

June 15, 2009

**Hamner Institutes And UNC Launch International Drug Safety Institute**  
*Scientific Collaboration Takes Aim At  
Improving Drug Safety, Advancing Drug Development*

**RESEARCH TRIANGLE PARK, N.C.** – The Hamner Institutes for Health Sciences ([www.thehamner.org](http://www.thehamner.org)) and the University of North Carolina at Chapel Hill have announced the official launch of The Institute for Drug Safety Sciences, strategically located on The Hamner's 56-acre campus in Research Triangle Park. The Institute will be led by Dr. Paul Watkins, one of the world's leading experts in drug-induced liver injury who currently also serves as the Verne S. Caviness Distinguished Professor of Medicine at UNC-Chapel Hill. As founding director for this innovative research Institute, Watkins has already assembled a core group of internal scientists and academic partners to develop new global drug safety initiatives in collaboration with the bio/pharmaceutical industry, the National Institutes of Health (NIH), and the FDA. A major initial focus will be to develop new computational models and *in vitro* assays, starting first with evaluating liver toxicity and expanding into cardiovascular and kidney drug side effects.

The Institute for Drug Safety Sciences, which includes a 14,000-square-foot, state-of-the-art research laboratory, was officially unveiled at a grand opening event on June 11. The event featured a keynote address from Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, which oversees the approval and regulation of all medications in the United States. The June 11 grand opening built on a memorandum of understanding signed by The Hamner and UNC in April 2008 and a \$10 million funding commitment established in September 2008. The Hamner-UNC partnership capitalizes on the scientific strengths of a leading university and an independent research institute, both of which are committed to accelerating advances in human therapeutics and public health, both in North Carolina and internationally.

In March 2009, scientists at the Institute for Drug Safety Sciences launched their first research initiative in the study of drug-induced liver injury when they formed a partnership with Entelos, a leading Silicon Valley computational modeling company. Besides being a main cause of acute liver failure in the United States, liver toxicity is also the major reason global regulatory agencies take action on drugs, such as denying approval for drug development candidates or withdrawing drugs from the marketplace. By creating a virtual liver model, the researchers hope to predict how pharmaceutical drugs and chemical agents damage the liver. The project also supports the FDA's "Critical Path Initiative," which aims to reduce the time it takes to develop and approve safe and effective medical products.

The Institute for Drug Safety Sciences has also signed an agreement with the Shanghai Center for Disease Control to conduct a study in patients who have experienced liver toxicity as a result of taking drugs to treat tuberculosis. Knowledge from this study in China will enable the Institute to create strategies to develop safer drugs in the United States, China, and around the world. Recently, The Hamner announced a translational research and business development partnership with China Medical City and Newsummit Biopharma to establish an Institute for International Drug Development to further enhance the process of taking drugs from the "bench to the bedside."

**Related Links:**

[www.thehamner.org](http://www.thehamner.org)

[www.med.unc.edu](http://www.med.unc.edu)

[www.pharmacy.unc.edu](http://www.pharmacy.unc.edu)

[www.entelos.com](http://www.entelos.com)

[www.thehamner.org/docs/Press\\_045\\_Hamner-CMC\\_Announcement.pdf](http://www.thehamner.org/docs/Press_045_Hamner-CMC_Announcement.pdf)

**Quotes:**

“I am extremely pleased that we have been able to forge this milestone partnership with the University of North Carolina at Chapel Hill,” said Dr. William Greenlee, President and CEO of The Hamner Institutes for Health Sciences. “The Institute for Drug Safety Sciences is positioned to make transformative advances in human predictive safety sciences that will accelerate the development of new and safer therapeutics.”

“The UNC Eshelman School of Pharmacy is proud to be associated with The Hamner Institutes for Health Sciences,” said Dr. Robert A. Blouin, Dean of the UNC Eshelman School of Pharmacy. “This collaboration will facilitate significant advances in the discovery and development of new drugs for society.”

“It now takes over decade and \$1 billion from the time a new drug is discovered to the time it is approved for by the FDA,” said Dr. Paul Watkins. “Increasingly, these costs and delays relate to proving a drug is safe well after it has been shown to be beneficial. The Institute for Drug Safety Sciences is dedicated to using the latest scientific techniques to understand, predict, and avoid adverse events from drugs to speed delivery of important new drugs to the patients who need them.”

**About The Hamner Institutes for Health Sciences:**

The Hamner Institutes for Health Sciences is a nonprofit research organization strategically located in Research Triangle Park, North Carolina. The Hamner has a strong heritage in scientific scholarship and translational research. For 35 years, scientists at The Hamner have conducted small-molecule chemical safety studies to inform public health policy. The Hamner has recently expanded its mission to include drug safety, NIH-funded human disease research, and support for life science start-ups. As a neutral, independent research institute, The Hamner works collaboratively with academia, government regulatory agencies, and commercial companies to accelerate the development of new bioscience technologies.

During the past year, The Hamner has played an active role in linking together translational research programs in the RTP-Winston Salem corridor of North Carolina. For example, The Hamner and the University of North Carolina-Chapel Hill jointly created an integrated Institute for Drug Safety Sciences, which is already being recognized as a leader in studying the safety of biotechnology and pharmaceutical products. Additional research and business development agreements have been established with Duke University, North Carolina State University, and Wake Forest University. For more information, please see [www.thehamner.org](http://www.thehamner.org) or call (919) 558-1200.

**About The University of North Carolina at Chapel Hill:**

The University of North Carolina at Chapel Hill, the nation’s first public university, is a leader in American higher education and known around the world for innovative teaching, research and public service. Now in its third century, Carolina offers 76 bachelor’s, 108 master’s, 74 doctorate and four professional degree programs. This fall, the University enrolled more than 28,000 students who are taught by a 3,200-member faculty. Every day, faculty, staff and students shape their teaching, research and public service priorities to meet North Carolina’s most pressing needs in every region and all 100 counties.

**Keywords:**

The Hamner Institutes, University of North Carolina at Chapel Hill, School of Medicine, UNC Eshelman School of Pharmacy, Institute for Drug Safety Sciences, FDA, Dr. Paul Watkins, New Medicines, Safer Medicines, Drug Safety, Translational Research, Economic Development, Dr. William Greenlee, Dr. Charles Hamner, International Drug Safety, Janet Woodcock, Pharmaceutical Industry, FDA Critical Path Initiative

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