REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Affecting the Aging Trajectory: Regulatory Constructs for Gerotherapeutic Drug, Biologic, and Device Development

Speaker Bios

Opening Remarks

Steven Kozlowski, MD
Chief Scientist, FDA

Dr. 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.

Speakers

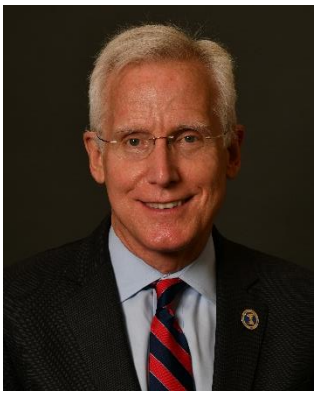
David B. Allison, PhD
Chief of Nutrition and Director, USDA Children's Nutrition Research Center, Baylor College of Medicine

Dr. David B. Allison, Ph.D., is Professor of Pediatrics and Endowed Chair through Texas Children's Hospital, as well as Chief of Nutrition and Director of the USDA-ARS Children's Nutrition Research Center at Baylor College of Medicine. Continuously NIH-funded as a PI for over 30 years, he has authored or co-authored more than 700 scientific publications. Awards include the Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring (2006), the Harry V. Roberts Statistical Advocate of the Year Award (American Statistical Association, 2018), the Friends of Albert (Mickey) Stunkard Lifetime Achievement Award (The Obesity Society, 2021), the Bodil M. Schmidt-Nielsen Distinguished Mentor and Scientist Award (American Physiological Society, 2023), the Alumni Spotlight Award (Hofstra College of Liberal Arts and Sciences, 2024), and the Irving S. Wright Award of Distinction (American Federation for Aging Research, 2025). In 2022, he was named a Distinguished Lecturer by Sigma Xi, the Scientific Research Honor Society, and received the Hoebel Prize for Creativity (Society for the Study of Ingestive Behavior). In 2023, he was elected as a Fellow of Sigma Xi, elected as a Member of the International Statistical Institute, and inducted into the Academy for Health and Lifespan Research, the first global non-profit group focused on accelerating breakthroughs in the expansion of the human health span. In 2024, Dr. Allison was elected as a member of Cosmos Club, and in 2025, he began a term of leadership at Sigma Xi as president-elect. Elected to the National Academy of Medicine in 2012, he also serves as co-chair of the National Academy of Sciences' Strategic Council for Research Excellence, Integrity, and Trust. Dr. Allison is a staunch advocate for rigor in research methods and the uncompromisingly truthful communication of research findings.

Kelly Anderson, PhD
Scientific Engineering and Technical Advisor, ARPA-H

Dr. Kelly Anderson is a scientific advisor (SETA) contractor in the Proactive Health Office at ARPA-H, where she provides scientific analysis to support program development and evaluates proposals for scientific rigor, feasibility, and potential impact. She was founder of The Science Editors, LLC, where she provided editorial support for manuscripts, grants, and scientific communications across molecular biology. Previously, Dr. Anderson was a Scientific Editor for The EMBO Journal and EMBO Molecular Medicine at Wiley and completed postdoctoral research at the University of Rochester's Aab Cardiovascular Research Institute. She earned her Ph.D. in Genetics and Development from UT Southwestern Medical Center and holds dual bachelor's degrees in Neuroscience and Psychology from the University of Texas at Dallas. Her research has been published in leading journals including Cell, Nature, PNAS, and Science Signaling.

James C. Appleby, BSPharm, MPH
Chief Executive Officer, Gerontological Society of America



James C. Appleby, BSPharm, MPH is the Chief Executive Officer of the Gerontological Society of America (GSA), the nation's largest interdisciplinary organization devoted to research, clinical practice, education, and policy in the aging field. The Society's 6,500 expert members advance innovation in aging and disseminate research insights for scientists, practitioners, policy makers and the public. GSA's **Concentric Value of Vaccinations** platform showcases the way one vaccination has a positive impact well beyond the individual to include family members, co-workers, communities, and society. GSA's **National Center to Reframe Aging** is the trusted source for proven communication strategies reshaping the conventional narrative around aging and advancing new approaches to end ageism. Prior to joining GSA, Mr. Appleby served as Chief Operating Officer at the American Pharmacists Association. He is a pharmacist, holds an MPH degree from Temple University, and has been awarded an Honorary ScD degree from the University of the Sciences in Philadelphia. He is a member of the National Alliance for Caregiving Board of Directors and serves as Co-Chair of the Mayor's Age-Friendly DC Task Force in Washington, DC.

Nir Barzilai, MD
Director, Institute for Aging Research, Albert Einstein College of Medicine

Dr. Nir Barzilai, MD is a leading figure in the field of geroscience, whose pioneering work has shown that aging itself has distinct biological drivers that can be targeted to prevent age-related diseases. At Albert Einstein College of Medicine, he serves as Professor of Medicine and Genetics and directs the Institute for Aging Research and BIO VITAL, the Center for Validation of Interventions Targeting Aging and Longevity.

He has published more than 380 papers and made seminal contributions to understanding the mechanisms of exceptional longevity, extending healthspan in model organisms, and identifying genetic pathways linked to healthy aging in centenarian families. He is the recipient of numerous honors, including the IPSEN Longevity Award and the Precision Medicine World Conference (PMWC) Luminary Award.

He co-founded and serves as President of the Academy of Geroscience and sits on the Board of Directors of the American Federation for Aging Research, where he co-leads the biomarker program (FAST, ARPA-H), the Targeting Aging with Metformin (TAME) trial, and the Super Agers initiative. He also serves on the Executive Committee of the Longevity Biotech Association, the Council of the Healthy Longevity Medicine Society, and is a Fellow of both the Association of American Physicians (AAP) and the New York Academy of Medicine.

Dr. Barzilai is the author of *Age Later: Health Span, Life Span, and the New Science of Longevity*.

John R. Beard, MBBS, PhD
Irene Diamond Professor, Columbia University Mailman School of Public Health

Dr. John Beard, MBBS, PhD is the Irene Diamond Professor and Director of the International Longevity Center-USA at Columbia University. From 2009–2019, he served as Director of Ageing and Life Course at the World Health Organization in Geneva, where he led landmark global initiatives including the World Report on Ageing and Health — the foundational document introducing the constructs of intrinsic capacity and functional ability.

While at WHO, he led multiple global initiatives including development of the Global Network of Age-friendly Cities and Communities, now reaching over 300 million people, and the Integrated Care for Older People (ICOPE) program. He has collaborated extensively

with the World Economic Forum and served as a Commissioner for the National Academy of Medicine's Global Roadmap for Healthy Longevity.

Dr. Beard's research reframes health through the lens of functioning rather than disease. He led the first large-scale studies validating intrinsic capacity across English, European, Chinese, and American population cohorts, and his current work examines longitudinal trajectories of capacity – identifying behavioral, demographic, and contextual determinants of age-related functional decline. His findings suggest that more recently born older adults are experiencing improved trajectories compared to prior generations.

This research directly informs efforts to define meaningful endpoints and regulatory constructs for gerotherapeutic drug, biologic, and device development.

Andrew Brack, PhD
Program Manager, PROactive Health Office, ARPA-H

Dr. Andrew Brack, PhD joined ARPA-H as a Program Manager in April 2024 from Arrive Bio, a longevity biotechnology company that used machine learning and in-vivo screening to identify treatments for age-related diseases. Prior to that he served as a Professor at UCSF in the Orthopeadic Surgery department after achieving tenure as a Professor at the Center for Regenerative Medicine at Massachusetts General Hospital, Harvard University.

Brack is an expert in stem cell biology, regeneration, and aging, with more than two decades of experience in basic research, stem cell mechanisms, and translational applications aimed at restoring healthy function during aging. At ARPA-H, Brack manages a portfolio that covers topics including multimodal data collection for health trajectories and drug discovery for healthspan.

David A. Brown, PhD
Chief Scientific Officer, Stealth BioTherapeutics

Dr. David A. “Dave” Brown, PhD is Chief Scientific Officer for Stealth BioTherapeutics, a biotechnology company driven to improve the lives of others by targeting mitochondria. Dave’s relentless fascination with how cells make and use energy has been a driving force behind his twenty-five years researching bioenergetics. Dave is a seasoned mitochondrial scientist who ran an extramurally funded academic research lab for over ten years before transitioning into industry. In his current role, he leads the Discovery of new approaches designed to reduce aging/disease burdens by targeting mitochondria. Dave earned a Bachelor of Science from Virginia Tech (Exercise Science), a PhD from the University of

Colorado (Physiology), and completed a post-doctoral fellowship at the Johns Hopkins University School of Medicine (Molecular Cardiobiology).

Joshua Diamond, MD, MSCE
Medical Director Clinical Development, Respiratory Early Pipeline Unit, GSK

Dr. Joshua Diamond, MD, MSCE received his medical degree from the University of Rochester and completed residency, chief residency and pulmonary critical care fellowship at the University of Pennsylvania, where he also received a Master of Science degree in Clinical Epidemiology. Prior to joining GSK, Dr. Diamond spent 20+ years at the University of Pennsylvania, where he continues to serve as an Adjunct Associate Professor of Medicine in the Division of Pulmonary, Allergy, and Critical Care Medicine.

At Penn, his academic focus was clinical translational outcomes research in lung transplantation, with a specific interest in primary graft dysfunction, chronic lung allograft dysfunction, and the interaction of frailty and advanced lung disease.

He served as the Associate Medical Director of the Penn Lung Transplant program with clinical expertise in interstitial lung disease, cystic fibrosis, severe COPD, end stage pulmonary hypertension, and critical care.

Dr. Diamond joined GSK about one year ago and now serves as a Medical Director in Clinical Development within the Respiratory Early Pipeline Unit, responsible for clinical assessment of novel disease targets, interfacing with academic collaborators, and designing early phase clinical trials. Based on his prior clinical and research experience within the frailty space, he is incorporating the concept of pathologic aging into the assessment of respiratory disease states and how it intersects with response to therapy.

Zahi A. Fayad, PhD
Lucy G. Moses Professor of Medical Imaging and Bioengineering, Icahn School of Medicine, Mount Sinai

Dr. Zahi A. Fayad, PhD, is the Lucy G. Moses Professor of Medical Imaging and Bioengineering at the Icahn School of Medicine at Mount Sinai, founding Director of the BioMedical Engineering and Imaging Institute (BMEII), and co-leads Mount Sinai's system-wide Healthspan initiative. His work focuses on shifting medicine upstream — using advanced imaging, wearables, sensors, AI, and multi-omics to detect disease before clinical events occur and to extend healthy years of life. His NIH-funded research examines how lifestyle stressors — chronic stress, diet, exercise, and sleep — shape long-term health. He currently leads the Mount Sinai

DigiTwin Project, a prospective longitudinal precision health study and AI-driven digital twin platform that integrates multimodal imaging, blood biomarkers, multi-omics, wearable sensors, cognitive and physical performance assessments, lifestyle and environmental data, and longitudinal clinical follow-up to model individual health trajectories. The program includes comprehensive annual evaluations such as whole-body and brain imaging, cardiovascular and metabolic profiling, body composition, retinal imaging, fitness and strength testing, cognitive assessments, and continuous remote monitoring to enable early disease detection, personalized prevention, and healthspan optimization. Dr. Fayad and colleagues at Mount Sinai (Mount Sinai/NYC-Vita) are finalists in the XPRIZE Healthspan competition, where they are evaluating a multimodal strategy to meaningfully extend human healthspan. He is also a co-founder of Trained Therapeutix Discovery, an early-stage biotech company advancing immunotherapies using nanobiologics.

G. Alexander (Zan) Fleming, MD
President, Kitalys Institute

Dr. G. Alexander Fleming, MD is Founder and Executive Chairman of Kinexum, a company of professionals from across the world with diverse expertise in developing drugs, biotech products, medical devices, and digital health technologies. He is also President and co-founder of Kitalys Institute. Dr. Fleming received his M.D. and internal medicine training from Emory, fellowship training in endocrinology at Vanderbilt and metabolism at National Institutes of Health, where he was a senior fellow prior to service at the US Food and Drug Administration (FDA) from 1986-98.

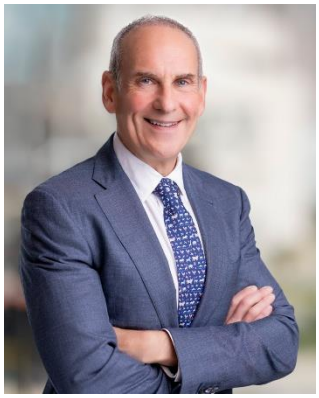
At FDA he led many landmark drug and biotech approvals and initiatives, as well as represented the Agency at the International Conference on Harmonization (ICH) and World Health Organization (WHO), Geneva, where he was posted for 18 months. Dr. Fleming has authored diverse scientific articles, books, and book chapters. He has served on many corporate and advisory boards to academic and commercial institutions and professional societies.

Dr. Fleming coined the term, Metabesity, which refers to the constellation of chronic diseases, cancer, and the aging process itself, all which share common metabolic root causes and potential for shared preventions. He organized the first Congress on Metabesity in London in 2017, which has since been followed by yearly conferences. He founded Kitalys Institute to support the conference [now called the Targeting Healthy Longevity Conference]. Other Kitalys objectives include development of the THRIVE ACT, comprehensive legislation intended to catalyze development of interventions that increase healthspan and slow the aging process.

David J. Glass, MD
Vice President, Research, Aging/Age-Related Disorders, Regeneron Pharmaceuticals

Dr. David J. Glass, MD, is a Vice President of Research at Regeneron Pharmaceuticals, overseeing a group focused on Aging and Age-associated Disorders. He's also the Director of Regeneron's Postdoctoral Fellowship program. Dr. Glass teaches courses on Experimental Design, and on the History and Philosophy of Experimentation in Biology; these courses are given via his Senior Lecturer position in the Department of Cell Biology at Harvard Medical School, and as an Adjunct Professor in the Department of Genetics & Development at Columbia University's Vagelos School of Medicine. He holds a BS from Columbia, an MD from New York Medical College and conducted postdoctoral work at Columbia University. He's an elected fellow of AAAS and ASCI, and an elected member of the National Academy of Sciences. He is the co-author of more than 140 peer-reviewed research articles on cell signaling mechanisms in neuromuscular junction formation, skeletal muscle atrophy & hypertrophy, obesity, and mechanisms associated with aging. He's the author of "Experimental Design for Biologists," published by Cold Spring Harbor Press, which is now in its 2nd edition.

William Greene, MD
Chief Investment Officer, Hevolution Foundation



Dr. William Greene, MD is a physician, epidemiologist, drug developer, seasoned CEO and experienced biotechnology investor. He is currently the Chief Investment Officer at Hevolution, where he originated, built, and leads the impact investment program in healthy aging science at the Foundation, which has become a global benchmark in healthspan investing.

His leadership positions have included CEO of Iconic Therapeutics where he led the Company through discovery, clinical development, venture financing, pharma partnership, and sale of the Company. He also was CEO of AI-driven ageing biotech company Fountain Therapeutics and co-founded digital therapeutics pioneer Pear Therapeutics.

Dr. Greene spent over a decade at MPM Capital where he was a Managing Director and member of its Investment Committee, responsible for biotechnology and medical technology investments worldwide. He was founding Chairman of the Board and Chief of the Investment Committee at the Global Health Investment Fund, a groundbreaking venture fund raised and deployed in collaboration with the Gates Foundation, which simultaneously scaled outstanding investment returns and highly significant global health impact, demonstrating the power and potential of healthcare impact investing.

Earlier in his career, Dr. Greene was an Assistant Professor of Medicine at the University of California, San Francisco (UCSF) and led clinical trials and strategy in a variety of therapeutic areas at Genentech.

Dr. Greene earned his BA from Wesleyan University and his MD from UCSF. He was a Robert Wood Johnson Clinical Scholar at Yale (epidemiology) and a Howard Hughes Medical Institute Research Scholar at the US National Institutes of Health (molecular neurobiology).

Jamie Justice, PhD
Executive Director, XPRIZE Healthspan, XPRIZE Foundation

Dr. Jamie Justice, PhD is the Executive Vice President Health Domain, Director of the $101M Healthspan Prize at XPRIZE Foundation, and Adjunct Professor in Internal Medicine at Wake Forest University School of Medicine (WFUSM). She was the recipient of the Jarrahi Research Scholars Fund in Geroscience Innovation, the 2022 Vincent Cristofalo Rising Star in Aging Research, and the 2022 NIA Nathan W Shock Awardee. Her training background at University of Colorado Boulder, academic research at WFUSM, and global leadership at XPRIZE advance translation of therapeutics to improve human healthspan and ovarian function.

Stephen B. Kritchevsky, PhD
Toby R. Alligood, MD Endowed Professor in Geroscience, Wake Forest University School of Medicine

Dr. Stephen B. Kritchevsky, PhD is the Toby R. Alligood, MD Endowed Professor in Geroscience at the Wake Forest School of Medicine where he leads the Sticht Center for Healthy Aging and Alzheimer's Prevention and Wake Forest's NIA-funded Claude D. Pepper Older Americans Independence Center (OAIC). Dr. Kritchevsky studies nutritional influences that affect trajectories of health and disability in older adults including vitamins, protein, energy balance, obesity and exercise. His recent interest is in the evaluation of geroscience-inspired therapies. Dr. Kritchevsky has held leadership positions in notable aging studies including the Health ABC study, the LIFE trial, and the on-going Study of Muscle, Mobility and Aging. He is a former Editor-in-Chief of the Journal of Gerontology: Medical Sciences, a past member of the National Advisory Council on Aging and a recently-elected member of the Academy for Health and Lifespan Research. He is also a leader of the NIA-funded Translational Geroscience Network, the

goal of which is to establish an infrastructure for the efficient clinical evaluation of interventions targeting the biology of aging to improve human health.

George A. Kuchel, MD CM
Director, UConn Center on Aging, UConn Health, University of Connecticut

Dr. George A. Kuchel MD CM is an internist, geriatrician and translational geroscientist at the University of Connecticut and UConn Health in Farmington, CT, USA. He was born in the former Czechoslovakia, and grew up in Montreal, Quebec, Canada where he graduated from McGill Medical School. Dr. Kuchel is professor of medicine, serves as director of the UConn Center on Aging and holds the Travelers chair in Geriatrics and Gerontology at UConn.

His research has focused on multidisciplinary team-based approaches to enhancing independence in older adults in terms of mobility, host defense, cognition and continence through the development of interventions rendered more precise and effective by studying the heterogeneity of aging. Dr Kuchel leads the NIA Claude D. Pepper Older Americans Independence Center at UConn, the NIA Geroscience Education and Training Network, and the NIH Common Fund KAPP-Sen Cellular Senescence Tissue Mapping Center which has been generating high quality maps of senescent cells in human kidney, adipose, pancreatic, and placental tissues. He also serves as multiple PI of the NIA Translational Geroscience Network.

Sandra Kweder, MD
Principal, Drug and Biological Sciences, Eliquent

Dr. Sandra Kweder, MD is an internal medicine expert with more than 30 years of experience in U.S. and international medical products regulation and policy. At ELIQUENT, she offers broad expertise in drug development and regulatory strategy for clients as they navigate the lifecycle of drug and biologicals. The mature approach and keen insights she brings to ELIQUENT accrued through multiple senior leadership roles at the FDA, where she oversaw significant regulatory developments during periods of transformation in the landscape of science policy and public health.

Prior to her work at ELIQUENT served for six years as Deputy Director of the FDA's Europe Office and Liaison to the European Medicines Agency (EMA), first in London and later in Amsterdam, working to strengthen international collaboration across all areas of FDA regulation, especially medical products. She launched new engagements with the EMA in areas including labeling and study of drugs in pregnancy, patient engagement

strategy, rare disease product development, and an invigorated parallel scientific advice program.

For 33 years Sandy served in the U.S. Public Health Service (PHS), rising to the rank of Rear Admiral and receiving numerous PHS awards before retiring from the service in 2013.

Jill Lee, JD
Senior Director, Regulatory Policy & Intelligence, Novo Nordisk

Jill Lee, JD is Director, Regulatory Policy & Intelligence at Novo Nordisk Inc., where she leads U.S. regulatory policy development and intelligence across a broad portfolio of areas, with a particular focus on cardiometabolic disease and obesity. In this role, she shapes company positions on emerging FDA policies and programs, translating complex regulatory landscapes into actionable insights for the organization. Jill has over 18 years of industry experience and began her career providing regulatory legal support for medical devices and pharmaceuticals. Jill holds a JD from Rutgers University and a BA from Mary Washington University.

Joan Mannick, MD
Chief Medical Officer, Altos Labs

Dr. Joan Mannick, MD is the Chief Medical Officer at Altos Labs whose mission is to restore cell health and resilience to reverse disease, injury and the disabilities that can occur throughout life. Previously she was the Chief Executive Officer and Co-Founder of Tornado Therapeutics which developed next generation rapalogs to treat aging-related conditions. Prior to that, Joan was the Head of Research and Development at Life Biosciences, and Co-Founder and Chief Medical Officer of resTORbio. resTORbio was a spinout of a clinical program targeting aging biology that she led as an Executive Director at the New Indications Discovery Unit of the Novartis Institutes of Biomedical Research. Before joining Novartis, Joan was a Medical Director at Genzyme working in multiple therapeutic areas and was faculty member at Harvard Medical School and University of Massachusetts Medical School. Joan received her A.B. from Harvard College and her M.D. from Harvard Medical School.

Evan Mills, MA
Vice President, Global Business Development, Olink, part of Thermo Fisher Scientific

Evan Mills is Vice President of Global Business Development at Olink, part of Thermo Fisher Scientific, where he leads strategic business development initiatives focused on advancing next-generation proteomics solutions in pharmaceutical, biotechnology, academic, and population health applications. With more than a dozen years of experience supporting scientists at the forefront of proteomics innovation, Evan is passionate about enabling researchers to leverage cutting-edge technologies to better understand human biology and accelerate the development of precision medicine.

Throughout his career, Evan has played a key role in helping organizations adopt scalable proteomics approaches to drive translational research, biomarker discovery, and clinical development. He has been deeply involved in some of the field's most ambitious and impactful initiatives, including serving as an integral contributor to the design, execution, and support of the UK Biobank Pharma Proteomics Project, the world's largest proteomics study to date. This landmark effort is transforming how large-scale proteogenomic data are used to identify therapeutic targets, improve disease understanding, and inform drug development.

Known for his ability to bridge scientific innovation with commercial strategy, Evan is committed to advancing technologies that enable faster, more informed decision-making across the drug development pipeline. He is particularly passionate about the role of proteomics in unlocking new insights into disease biology and helping bring better therapies to patients worldwide.

Eric Morgen, MD, MPH
Co-founder, Chief Operating Officer, BioAge Labs

Dr. Eric Morgen, MD, MPH, FRCPC is co-founder and Chief Operating Officer at BioAge. He has extensive experience in drug target and biomarker discovery using high-dimensional datasets from human cohorts, with >20 published papers spanning these areas in aging and diagnostic medicine. Eric was previously an assistant professor at the University of Toronto. He completed residency, clinical fellowship, and a research fellowship in computational biology and molecular epidemiology at Mount Sinai Hospital and the University Health Network in Toronto, where he was also a Canadian Institutes of Health Research (CIHR) research fellow. Eric received his MD, MPH, and bachelors in artificial intelligence from the University of Toronto, where he held a Canada Graduate Scholarship from the CIHR.

He is a licentiate of the Medical Council of Canada, a fellow of the Royal College of Physicians and Surgeons of Canada, and holds a specialty designation in pathology.

Justin Penzenstadler, PharmD
Acting Associate Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Office of New Drugs, CDER, FDA

Dr. Justin Penzenstadler, PharmD is an acting Associate Director in the Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) at the U.S. Food and Drug Administration (FDA). He holds a Doctor of Pharmacy (PharmD) and a Master of Science in Pharmacometrics from the University of Maryland, and completed a fellowship in Clinical Pharmacology. His clinical and regulatory expertise centers on the evaluation of therapies for chronic disease. In his current role, Dr. Penzenstadler focuses on the application of quantitative methodologies to inform and strengthen regulatory decision-making. Prior to his current position, Dr. Penzenstadler managed FDA reviews as a Cross-Discipline Team Leader (CDTL) in the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) within OCHEN.

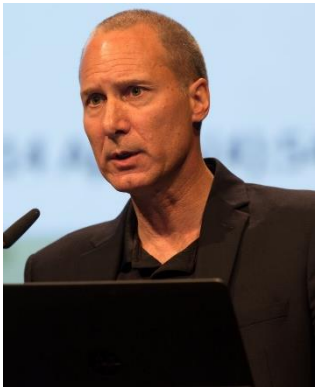
James Peyer, PhD
Founder and CEO, Cambrian Bio

Dr. James Peyer, PhD is the Founder and CEO of Cambrian Bio, a clinical-stage drug development company advancing therapeutics that target the biological drivers of metabolic decline. Cambrian's lead program in obesity, ATX-304, is a first-in-class, oral small molecule that increases energy expenditure by activating mitochondrial respiration and AMPK, the central sensor of cellular energy levels. In animal models, ATX-304 delivers GLP-1-like weight loss with no reduction in appetite, no loss of muscle, no nausea, and with a NOAEL of exaggerated weight loss. In a Phase 1b translational study, ATX-304 increased resting metabolic rate and adiponectin while reducing triglycerides and liver and visceral fat, readying the program for Phase 2 in obesity at higher exposures. Cambrian is also developing mTORC1-selective rapamycin analogs, including TOR-101, which has received non-dilutive support for a first-of-a-kind trial to improve Intrinsic Capacity.

Blake B. Rasmussen, PhD
Professor & Chair, Department of Cellular & Integrative Physiology, Barshop Institute for Longevity & Aging Studies, UT San Antonio School of Medicine

Dr. Blake B. Rasmussen PhD's area of expertise is muscle physiology and metabolism in aging. He is currently a professor & chair of the Department of Cellular & Integrative Physiology in the Long School of Medicine at UT Health San Antonio. He has been continuously funded by the NIH as a PI for more than 20 years to conduct translational studies on muscle and aging. He has extensive experience in leading large clinical trials in exercise training and disuse in older adults, and in performing comprehensive molecular, metabolic and physiological phenotyping of research participants. For example, he was a clinical site PI for the NIH supported Molecular Transducers of Physical Activity Consortium (MoTrPAC), the largest study to date on the mechanisms by which exercise improves health. Current translational and clinical research projects include an NIH R01 examining disuse muscle atrophy in older adults, an XPRIZE semi-final study on use of a new low-frequency ultrasound device for healthy aging, and he is a co-investigator on the ARPA-H PROSPR TA2b project VITAL-H. He is currently the Leader of the Molecular Phenotyping Resource Core of the NIA San Antonio Claude D. Pepper Older Americans Independence Center, and Co-Leader of the GeroMetabolism Core of the NIA San Antonio Nathan Shock Center. He has published 160 papers examining the mechanisms responsible for how physical activity influences muscle cellular metabolism, cell size and protein synthesis across the lifespan. He is an Associate Editor of Aging Cell and has served as reviewer in many NIH study sections.

Nicholas J. Schork, PhD
Research Director: Longevity, Prevention and Interception, HonorHealth Research Institute



Dr. Nicholas J. Schork, PhD, is Research Director: Longevity, Prevention and Interception at the HonorHealth Research Institute and new Arizona State University (ASU)/HonorHealth John Schufeldt School of Medicine and Medical Engineering (SOMME). Dr. Schork is also a Professor at ASU and has secondary appointments at The Translational Genomics Research Institute (TGen), a part of the City of Hope (COH) National Medical Center, COH, UCSD, and Scripps Research. His interests are in quantitative aspects of human biomedical research, particularly integrated approaches to complex biological and medical problems. He has published 650+ peer-reviewed scientific articles and book chapters, mentored 75+ trainees, has 12 patents, and has helped establish 10 companies. Among the many large projects Dr. Schork leads or is

associated with, he is currently the Principal Investigator for the NIA-sponsored Longevity Consortium as well as the Integrated Longevity OMICS initiative. Dr. Schork received a BA (1985), MA (1990), MS (1992) and PhD (1994) all from the University of Michigan.

Jeffrey Siegel, MD
Office Director, Office of Drug Evaluation Sciences, Office of New Drugs, CDER, FDA

Dr. Jeffrey Siegel, MD is the director of the Office of Drug Evaluation Sciences (ODES) in the Office of New Drugs (OND), CDER, FDA. ODES oversees Clinical Outcome Assessments, Biomarker Qualification, Research and Bioinformatics in OND. Dr Siegel has over 20 years of experience in research, regulatory, and clinical drug development. Jeff received his B.A. from Columbia University and M.D. from Yale University. He trained in internal medicine at University Hospitals of Cleveland. Then he did a fellowship in Immunology and Signal Transduction at NIH. He served at FDA from 1996-2010 as a medical officer and then Medical Team Leader. In 2010, he left FDA for industry and worked at Genentech/Roche as Senior Group Medical Director and global lead for Rheumatology and Rare Diseases and subsequently at Gilead Sciences as Translational Medicine lead in Clinical Research/Inflammation before rejoining FDA in February 2021.

Brianna Stubbs, PhD
Director of Translational Science, The Buck Institute for Research on Aging

Dr. Brianna Stubbs is a Research Assistant Professor and Director of Translational Science at The Buck Institute for Research on Aging, where her work focuses on researching ketone esters for healthy aging. She completed her PhD in Metabolic Physiology at the University of Oxford. Whilst completing her studies she was a two-time World Champion in lightweight rowing on Team Great Britain. Brianna spent two years as Research Lead at a San Francisco start-up, where she launched the world's first ketone ester consumer product and received $6M of funding from the US Special Operations Command to investigate exogenous ketone impacts on performance in extreme environments. Since moving to The Buck, she received the inaugural NIA Research and Entrepreneurial Development Immersion K01 award, launched a second consumer product and co-founded a ketone-therapeutic company. In 2023, Dr Stubbs co-established the Buck Clinical Geroscience Unit to run the first onsite clinical studies at The Buck.

Lisa Yanoff, MD
Deputy Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Office of New Drugs, CDER, FDA

Dr. Lisa Yanoff, MD. is the Deputy Director of the Office of Cardiology, Hematology, Endocrinology, and Nephrology in CDER's Office of New Drugs. Dr. Yanoff oversees the development, review, and regulation of drug and biologic products for cardiovascular, metabolic, endocrine, renal, and hematologic diseases including diabetes, obesity, frailty and sarcopenia.

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.