

## FDA News

FOR IMMEDIATE RELEASE  
P05-101  
December 16, 2005

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### **FDA Announces Partnership with Critical Path Institute to Conduct Essential Research to Spur Medical Innovation Safety Consortium Study and Community Pharmacy Network Among First Projects**

The Food and Drug Administration today announced a first-of-its kind partnership with the newly formed Critical Path Institute (C-Path), an independent, publicly funded institute bringing together scientists from FDA, academia and industry to accomplish goals outlined in the Critical Path Initiative (CPI), FDA's premier program to improve the efficiency and safety of medical product development. Since the release of the first Critical Path report, FDA has forged many public-private partnerships to collaborate on projects under the initiative. C-Path is the only institution created solely to fulfill the mission of the Critical Path Initiative.

"The power of public-private partnerships is vital to accomplish the tasks set forth in the Critical Path report and the upcoming opportunities list," said Janet Woodcock, MD, FDA Deputy Commissioner for Operations, at the opening ceremonies for C-Path in Tucson, AZ. "The collective sharing of scientific information and research across the entire healthcare community is crucial to igniting the medical innovation required to keep pace with biomedical research- no one entity can accomplish this independently."

Through its programs, C-Path intends to address the three areas of the FDA's Critical Path Initiative for testing new medicines on the "critical path" from the laboratory to the patients-faster, smarter, and safer processes. The agreement signed between FDA and C-Path is one of many strategic partnerships formed in anticipation of the release of the Critical Path National Opportunities List that will outline 75 research priorities essential to the agency's goal of spurring medical innovation to improve public health. Some of the projects in development by C-Path will help to accomplish objectives outlined in the opportunities list.

"The Critical Path Institute was founded to provide 'neutral ground' for the collaboration of scientists from the FDA, academia and industry. This provides C-Path and the FDA with access to the expertise that will be essential to the testing and evaluation of innovative methods for developing new medical products" said Raymond Woosley, MD, PhD, founder and President of C Path. "C-Path is neutral because it is not vested in the development of any medical products, so we will act as catalyst for bringing resources together to break new ground in science and then share it broadly to be used by different entities in product development."

#### *Toxicogenomic Safety Study*

One of the first projects being developed through the partnership involves a consortium of six major pharmaceutical companies that have agreed to come together with C-Path and FDA to share internally developed laboratory methods to predict the safety of new drugs. This sharing of potential early indicators of clinical safety may streamline the cost and time of preclinical drug safety evaluation and better inform post-marketing surveillance. With FDA

advice and C-Path scientific oversight and coordination, these methods will be evaluated by other members of the consortium to be used in future drug testing.

#### *Community Pharmacy Safety Network*

The Critical Path Institute (C-Path) will partner with Arizona-based pharmacy chain Bashas' United Drug and The Arizona Poison and Drug Information Center (Center) to create the Community Pharmacy Safety Network (CPSN). The network is designed to become a national network of pharmacies that evaluates the comparative safety and effectiveness of medications. Through the network, patients will have the opportunity to actively participate in their care and provide valuable information on medication outcomes and to report adverse effects.

Based in Tucson, Arizona, The Critical Path Institute was established in early 2005 as an independent non-profit research and education institute to facilitate collaboration among its founding partners, the U.S. Food and Drug Administration, The University of Arizona, and SRI International. The Institute has received more than \$11 million in contributions from the State of Arizona, the City of Tucson, Pima County, regional municipalities, foundations, organizations, and private individuals. Its mission is to facilitate the Critical Path Initiatives of the FDA to create faster, safer, and smarter pathways for developing new medicines.