

# Critical Path Initiative: 10 Years Later Briefing to Hill Staffers

Tuesday, October 20, 2015

2:00-3:30 pm

Dirksen Room 406:  
Senate Environment and Public Works Committee Hearing Room

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## 2:00 pm WELCOME

*Dr. Martha A. Brumfield, President and CEO, Critical Path Institute*

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## 2:05 pm PANEL PRESENTATIONS

Critical Path Initiative: Past, Present, and Future

*Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA*

Collaborating to Accelerate Drug Development

*Dr. Martha Brumfield*

Value of Public-Private Partnerships

*Dr. John D. Porter, CEO, Parent Project Muscular Dystrophy*

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## 3:00 pm DISCUSSION AND AUDIENCE QUESTIONS

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## OBJECTIVE OF BRIEFING

The **Critical Path Institute (C-Path)** will host a briefing for Congressional staff on the progress made over the past decade on the regulatory science opportunities identified in FDA's **Critical Path Initiative**. By taking a collaborative approach with industry, academia and government, C-Path is focusing on needs identified by the FDA and other stakeholders such as industry and patient groups, marshaling the evidence needed to advance innovation in regulatory science. The briefing will highlight the value of the public-private partnership model in addressing complex scientific and regulatory issues in medical product development. Specific C-Path consortia-related examples, which have resulted in new drug development tools, will be highlighted, such as a biomarker for use in polycystic kidney disease. Recently announced collaborations that focus on special and underserved populations, such as neonates and Duchenne Muscular Dystrophy patients, will also be discussed.

## ABOUT THE SPEAKERS

### ***Martha Brumfield***

Martha A. Brumfield, PhD, is President and Chief Executive Officer of Critical Path Institute (C-Path); she also served as C-Path's Director of International & Regulatory Programs. Dr. Brumfield is a professor in the Department of Pharmacy Practice and Science at The University of Arizona, and worked for 20 years at Pfizer Inc. She is President of the Board of Directors for the Regulatory Affairs Professional Society and chairs the Global Curriculum Coordinating Committee with FDA's Office of International Policy. She is also active with global nonprofits, and serves on the Steering Committee of the Multi-Regional Clinical Trials Center of Harvard and Brigham and Women's Hospital. Dr. Brumfield earned a B.S. and an M.S. in chemistry from Virginia Commonwealth University, a Ph.D. in organic chemistry from the University of Maryland, and served as a post-doctoral fellow at the Rockefeller University.

### ***Janet Woodcock***

Janet Woodcock, MD, is the Director of the Center for Drug Evaluation and Research within the United States Food and Drug Administration. Dr. Woodcock has served the FDA as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. In these roles, she oversaw scientific and medical regulatory operations. Dr. Woodcock served as Director of the Center for Drug Evaluation and Research from 1994 to 2005. She previously held other positions at the FDA, including Director of the Office of Therapeutics Research and Review, and Acting Deputy Director of the Center for Biologics Evaluation and Research. Dr. Woodcock received her medical degree from the Fienberg School of Medicine from Northwestern University and completed further training and held teaching appointments at Pennsylvania State University and the University of California in San Francisco. She joined the FDA in 1986.

### ***John Porter***

John D. Porter, PhD, former program director of the National Institutes of Health (NIH)/National Institute of Neurological Disorders and Stroke (NINDS), became Chief Executive Officer for Parent Project Muscular Dystrophy (PPMD) in January 2015. As program director at the NIH/NINDS, Dr. Porter was responsible for managing a portfolio of research grants across neuromuscular disorders and served as Executive Secretary of the interagency Muscular Dystrophy Coordinating Committee. Prior to that, he served as Professor of Neurology at Case Western Reserve University. As PPMD CEO, Dr. Porter continues to integrate programs to maximize impact, building upon current programs and exploring opportunities to expand the research pipeline, with the goal of accelerating progress and approvals. Dr. Porter earned a B.S. in biology from the College of William and Mary, and a Ph.D. in Anatomy from the Medical College of Virginia.