

FDA AWARDS NIPTE POTENTIAL \$35 MILLION IN GRANTS TO REFORM DRUG MANUFACTURING PROCESS

National Institute for Pharmaceutical Technology and Education: Reforming Process Will Improve Drug Safety, Create U.S. Jobs and Bring Down Health Care Costs

Chicago, IL-- In a move that seeks to cut health care costs, create jobs, and improve drug safety, the US Food and Drug Administration (FDA) has awarded a grant worth up to \$35 million over the next five years to the National Institute for Pharmaceutical Technology and Education (NIPTE) to improve drug manufacturing standards. The grant comes at a time when the current cost of bringing a drug to market in the US exceeds \$1 billion and an increasing number of drugs and drug ingredients are being imported from abroad. Investment in research of drug development and manufacturing will not only improve America's manufacturing competitiveness and create high-paying jobs at home, but will help to reverse the current outsourcing trends in the pharmaceutical industry in the long term by decreasing the cost of manufacture and by improving quality and safety of our drugs.

"Over the last several years, NIPTE has contributed a great deal of research toward our understanding of quality pharmaceutical manufacturing," said Helen N. Winkle, Director, FDA Office of Pharmaceutical Sciences. "Progress in this area will mean safer, more efficient, and less costly drug production here in the US, and we are looking forward to NIPTE's findings."

NIPTE, Inc. is an academic not-for-profit organization dedicated to fundamental research and education in pharmaceutical product development and manufacturing. NIPTE's goal is to increase science and engineering-based understanding of this area so that novel state-of-the-art technologies can be developed and science-based regulations can be implemented. These technologies will also enable new drug discoveries to be brought to market faster with less variability, higher predictability of performance and at a significantly lower cost.

"Outsourcing of drugs and drug intermediates are increasing at an alarming rate, potentially threatening overall quality of our drugs accompanied by huge job losses in this country," said NIPTE Executive Director Prabir Basu. "Development and manufacturing costs can be reduced, quality of our drugs can be improved, and outsourcing trends can be reversed by developing science-based standards for drug development and manufacturing."

The FDA grant will support programs to rectify these drug development and manufacturing problems, by creating ways to reduce time to market, enabling new performance attributes, improving small-batch production, promote continuous manufacturing, saving money or energy, or reducing environmental impact from the manufacturing of products. "We are thrilled to see the FDA's commitment to invest in the science of pharmaceutical manufacturing," said Basu. "I sincerely hope that other federal funding agencies will take the lead from the FDA and will take similar steps to fund this critical area of translational and manufacturing research to improve health care in the US."

NIPTE partners with 10 U.S. universities that are leaders in pharmaceutical science and engineering. The member universities are Duquesne, University, Illinois Institute of Technology, Purdue University, Rutgers University, University of Puerto Rico, University of Connecticut, University of Iowa, University of Kentucky, University of Maryland - Baltimore, and the University of Minnesota. It is the only partnership of universities of its kind. Research conducted by NIPTE faculty is collaborative by design to provide for coordinated publication of the cutting edge research results.