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CRITICAL PATH INSTITUTE CONTINUES TO EXPAND Stephen Joel Coons, PhD, Joins as Director of Newly Formed Patient-Reported Outcomes Consortium

Tucson, Arizona, March 31, 2010 – In cooperation with the U.S. Food and Drug Administration (FDA) and the pharmaceutical industry, Critical Path Institute (CPI) has formed the Patient-Reported Outcomes (PRO) Consortium for the purpose of developing, evaluating, and qualifying patient-based measures of treatment effectiveness for use in clinical trials testing new medical products. **Stephen Joel Coons, PhD**, has joined CPI to lead this new consortium.

Dr. Coons has been actively engaged in this area of research for almost two decades and brings an exceptional level of expertise to the Institute. As Director of the PRO Consortium, he is responsible for operations, organizational effectiveness and scientific integrity. Additionally, Dr. Coons chairs the consortium's coordinating committee and directs the establishment and implementation of the processes used for identification, prioritization, and development of potential PRO instruments. Current consortium focus areas include asthma, advanced breast cancer, depression, irritable bowel syndrome, lung cancer, and mild cognitive impairment.

Historically, in the development of new drugs and other medical products, clinician-reported outcomes or laboratory tests have been used to assess a particular treatment's impact. However, based on the recognition that some of the most important treatment effects are known only to the patient (e.g., pain relief), these assessments are increasingly based on patient input obtained using PRO questionnaires specifically designed for that purpose. Hence, these instruments must be shown to be valid and reliable measures of the specific outcome of interest. Dr. Coons asserts, "It is critical for the patient's voice to be incorporated into the evaluation of the safety and effectiveness of medical interventions. The PRO Consortium is committed to making this increasingly possible."

States Laurie B. Burke, Director of Study Endpoints and Labeling in FDA's Center for Drug Evaluation and Research, "This public-private partnership is aimed at reducing duplication of effort and bringing efficiencies to PRO instrument development and qualification for both clinical trial sponsors and the FDA. The PRO Consortium provides the neutral ground for interaction and scientific collaboration that will lead to publicly available PRO instruments intended to enhance the quality of information available

not only to the FDA and study sponsors, but to prescribers and patients as well. Because of his vast experience and reputation as an academic leader in this field of research, I am delighted that Stephen has been chosen to lead the PRO Consortium.”

According to Dr. Raymond Woosley, President/CEO of Critical Path Institute, “We are extremely fortunate to have Dr. Coons, an internationally recognized leader in this field, assume the leadership of this very important consortium. He is passionate about changing medical product development to more accurately reflect the voice of the patient. He reminds us that medicine really is all about the patients, and we should listen to them.”

Dr. Coons comes to CPI from The University of Arizona, where he spent 18 years as a professor in the College of Pharmacy and served as Co-Director of the Arizona Cancer Center’s Behavioral Measurements Shared Service. Prior to that, Dr. Coons held faculty positions at the University of Kentucky College of Pharmacy and College of Medicine and the University of California, San Diego School of Medicine. He received his Bachelor of Science in Pharmacy from the University of Connecticut, and holds Master’s degrees in Pharmacy and Education (Higher Education) as well as a PhD in Pharmacy from The University of Arizona. Dr. Coons completed his post-doctoral fellowship at the University of California, San Diego. He retains a part-time faculty position at the University of Arizona and is a fellow in the American Association of Pharmaceutical Scientists. The primary focus of Dr. Coons’ research over the past 20+ years has been the measurement of patient-reported outcomes, particularly self-reported health status and health-related quality of life.

About Critical Path Institute

Critical Path Institute (CPI) is an independent, non-profit organization whose mission is to serve as the impartial facilitator of collaborative efforts among scientists from government, academia, patient advocacy organizations and the private sector to support the U.S. Food and Drug Administration’s regulatory science initiatives. This involves creating faster, safer and smarter pathways for innovative new drugs, diagnostics and devices that will significantly improve public health. Established in 2005, CPI is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. Visit www.c-path.org for more information.

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