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CONTACTS:

FDA: Karen Riley, 301-796-4674, <e-mail: karen.riley@fda.hhs.gov>

NIH: Calvin Jackson, 202-594-8750, <e-mail: cj8e@nih.gov>

NIH AND FDA ANNOUNCE AWARDS TO ADVANCE REGULATORY SCIENCE

The National Institutes of Health will award \$9.4 million over three years to support four research projects in regulatory science. This research is conducted in partnership with the U.S. Food and Drug Administration, which will contribute approximately \$950,000. These projects will better inform scientists and regulatory reviewers alike about medical product safety, and improve the evaluation and availability of new medical products to the community.

The projects include research on nanoparticles (extremely small molecules that may be used to deliver drugs in a targeted manner) and their characterization, a heart-lung model to test the safety and efficacy of drugs, innovative clinical trial design, and a novel strategy to predict eye irritation.

"These four projects were chosen among many applications because they were the most meritorious proposals for addressing high priority areas in cutting-edge biomedical research and regulatory science. This partnership marks the beginning of our work with FDA to use new scientific and technological tools to aid/enhance the review of new drugs and devices. It is one facet of our shared commitment to speed the delivery of new medical products to patients," said NIH Director Francis S. Collins, M.D., Ph.D.

The awards follow a February 2010 announcement by the NIH and the FDA to work together in an unprecedented manner on important public health issues. As part of that effort, the agencies established an NIH-FDA Joint Leadership Council to spearhead collaborative activities. In addition, the NIH and the FDA issued a request for applications to stimulate a new research initiative in a priority area, Advancing Regulatory Science through Novel Research and Science-Based Technologies.

Regulatory science involves the development and use of the scientific knowledge, tools, standards, and approaches necessary for the assessment of medical product safety, efficacy, quality, potency, and performance.

"These projects show the potential breadth of opportunity that comes from advancing regulatory science. The results are likely to have broad application to researchers across scientific disciplines and will result in better-informed regulatory decision-making and faster drug development and approval processes," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D.

The four grantees include:

-- William G. Barsan, M.D., Donald A. Berry, and Roger J. Lewis, University of Michigan, Ann

Arbor - Accelerating Drug and Device Evaluation through Innovative Clinical Trial Design
-- Daniel R. Cerven, M.S. and George L. DeGeorge, Ph.D., MB Research Laboratories, Inc., Spinnerstown, Penn. - Replacement Ocular Battery (ROBatt)
-- Dennis E. Hourcade, Ph.D., Washington University, St. Louis - Characterization/Bioinformatics-modeling of Nanoparticle: Complement Interactions
-- Donald E. Ingber, M.D., Ph.D., Harvard University Medical School, Boston - Heart-Lung Micromachine for Safety and Efficacy Testing

For more information on the Regulatory Science Program
<<http://commonfund.nih.gov/regulatoryscience/>>

The NIH Common Fund encourages collaboration and supports a series of exceptionally high impact, trans-NIH programs. The Regulatory Science Program is funded through the Common Fund and managed by the NIH Office of the Director in partnership with the various NIH Institutes, Centers and Offices. Common Fund programs are designed to pursue major opportunities and gaps in biomedical research that no single NIH Institute could tackle alone, but that the agency as a whole can address to make the biggest impact possible on the progress of medical research. Additional information about the NIH Common Fund can be found at <<http://commonfund.nih.gov/>>.

The U.S. Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. It is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation. It also regulates tobacco products. For more information about FDA, visit <www.fda.gov>.

The National Institutes of Health (NIH) -- The Nation's Medical Research Agency -- includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <www.nih.gov>.

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