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Dr. Raymond Woosley provides expert testimony in Congressional Hearings

Raymond Woosley, MD, PhD, President and CEO of The Critical Path Institute (C-Path) provided testimony and answered questions about drug development yesterday at the Committee on Energy and Commerce's Subcommittee Hearing on Oversight and Investigations entitled "The Adequacy of FDA Efforts to Assure the Safety of the Drug Supply."

As a physician and pharmacologist, Dr. Woosley shared some of the lessons he has learned about drug safety and gave his perspective on the threats preventing new drugs from rapidly reaching the market and patients in need of cures for serious illnesses.

Dr. Woosley highlighted opportunities for improvement of the outdated medical product development process which has remained largely unchanged for 50 years. As an example, he cited a C-Path project that the FDA helped to create as part of its Critical Path Initiative. He called for more pre-competitive collaborations among companies like the one now underway in which 16 companies have agreed to share and validate each others' safety tests. This type of work will ultimately streamline the process thereby shortening the amount of time and money it takes to develop a drug.

Dr. Woosley also stated the need for a post marketing safety assessment program in the United States that is capable of rapid and accurate detection of adverse drug events. With modest investment, the Agency for Healthcare Research and Quality-funded Centers for Education and Research on Therapeutics (CERTS) could readily be expanded to serve as an early detection system to inform the FDA of adverse effects of drugs.

Dr. Woosley concluded with his belief that the FDA does not need substantial reform or overhaul and that current problems there can be best addressed if the Agency has stable leadership, adequate resources and the additional scientists it needs to execute its mission.

About The Critical Path Institute
Headquartered in Tucson, Arizona with an office Rockville, MD, C-Path was established in 2005 as a publicly funded, nonprofit research and education institute to serve as a trusted third party for collaborations between scientists and others from government, industry and academia. C-Path's mission is to help implement the FDA's Critical Path Initiative by developing faster, safer and smarter pathways to new medical products. Visit www.c-path.org for more information.