

# FDA Unveils Product Development Priorities

**H**ealth and Human Services (HHS) Secretary Mike Leavitt and the Food and Drug Administration (FDA) released on March 16 an initial list of priority research projects aimed at advancing innovation in medical products. The Critical Path Opportunities List, part of the FDA Critical Path Initiative, outlines 76 initial projects to bridge the gap between the quick pace of new biomedical discoveries and the slower pace at which those discoveries are currently developed into therapies. In a press release accompanying the announcement, FDA officials noted that, "If accomplished, the new tests and tools developed under the Critical Path Initiative will modernize the drug development process by 2010 and help to get new medical discoveries to patients faster and at a lower cost."

"Right now, researchers are trying to bring 21st century medical innovations to market using 20th century tools to evaluate them. Under the Critical Path Initiative, we anticipate being able to dramatically increase the success rate in moving products from the lab to the patient," said Dr. Andrew C. von Eschenbach, then acting FDA commissioner. "The keys to a smarter more modern medical prod-

uct development process are the standardization of new tools to test potential products along with the unprecedented integration of information within government, industry, and academic partnerships."

The Critical Path Opportunities Report is organized into 6 broad topic areas: development of biomarkers, clinical trial designs, bioinformatics, manufacturing, public health needs, and pediatrics. In compiling the list, FDA administrators indicated that priority efforts will focus on accelerated biomarker development and streamlining clinical trial design, each of which have direct implications for nuclear and molecular medicine researchers. "Most researchers agree that a new generation of predictive biomarkers would dramatically improve the efficiency of product development, help identify safety problems before a product is on the market (and even before it is tested in humans), and facilitate the development of new types of clinical trials that will produce better data faster," said Janet Woodcock, MD, deputy commissioner for operations and head of the FDA Critical Path Initiative. "Similarly, researchers stressed that

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## JNM Editor, SNM Members Receive Imaging Awards

**A**t the Academy of Molecular Imaging (AMI) annual conference March 25 to 29 in Orlando, FL, awards were made to 3 SNM Members, including the editor-in-chief of *The Journal of Nuclear Medicine (JNM)*, for outstanding contributions in molecular imaging.

Heinrich R. Schelbert, MD, PhD, George V. Taplin Professor of Nuclear Medicine at the David Geffen School of Medicine of the University of California at Los Angeles and editor-in-chief of *JNM*, was presented with the 2006 Peter Valk Distinguished Clinical Science Award. His major research interest has been the development and validation of noninvasive radionuclide imaging techniques for the study of cardiovascular function and the application of these novel techniques in the study of functional and metabolic consequences of coronary artery disease. Major accomplishments include the discovery of the specific pattern of blood flow and metabolism in chronically dysfunctional myocardium that is predictive of potential reversibility and the development and validation of PET-based techniques

for measuring regional myocardial blood flow in absolute units using  $^{13}\text{N}$ -ammonia. He has edited several books on cardiovascular imaging, published more than 300 peer-reviewed articles, and serves as a regular reviewer for numerous cardiology and nuclear medicine journals. He is a 2-time recipient of the Georg von Hevesy Prize from the World Federation of Nuclear Medicine and Biology and has been recognized with the Georg de Hevesy Nuclear Medicine Pioneer Award by SNM and the Distinguished Scientific Achievement Award by the American Heart Association.

The 2006 Distinguished Basic Science Award was presented to Ralph Weissleder, MD, PhD, a professor at Harvard Medical School, director of the Center for Molecular Imaging Research at Massachusetts General

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**Heinrich R. Schelbert, MD, PhD**