



## **For Immediate Release**

Institute for Pediatric Innovation contact:  
Ross Trimby  
COO  
617-401-2375  
[ross.trimby@pediatricinnovation.org](mailto:ross.trimby@pediatricinnovation.org)  
[bheffner@chenpr.com](mailto:bheffner@chenpr.com)

Press contact:  
Barbara Heffner  
CHEN PR, Inc.  
781-672-3112

## **Institute for Pediatric Innovation Awarded Funding by University of Kansas to Analyze the Use of Extemporaneously Prepared Medicines in Children's Hospitals**

Cambridge, Mass. – June 25, 2008 – The Institute for Pediatric Innovation (IPI), Inc., a nonprofit focused on catalyzing the commercialization of products optimized for pediatric care, today announced that it has been awarded a \$50,000 grant to analyze the use of extemporaneously prepared liquid formulations in children's hospitals. The study is being funded by the University of Kansas.

Most children under the age of seven have difficulty taking tablets or capsules, yet medicines often are not available in a liquid form with provisions for age- and size-appropriate doses. As a result, pharmacists in pediatric hospitals frequently must extemporaneously prepare liquid formulations of drugs by making a suspension or solution from crushed pills. This introduces the potential for errors and resultant risk to young patients due to lack of efficacy and safety data.

"The pediatric community recognizes the problem of extemporaneous preparations of medications for young patients," said Dr. Stephen P. Spielberg, Principal Investigator for IPI's Pediatric Pharmaceutical Reformulation Project. "In order to translate this awareness into an action plan, we need to gather hard data from children's hospitals, so that we can identify the medications that are most commonly reformulated, and set priorities for future efforts. We are fortunate to have the support of some of the leading pediatric institutions in the country in collaborating to achieve the goals of this study."

"We are very pleased to work with the Institute for Pediatric Innovation on this important market analysis project," said Scott Weir, PharmD, Ph.D., director of the Office of Therapeutics, Discovery and Development at the University of Kansas. "We are

currently developing a business plan to establish a Kansas Bioscience Authority funded Center of Innovation in Drug Delivery. The data generated by IPI will assist us in defining our drug delivery core competencies as well as identifying pediatric drug products the Center will help develop. Ultimately, our goal is to meet the therapeutic needs of children.”

### **Study Details**

The study will involve collecting data from 25 children’s hospitals in North America on the production and use of extemporaneously compounded liquid formulations. Each institution will collect data on the most frequently reformulated products, stability information and financial data related to the compounding of these medications. Each participating hospital will agree to release the summarized data.

The study will be led by Ralph A. Lugo, PharmD, Professor and Chair, Department of Pharmacy Practice, East Tennessee State University College of Pharmacy; Dr. Robert M. Ward, M.D., Director of Pediatric Pharmacology, University of Utah; and Dr. Stephen Spielberg, M.D., Ph.D. and Principal Investigator for IPI. The study also will be supported by the Pediatric Pharmacy Advocacy Group (PPAG) and founding members of IPI’s Consortium of Pediatric Hospitals: Children’s Mercy Hospitals and Clinics, University Hospitals Rainbow Babies and Children’s Hospital and the Lucile Packard Children’s Hospital at Stanford.

Although pharmacists in pediatric hospitals have recognized concerns regarding extemporaneous pediatric formulations for many years, there are no current data on the scope of the problem on a national or international scale. The last published information on this topic was a survey conducted by the PPAG in 1997, highlighting the extent of the problem, including the lack of data on validation of the formulations used, in terms of stability and bioavailability, the potential for human error and the risk to patients.

This study is part of IPI’s Pediatric Pharmaceutical Reformulation Program, which aims to define the most critical unmet clinical needs for better formulated drugs for children. The program will set priorities for the development of the identified pharmaceuticals according to potential for clinical impact, formulation development requirements, clinical testing and regulatory pathway, and commercialization considerations. The program team is led by Dr. Stephen Spielberg.

### **About the Institute for Pediatric Innovation (IPI)**

The Institute for Pediatric Innovation ([www.pediatricinnovation.org](http://www.pediatricinnovation.org)) is a nonprofit organization that was formed to improve the health of children by increasing the availability of innovative medical products with the unique attributes required for pediatric care. IPI seeks to transform pediatric healthcare from a neglected orphaned market to a magnet for industry and investor interest. IPI is led by an experienced team of experts in licensing technology in pediatric medical care, commercializing medical technology, and marketing medical devices and pharmaceutical products. To date, IPI has received support from its consortium members along with the Ewing Marion

Kauffman Foundation, Children's Medical Ventures, Inc., AGA Medical and Oxford Bioscience Partners.

# # #