospital, he received training in Medical Oncology and Clinical Pharmacology at the National Cancer Institute from 1977 to 1981. He then served as Assistant Professor of Medicine at the University of Missouri-Columbia School of Medicine from 1981-1984 when he returned to the University of Chicago. At the University of Chicago, Dr. Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991-99), as Associate Dean for Clinical Research (1999-2007) and as Chief of the Section of Hematology-Oncology (2009-2012). From 1995-2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group.

An international expert in gastrointestinal malignancies and cancer pharmacology, Dr. Schilsky has published more than 300 scientific articles, reviews, and commentaries. He has served on several peer review and advisory committees for the NCI including as a member and chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and chair of the Oncologic Drugs Advisory Committee of the Food and Drug Administration. Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009.

Dr. Schilsky joined the Reagan-Udall Foundation for the FDA Board of Directors in 2013.

Edward John Allera, JD
Board Member, Reagan-Udall Foundation for the FDA

Edward John Allera, JD, serves as Stakeholder and Co-Chair of the Food and Drug (FDA) Practice at Buchannan Ingersoll & Rooney PC, where he counsels clients on new product development and business opportunities in the areas of pharmaceuticals, hi-tech products, medical devices, food, and cosmetics.
He has devoted his entire career to health care, as both a pharmacist and an attorney. He began his career at the FDA, where he served as Associate Chief Counsel. One of his biggest strengths is the ability to integrate science into practical applications under the law.

In the private sector, he has represented clients before almost every reviewing division of the Centers for Drugs and Biologics. Additionally, he possesses a cadre

of experts with whom he works that enables him to create both legally and scientifically accurate plans and proposals.

Mr. Allera has extensive expertise in product life cycle management. He has worked with almost every dosage form, from patches to MDI's and oral controlled release to parenterals. Because of his specific background in science surrounding dosage forms and pharmacokinetics, he has filed a large number of Citizen Petitions within the product life cycle management process.

Over the years, Mr. Allera has been able to build a coordinated team that integrates Buchanan Ingersoll & Rooney's FDA, healthcare, Centers for Medicare and Medicaid Services (CMS), and federal government affairs expertise into a seamless unit. Mr. Allera was recently inducted into the West Virginia University College of Pharmacy Hall of Fame.

Mr. Allera joined the Reagan-Udall Foundation for the FDA Board of Directors in 2018.

Debra L. Ness, MS
Treasurer, Reagan-Udall Foundation for the FDA

Debra L. Ness, MS, recently concluded a distinguished tenure as president of the National Partnership for Women & Families, an organization that works to improve the lives of women and families by achieving equity for all women.
Under her stewardship, the National Partnership, along with its partners and allies, has significantly influenced national health policy on behalf of consumers, patients and families. Today, more than 30 jurisdictions have adopted laws that allow workers to earn paid sick days, hundreds of corporations and six states plus the District of Columbia have enacted paid family and medical leave programs, and dozens of states have adopted strong laws that prohibit and punish pregnancy discrimination.

Ms. Ness is an innovative and sought-after health policy strategist who has helped shape the programs that are making health care in this country more accessible and affordable. She has worked collaboratively with some of the most reputable health institutions to improve health outcomes and disparities by delivering better quality, more patient- and family-centered care. Through her leadership, the organization has worked to de-stigmatize abortion and to illustrate the inextricable connection between people's economic prosperity and their ability to decide whether and when to start a family.

She serves on the Executive Committee of the Leadership Conference on Civil and Human Rights (LCCHR) and co-chairs its Health Care Task Force. She has served on the boards of the American Board of Internal Medicine (ABIM), the National Committee for Quality Assurance (NCQA), the American College of Cardiology (ACC), the National Quality Forum (NQF), and others. She is one of the first public members of the American Board of Internal Medicine (ABIM) Board of Directors. She was appointed by the U.S. Department of Health and Human Services to serve on the Guiding Committee of the Health Care Payment Learning & Action Network (HCPLAN).

Ms. Ness graduated summa cum laude from Drew University with a bachelor's degree in psychology and sociology. She received her master's degree from Columbia University School of Social Work. She worked in numerous capacities at the Service Employees International Union (SEIU). Prior to that she headed field operations for NARAL, where she worked to revitalize the organization's grassroots political capability and affiliate network, before becoming its deputy director and helping transform the organization into a major force in electoral politics.

Ms. Ness joined the Reagan-Udall Foundation for the FDA Board of Directors in 2022.

Pietro Antonio Tantaranni, 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.

Andrew C. von Eschenbach, MD
Board Member, Reagan-Udall Foundation for the FDA

Dr. von Eschenbach currently serves as President of Samaritan Health Initiatives, Inc. and as an Adjunct Professor at University of Texas MD Anderson Cancer Center. He served as the 20th Commissioner of Food and Drugs (2005-09) where he championed an agenda to modernize the FDA. He emphasized innovation by fostering creative projects, including the FDA's Critical Path Initiative, which was designed to bring modern tools of science to the product development process.

He also launched the FDA's Food Protection Plan and focused on initiatives to nurture the workforce, such as an agency-wide fellowship program and development of a new integrated campus for the agency in White Oak, MD. Under his leadership, the FDA experienced dramatic increases in resources, enabling implementation of many new programs designed to strengthen the agency in its mission to protect and promote public health.

Dr. von Eschenbach joined FDA after serving for four years as Director of the National Cancer Institute (NCI) at the National Institutes of Health where he set an ambitious goal to eliminate the suffering and death due to cancer by rapid acceleration and integration of the discovery-development-delivery continuum.
Dr. von Eschenbach entered government service after an outstanding career over three decades as a physician, surgeon, oncologist, and executive that included numerous leadership roles from Chairman of the

Department of Urologic Oncology to Executive Vice President and Chief Academic Officer at the University of Texas MD Anderson Cancer Center in Houston, Texas.

An internationally renowned cancer specialist and author of more than 300 scientific articles and studies, Dr. von Eschenbach has served in numerous leadership roles, and has received many professional awards and honors. In 2006, Dr. von Eschenbach was named one of Time magazine's "100 most influential people to shape the world," and in both 2007 and 2008, he was selected as one of the Modern Healthcare/Modern Physician's "50 Most Powerful Physician Executives in Healthcare."

Dr. von Eschenbach earned a bachelor's degree from St. Joseph's University in Philadelphia and his MD from Georgetown University. After completing a residency in urologic surgery at University of Pennsylvania Hospital in Philadelphia, he served as was an instructor at University of Pennsylvania School of Medicine and completed a Fellowship in Urologic Oncology at the University of Texas MD Anderson Cancer Center.

Dr. von Eschenbach joined the Reagan-Udall Foundation for the FDA Board of Directors in 2018.

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

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the FDA (Foundation). The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, 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, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her juris doctorate *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, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.