



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

Wednesday, May 27, 2026

10am - 4pm (eastern) | Hybrid Public Meeting

10am

Welcome & Opening Remarks

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

Steven Kozlowski, MD

Chief Scientist, Office of the Chief Scientist, Office of the Commissioner, FDA

10:20am

The Healthspan Imperative: Geroscience, Federal and Private Sector Investment, and the Evidence Base

- James Appleby, BSPHarm, MPH, *Chief Executive Officer, Gerontological Society of America*
- William Greene, MD, *Chief Investment Officer, Hevolution Foundation*
- Jamie Justice, PhD, *Executive Director, XPRIZE Healthspan, XPRIZE Foundation*
- Andrew Brack, PhD, *Program Manager, PROactive Health Office, ARPA-H*

10:45am

Landmark Evidence: What Aging Trials Have Taught Us About Endpoints, Populations, and Feasibility

- Nir Barzilai, MD, *Director, Institute for Aging Research, Albert Einstein College of Medicine, President of the Academy of Geroscience*
- Stephen B. Kritchevsky, PhD, *Professor, Gerontology and Geriatrics Internal Medicine, Wake Forest University School of Medicine*
- Joan Mannick, MD, *Chief Medical Officer, Altos Labs*
- Eric Morgen, MD, MPH, FRCPC, *Chief Operating Officer, BioAge Labs*

11:30am

Toward Regulatory Constructs: Intrinsic Capacity, Adult Health Curves, and Multi-Domain Endpoints

- David B. Allison, PhD, *Chief of Nutrition and Director, USDA Children's Nutrition Research Center, Baylor College of Medicine*
- John Beard, MBBS, PhD, *Irene Diamond Professor, Columbia University Mailman School of Public Health*
- Kelly Anderson, PhD, *Scientific Engineering and Technical Advisor, ARPA-H*
- Nicholas Schork, PhD, *Director, Quantitative Medicine & Systems Biology, HonorHealth Research Institute*

12:15pm

Lunch

- 1:05pm** **XPRIZE Healthspan and ARPA-H PROSPR Awardees: Evidence Being Built at Scale**
Introductions by Justice and Brack
- XPRIZE Healthspan Presenters
- David A. Brown, PhD, *Chief Scientific Officer, Stealth BioTherapeutics*
 - Zahi A. Fayad, PhD, *Lucy G. Moses Professor of Medical Imaging and Bioengineering, Icahn School of Medicine, Mount Sinai*
 - Blake B. Rasmussen, PhD, *Professor and Chair, UT San Antonio Long School of Medicine*
- ARPA-H PROSPR Presenters
- Brianna Stubbs, PhD, *Director of Translational Science, Buck Institute for Research on Aging*
 - James Peyer, PhD, *Founder & CEO, Cambrian Bio*
 - George A. Kuchel, MD, CM, FRCP, *Director, UConn Center on Aging, University of Connecticut*
- 2:05pm** **Regulatory Landscape: What Pathways Exist, Where They Break Down, and What Constructs Are Needed**
- Sandra Kweder, MD, *Principal, Drug and Biological Sciences, Eliquent*
 - G. Alexander (Zan) Fleming, MD, *President, Kitalys Institute*
- 2:25pm** **Industry Perspectives: What Product Sponsors Need from FDA to Bring Gerotherapeutics to Market**
- Joshua Diamond, MD, MSCE, *Medical Director Clinical Development, Respiratory Early Pipeline Unit, GSK*
 - David J. Glass, MD, *Vice President, Research, Aging/Age-Related Disorders, Regeneron*
 - Jill Lee, JD, *Senior Director, Regulatory Policy & Intelligence, Novo Nordisk*
 - Cindy Lawley, PhD, *Senior Director, Population Health and Scientific Strategy, Olink, part of Thermo Fisher Scientific*
- 3:05pm** **Next Steps to Designing Workable Regulatory Constructs for Gerotherapeutics**
- Andrew Brack, PhD, *Program Manager, PROactive Health Office, ARPA-H*
 - G. Alexander (Zan) Fleming, MD, *President, Kitalys Institute*
 - Jamie Justice, PhD, *Executive Director, XPRIZE Healthspan, XPRIZE Foundation*
 - Jill Lee, JD, *Senior Director, Regulatory Policy & Intelligence, Novo Nordisk*
 - Justin Penzenstadler, PharmD, *Acting Associate Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Office of New Drugs, CDER, FDA*
 - Jeffrey Siegel, MD, *Office Director, Office of Drug Evaluation Sciences, Office of New Drugs, CDER, FDA*
 - Lisa Yanoff, MD, *Deputy Director, Office of Cardiology, Hematology, Endocrinology, and Nephrology, Office of New Drugs, CDER, FDA*
- 3:55pm** **Closing Remarks**
- 4pm** **Adjourn**
- ARPA-H and XPRIZE Foundation provided funding for this meeting*