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### Curbing the Costs of Cancer Treatment

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#### Abstract

According to the Tufts Center for the Study of Drug Development, the average expenditures for making a prescription drug commercially available in the United States surpassed \$2.6 billion in 2014. Adding to these costs is the decade, on average, that it takes to navigate the research, development, and regulatory hurdles associated with prescription drugs. Such rising costs are passed on to the consumer resulting in a mounting financial burden that threatens the sustainability of public and private insurance programs, alike. In the wake of growing criticism of the U.S. Food and Drug Administration for the role of its protracted regulatory processes in the rising costs of drugs, Congress unveiled the 21st Century Cures Act. While this legislation is intended, among other things, to shorten the drug approval process, there is concern that it may compromise current standards for the safety and efficacy of prescription drugs. Is the 21st Century Cures Act the answer to enhancing access to life saving cancer treatments while curbing costs or is it a recipe for disaster?

**Keywords:** Prescription Drugs, Costs, 21st Century Cures Act.

#### Introduction

The financial burden of supporting the rising costs of cancer treatments threatens to topple both private and public insurance programs. For life threatening conditions, such as cancer, patients and their families are willing to go to extreme measures for even slight increases in life expectancy. Take, for example, Zaltrap which is marketed by Sanofi for the clinical management of metastatic colorectal cancer. Though it extends median survival by only 1.5 months, it was released in the U.S. with a price tag of \$11,000/month [1]. In response to public criticism of the pharmaceutical industry regarding the rising costs of drugs, pharmaceutical companies often cite the Tufts Center for the Study of Drug Development which estimates that the average cost for making a prescription drug commercially available in the United States exceeded \$2.6 billion in 2014 [2]. The federal government, too, has taken its own share of criticism for not doing more to curb the costs of life saving drugs. In particular, the U.S. Food and Drug Administration (FDA) have been blasted for the perception that its regulatory processes are antiquated

and prevent timely approval of safe and effective drugs.

In response to an increasing public outcry for regulatory and funding reforms, Congress has received strong support for its proposed 21st Century Cures Act [3]. This legislation is intended to aid the development and approval processes for prescription drugs in an effort to improve access while reducing costs. However, there is concern that efforts to shorten the approval times for drugs may actually compromise the current standards for the safety and efficacy. This begs the question, is the 21st Century Cures Act the answer to enhancing access to life saving cancer treatments while curbing costs or is it a recipe for disaster?

#### Discussion

The 21st Century Cures Act has been widely praised by the pharmaceutical industry and was recently approved, on May 21, in a unanimous decision by the US House of Representatives' Committee on Energy and Commerce. The bill includes an increase in funding to the tune of \$10 billion over 5 years for the National Institutes of Health (NIH) and \$550 million over 5 years for the FDA. It also calls for a wide range of regulatory reforms and supports efforts to enhance access to data, encourage the application of new generation biomarkers, and employ methods in precision medicine.

The funding included in the bill is a much needed boost to the NIH, which is currently operating on a budget that is diminished by 12% relative to 2009, and the FDA, which is strapped for resources and far overextended. However, there is growing apprehension over the inclusion of language that directs the FDA to develop innovative trial study designs and more efficient methods for analyzing data. The idea that these may result in the employment of abbreviated clinical trials with fewer test subjects or reduce the use of randomized, controlled studies is particularly alarming. Other changes may include a fast track approval for antibiotics in life threatening circumstances and a simplification of the approval process for medical devices. Although there is broad accord for the need to allow special considerations for the sake of human health, there is concern that the language for these considerations in the 21st Century Cures Act may leave too much open for interpretation.

## Conclusion

While there is reasonable concern that the bill, in its current form, lacks certain measures to prevent the implementation of discretionary practices which may compromise the safety and efficacy of prescription drugs, there is no doubt that the 21st Century Cures Act will undergo major revision prior to passing. The idea that it may serve as a recipe for disaster by providing backing from congress for FDA to approve drugs based on less rigorous testing is simply unfounded. The bill is currently being dissected by personnel at NIH and FDA, industry and legal experts, scientists, and more. The final bill promises to make a great stride toward improving the development of and access to life saving cancer therapeutics. Whether these will curb the rising costs of drug prices has yet to be seen.

## References

1. Ingram I. FDA Approves Aflibercept (Zaltrap) for Metastatic Colorectal Cancer. *Oncology*. 2012; 26(9):842, 873.
2. Avorn J. The \$2.6 Billion Pill — Methodologic and Policy Considerations. *N Engl J Med*. 2015; 372(20):1877-1879. doi: 10.1056/NEJMp1500848.
3. Jaffe S. 21st Century Cures Act Progresses through US Congress. *Lancet*. 2015; 385(9983):2137–2138. doi: 10.1016/S0140-6736(15)61008-X.