

Bringing Treatments from the Laboratory to the Bedside

Provide \$2.9 billion 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 medical research funded by the National Institutes of Health and the National Cancer Institute continues to produce scientific breakthroughs, the Food and Drug Administration (FDA) serves as the nexus between new discoveries and routine cancer care. All new cancer treatments must be reviewed and approved by the FDA before being made available to cancer patients.

The 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, the FDA must balance this with the role of providing patients access to potentially life-saving medicines. A chronic lack of resources at 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 the FDA the resources that it requires to further integrate cutting-edge science will help breakthroughs move more rapidly into clinical practice while protecting patients from treatments that do not work or are unsafe. A well-resourced FDA, with modern scientific tools, is an asset to the development of drugs and devices by ensuring their safety and helping to accelerate the rate at which patients can access life-saving treatments.

By some estimates, there are over 800 new, potentially lifesaving, cancer therapies currently in development. New oncology drug applications are the most active area of FDA medical product regulation. With appropriate resources, the FDA will 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.

Increases in the FDA's budget would:

- Allow the FDA to provide faster and safer approval of products that are saving lives and transforming health care;
- Give the FDA more resources to prevent or mitigate drug shortages in the U.S.;
- Promote new drug technologies that will revolutionize pharmaceutical therapies;
- Ensure continued U.S. leadership in drug innovation;
- Enhance the surveillance capability over new drugs once they reach the market;
- Further integrate emerging science into the regulatory process; and,
- Continue to involve stakeholders to encourage pediatric cancer therapy development.

For millions of patients, a stalled pipeline means a delay of lifesaving products. All patients benefit when the FDA has more resources.