Science at FDA:
The Mainstay of Public Health Protection
New Technology is FDA's Greatest Challenge

Science is the **solid bedrock** of all the FDA's decisions, whether they involve product review, research, policy development, or law enforcement. In recent years, findings by the FDA's scientists have been critical to the agency's most significant public health accomplishments, including its ability to do the following:

- Determine the safety of **bioengineered foods** and enhance their acceptance by the public.
- Characterize and mitigate the real public health threat of **antimicrobial resistance.**
- Understand the cause and transmission of BSE, or bovine spongiform encephalopathy (**"mad cow disease"**), which has enhanced the FDA's ability to keep this disease out of the United States.

At present, the quickening pace of scientific discoveries is propelling the development of a tidal wave of novel, extremely complex products and processes that will soon put the FDA to a crucial test. They include genomics- and proteomics-assisted drug development and disease detection and diagnosis; robotics; nanotechnology; minimally invasive surgery and medical imaging; xenotransplantation and organ replacements; stem cell-derived products and assisted reproduction; biosensors and new drug delivery systems; individualized drug therapy; and transgenics.

The FDA will have to acquire expertise in new informatics, artificial intelligence, and new knowledge management; develop better tools for quantitative risk assessment, modeling, clinical trial design and analysis; design better predictive tests involving transgenics, biomarkers, alternatives to test animals, and computational science; and find better methods for rapid product testing, and for easier identification of foodborne, waterborne and other natural toxins, allergens, and transmissible spongiform encephalopathies.

And as if that were not sufficiently challenging, the FDA will have to accomplish these tasks at a time when our rapidly aging population will increase the need and expectations for the FDA's public health services. To meet this historic test, and to expedite the availability of new medical marvels to the public, the FDA cannot wait until the products emerge from R&D pipelines. The agency must achieve the critical mass of scientific, medical and financial resources—without delay.

The Human Genome Mapped—New Horizons

Francis S. Collins, MD, PhD, the director of the National Human Genome Research Institute at the National Institutes of Health, predicts that within 10 years genome research will lead to genetic testing for a dozen medical conditions. In 20 years, there will be gene-based designer drugs to treat diabetes, hypertension, and cancer. In 30 years, comprehensive genomics-based health care will be "the norm."

As the gatekeeper for these products and technologies, the FDA will have a decisive impact on their safety, effectiveness, and the speed of their availability to the public.

For more information, call the FDA's Office of Science Communication and Coordination at 301-827-3340 and refer to the Science @ FDA Web site, *www.fda.gov/oc/science.html.*

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