# Bringing Treatments from the Laboratory to the Bedside

***Provide at least a $374 million (18%) increase for the Food and Drug Administration***

The goal of medical research is to produce the knowledge, treatments, and medicines that help people in need. As NIH and NCI funded medical research continues to produce scientific breakthroughs, the Food and Drug Administration (FDA) serves as the nexus between new discoveries and routine cancer care. FDA plays dual roles in its mission to protect and promote public health. While public safety is paramount when evaluating, approving and monitoring new products, FDA must balance this with the role of providing patients access to potentially life-saving medicines. Both aspects are at significant risk if the scientific capability of the agency is not contemporary and comprehensive. A chronic lack of resources of the FDA has resulted in insufficient IT systems, challenges with personnel recruitment, training and retention, and the inability to develop advanced methods and tools for product evaluation. Providing FDA the resources that it requires to further integrate cutting-edge science will streamline the translation of cancer research from early stage discovery to clinical application.

By some estimates, there are over 800 new, potentially life saving, cancer therapies currently in development. New oncology applications are the most active area of FDA medical product regulation. With appropriate resources, FDA would be able to develop a seamless, cross-disciplinary, cross-center approach to product review, so that the best possible expertise is brought to bear on any specific problem, and to ensure consistency.

One example of a program FDA has established to begin to address these scientific challenges is a project to evaluate potential alternative endpoints for cancer drug approval. The decisions made by cancer patients and their health care providers are often complex and difficult to assess or fully understand during the regulatory process. The validation and use of alternative endpoints to supplement data on overall survival could help indicate the safety and efficacy of a new therapy at earlier stages in the development process. Endpoints such as measures of disease progression, health-related quality of life, patient-reported symptoms, and biomarkers have been proposed and tested in clinical studies. Endpoints will be examined for the most common cancers, such as lung, colorectal, multiple myeloma, leukemia, ovarian, brain, and prostate.

Providing the FDA with the resources needed to be scientifically rigorous will help ensure product safety and effectiveness. For millions of patients, a stalled pipeline means a delay of life-saving products.

| Area of Oversight | FY 2009 Budgeted | FY 2010 Requested |
|---|---|---|
| | | |
| Food | $649 million | $790 million |
| Human Drugs | $413 million | $500 million |
| Biologics | $183 million | $223 million |
| Devices & Radiology | $280 million | $340 million |
| Other | $526 million | $572 million |
| TOTAL | $2.051 billion | $2.425 billion |

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