

Dr. Janet Woodcock: A Visionary Leader in Regulatory Science and the Inspirational Force behind the Creation of Critical Path Institute

In her nearly four decades with the U.S. Food and Drug Administration, Dr. Janet Woodcock personally transformed the culture of the agency in ways that will be sustained and have an everlasting impact. She understood that for the next stage of FDA's regulatory mission to be effectively achieved, it would need to be grounded on a foundation of Regulatory Science. Moreover, she was the first to propose that regulatory science should not merely consist of declarations made by FDA scientists. Instead, it should be the result of consensus and collaboration among regulators, the regulated industry, academic scientists, and the communities with lived experiences. Dr. Woodcock embedded these principles in every FDA program and offices she directed.

Among her numerous achievements, one of her most enduring impacts may stem from her white paper on the FDA's Critical Path Initiative. This document advocated for public-private partnerships to identify the most efficient pathways to optimize the process for developing new drugs and medical products, with particular focus on areas in which there was an unmet therapeutic need. It promoted collaborations that enabled the FDA to establish a novel regulatory framework, namely the qualification process. This process evaluates the suitability of new testing methods for their intended purpose.

Under Dr. Woodcock's guidance, hundreds of highly productive collaborations have been initiated, significantly accelerating the safe development of new drugs and biomedical products.

"I had the pleasure of working with Janet to launch the highly successful Critical Path Institute," said C-Path founder Dr. Ray Woosley. "Based in Arizona, C-Path operates globally with programs and collaborations across the U.S., Europe, Japan, and beyond. This is but one of many examples of the breadth of Janet's impact on public health and biomedical technology."

"In reflecting upon the genesis and subsequent evolution of the Critical Path Institute, it's imperative to acknowledge Janet's visionary leadership, which was instrumental in the conceptualization of the FDA's Critical Path Initiative," said C-Path CEO Dr. Klaus Romero. "Her foresight and dedication to innovation set a transformative precedent for drug development. This initiative not only served as a beacon of progress but also inspired Dr. Ray Woosley to establish the Critical Path Institute in alignment with Janet's pioneering vision. As we navigate the complexities of modern drug development and strive to enhance public health outcomes, our endeavors at C-Path are fundamentally anchored in the principles Janet introduced."

"Critical Path Institute has embraced innovation outlined from Dr. Woodcock in the areas of model-informed and patient-focused drug development across chronic disorders of the nervous system in ways that have inspired tools that are accelerating the road to much needed therapies," said C-Path Critical Path for Parkinson's Consortium Executive Director, Dr. Diane Stephenson.

As C-Path approaches its 20th year, we stand on the shoulders of giants like Dr. Janet Woodcock, whose visionary leadership continues to shape our trajectory. Her influence on the Critical Path Institute and the broader landscape of biomedical technology is immeasurable. Her legacy will continue to inspire generations of researchers, regulators, and industry leaders. With gratitude, we honor her contributions and reaffirm our

dedication to building upon her foundation. We are committed to driving forward progress in drug development, and ultimately improving the lives of individuals and families worldwide. Thank you, Dr. Woodcock, for your unparalleled dedication and enduring impact.