



Florence S. Mahoney Seminar Series

Formerly known as Progress in Longevity Medicine Seminar Series (PLMSS)

The High Cost And Low Productivity Of Drug Development in the US: An Arizona Solution?

Louis Kirby, MD

*Director of the Phoenix office of the Critical Path Institute
Co-Chair of the Biomarkers Workgroup of the Coalition Against Major Diseases
Phoenix, AZ*

Date/Time: Friday, October 16, 2009; 5:30 pm (dinner included)

Location: Doubletree Guest Suites, 320 North 44th St., Phoenix, AZ 85008

Cost: No cost to attend

Abstract: Drug development in the United States is in crisis—characterized by billions spent for only a few drug approvals. Last year the industry spent over 50 billion dollars of drug development, and got only 21 drug approvals. Of these, only 12 were new, the rest were imitation drugs or drug extensions. Of the new drugs, four were significant advances and the rest were for rare diseases or diagnostics. The average cost per newly approved drug was 2.3 billion, the lowest productivity the industry has ever had. The industry develops drugs with tools and tests that are sometimes 50 years old. Because of the regulatory environment, innovation is very difficult between a pharmaceutical company and the regulatory agencies. The FDA wrote a white paper called the *Critical Path Initiative* that outlined a process to accelerate drug development and increase its efficiencies. The Critical Path Institute, an Arizona 501(c)(3) corporation was founded to become the vehicle for implementing many of the critical path initiatives. The seminar will discuss the current drug development crisis, its magnitude and how it is affecting the health of Americans. I will also describe the specific activities the Critical Path Institute has instituted to help address the drug development challenges.

Objectives

- Understand the magnitude of the difficulty in developing new drugs in the US
- Understand the impact these development problems have on the future development of significant drug therapies in the future
- Understand how the Critical Path Institute is working with industry and the regulatory agencies to free up this drug development logjam

Biography: Dr. Louis Kirby is the Director of the Phoenix office of the Critical Path Institute and is the Workgroup Co-Chair of the Biomarker section of the Coalition Against Major Diseases (CAMD), a division of the Critical Path Institute. He also consults with the pharmaceutical industry in various capacities including acting Medical Director of Neuraltus Pharmaceuticals.

Previously, Dr. Kirby served as Chief Medical Officer of Provista Life Sciences, which is in the process of developing a blood-based biomarker for the diagnosis of Alzheimer's disease.

Prior to that, he was the Founder and CEO of Pivotal Research Centers, which grew to become a large freestanding clinical trials research center. Dr. Kirby has been the Principal Investigator on nearly 400 clinical trials, most focused on the central nervous system, including over 100 trials in Alzheimer's and Parkinson's disease.

Dr. Kirby is on the Board of Directors of the Southwest Autism Research and Referral Center (SARRC) and serves on their scientific advisory committee. He has also served as Chief of Staff at Thunderbird Medical Center and sat on the Board of Directors of Samaritan Health System (now Banner Health).

He is a board certified neurologist and completed both his medical and his neurological training at the University of Texas Medical Branch in Galveston, Texas.

To RSVP or for additional information, please contact Stephanie Tusalem at (602) 778-7492 or via email at stephanie.tusalem@kronosinstitute.org.

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