Science and Progress at the FDA:
Realizing the Return on Investment from Biomedical Research

"Today, FDA is relying on 20th Century regulatory science to evaluate 21st Century medical products. Regulatory science is needed to provide better tools, standards, and pathways to evaluate products under development. It also serves to create efficiencies in the development process, and improve product safety, quality, and manufacturing. The Advancing Regulatory Science initiative represents the first comprehensive effort to modernize regulatory science at FDA."

– Dr. Margaret Hamburg, FDA Commissioner

The Food and Drug Administration serves as the nexus between the progression of laboratory research and the clinical use of new therapies. We urge Congress to support increased scientific capacity of the Food and Drug Administration.

President Obama's FY11 budget request contains a much needed 6% increase to the budget authority for the FDA, which includes $25 million allocated to *Regulatory Science*.

Regulatory Science aims to develop, assess and provide new, validated tools and approaches to better evaluate the utility of new medical products.

- The advancement of *Regulatory Science* at FDA is critical to ensure the public's health, the safety and efficacy of new drugs, and to foster the innovation of new therapies.
- Without further development of FDA *Regulatory Science* programs, the full potential of biomedical research may be stifled.

The Need for Improved Scientific Capacity at the FDA

- ***Laboratory science, which leads to the discovery of potential treatments, has vastly out-distanced regulatory science, which develops methods to evaluate their safety and approval.***
  - Multi-billion dollar investments in medical research, through the NIH, disease foundations and industry, have generated a **tremendous amount of knowledge** about the relationship between molecular information and human health in cutting edge disciplines such as genomics, stem cell research and nanotechnology.
  - However that **knowledge is not being translated into medical solutions** patients can use at a fast enough rate, in part because regulatory science simply can't keep pace with discovery.

- ***Deficiencies in capital – human, scientific, and financial – are creating a widening gap between the microscope and the marketplace, and hindering the FDA's ability to achieve its mission.***
  - Staffing levels from the 2010 appropriation have only just been restored to the previous high level achieved in 1994.
  - Increasing internationalization, scientific complexity and drug development costs add mounting pressure on the agency.

- ***A consistent multi-year funding approach is essential.***
  - The Institute of Medicine, U.S. Government Accountability Office, and FDA Science Board have highlighted deficiencies in the FDA's ability to carry out its responsibilities, noting resource limitations.
  - The Science Board report (December 2007) is particularly clear that a fundamental source of problems is chronic under-funding.
  - No systemic improvement is likely without resources to increase food science and inspection capacity, further fund drug and device approvals and safety monitoring, and upgrade mission-critical information technology systems.