

Kitalys Institute Issues Its Newest E-Book on Kindle: “Establishing Clear Pathways for Healthspan Products”

E-book contains edited transcript of a historic two hour moderated round table discussion held October 11, 2021 at the virtual Targeting Metabesity conference.

HARPER FERRY, WEST VIRGINIA, UNITED STATES, April 18, 2022 /EINPresswire.com/ -- The need for clear regulatory pathways for healthspan products is one of the most pressing issues in the explosively growing longevity space. At Targeting Metabesity 2021, Kinexum Founder and Executive Chairman Zan Fleming led a historic extended panel discussion on this critical topic that included three current and three former FDA officials, and half a dozen leaders in geroscience and Pharma.

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This e-book provides an important window into the thoughts of leaders from Pharma, Biotech, medicine and FDA, on questions such as:

- How do we get evidence in a timely and efficient way to support use of a product aimed at increasing healthspan?
- What regulatory pathways and indications are currently available (or are needed) for approval of healthspan products?
- What are the roles of functional endpoints and biomarkers in supporting development of healthspan indications?
- What should clinical trials of a healthspan product look like?

The discussion also centered on three examples of regulatory and clinical development strategies for healthspan products: (i) a proposed functional registration endpoint for sarcopenia; (ii) approaches to measure enhanced immune resilience in the elderly against infectious diseases; and (iii) an approach to measure delay in a composite basket of chronic diseases and conditions.

Moderator:

Alexander “Zan” Fleming, MD, Founder and Executive Chairman of Kinexum

Speakers:

Gordon Cutler, MD, Formerly Chief, Section on Developmental Endocrinology, NICHD, NIH, and Distinguished Medical Fellow, Eli Lilly & Company, Kinexum Consultant

Mark Espeland PhD, Professor of Gerontology and Geriatric Medicine and Public Health Sciences at the Wake Forest School of Medicine

David Fox, JD, Partner at Hogan Lovells

Stephen Grossman, JD, President of HPS Group, Formerly Deputy Assistant Secretary for Health, Regulatory and Policy Consultant

Brian Harvey, MD, PhD, Principal Consultant at Brian E Harvey LLC and Entrepreneur in Residence at Yale University

Theresa Kehoe, MD, Director (acting), Division of General Endocrinology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Peter Libby, MD, Cardiovascular Specialist at Brigham and Women's Hospital and Mallinckrodt Professor of Medicine at Harvard Medical School

Joan Mannick, MD, Head of Research & Development at Life Biosciences

Line Jee Hartmann Rasmussen, PhD, Senior researcher in the Department of Clinical Research, Copenhagen University Hospital Hvidovre, Denmark and the Department of Psychology & Neuroscience at Duke University

Ed Saltzman, Executive Chairman, Cello Health BioConsulting

Jeffrey Siegel, MD, Office Director, Office of Drug Evaluation Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Sue-Jane Wang, PhD, Biomarker Lead/Liaison and Deputy Division Director in the Office of Biostatistics, U.S. Food and Drug Administration

The session was held on Day 1 of the virtual [2021 Targeting Metabesity](#) conference, which assembled prominent speakers such as former FDA Commissioner Stephen Hahn, Scripps' Eric Topol, former Human Genome Sciences CEO William Haseltine, investor and philanthropist Esther Dyson, National Academy of Medicine President Victor Dzau, and many other leaders in diabetes, cardiovascular and neurodegenerative diseases, cancer, diet and nutrition, law, regulation and policy, health equity, healthy behaviors, national and global healthy longevity policy, and commercialization and finance in a 'silo-busting' conference conversation on how to accelerate the translation of advances in the biology of aging into public health, the protection

against chronic diseases, and the extension of healthy longevity for all.

About The Kitalys Institute:

The [Kitalys Institute*](#) is a not-for-profit entity dedicated to catalyzing the translation of science into solutions for protecting against chronic diseases and extending healthy longevity for all. It is the organizer of the annual Targeting Metabesity conferences, called “one of the most important longevity conferences of the year,” with a “staggering” speakers roster. Metabesity refers to the major chronic diseases, cancer, and the aging process, all of which are driven by shared metabolic and other root causes. These root causes can be targeted with science-based solutions to forestall all of these conditions, thereby increasing healthspan—the span of life free of chronic disease. Targeting Metabesity 2022 will be held October 10-12, 2022 (www.metabesity2022.org).

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