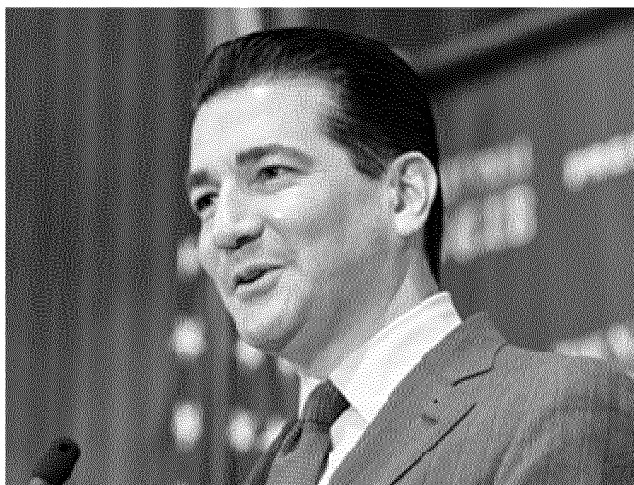


# Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap



January 11, 2018

I am delighted to share FDA's 2018 Strategic Policy Roadmap, the product of a close collaboration among the Agency's centers. This document provides an overview of some of the key priorities we will pursue together to advance FDA's public health mission.

[Read the 2018 Strategic Policy Roadmap \(/media/110587/download\)](/media/110587/download)

Many of these efforts are already underway, and will be further advanced in 2018, while other policies outlined in this document will be initiated during the coming months.

The countless, critical functions FDA provides every day to our fellow citizens are, at times, obvious and at other times indiscernible, even to those touched by our efforts. The work we do provides Americans with better ways to improve their health and welfare, helps families protect their children, and enables consumers to make safe and healthier choices about the products they use and the foods they feed to their families.

We have selected the specific policy efforts included in this Roadmap because we believe they embody the overall scope and spirit of our collective efforts as we work together to pursue FDA's public health mission. Each one of us has an important role to play in achieving this mission.

Our work is taking place during an inflection point in both science and policy. We have more opportunity to deliver on the promises of science than at any time before. Gene- and cell-based therapies hold the opportunity to treat a wider range of debilitating disorders, and deliver outright cures to intractable diseases. New gene-based technologies enhance the ability to increase crop and animal yields and identify foodborne and zoonotic outbreaks and trace them to their source. Mobile monitoring can offer patients and providers timelier and more actionable clinical information. More targeted medicines allow human and animal patients to realize more of the benefits of new drugs, with fewer side effects. At the same time, new medical devices are helping to restore mobility to paralyzed patients and allowing more people to live lives that are less hindered from the impact of chronic ailments.

These are just some of the extraordinary advances that are transforming health. But we also face challenges as we strive to ensure that Americans have access to these and other opportunities. Both the time and the cost of medical product development continues to rise for many types of products. We know that the cost of product development can impact how such products are priced, and can be a factor in limiting patients' ability to get timely access to beneficial new treatments and services. At the same time, FDA faces new public health challenges. Principal among them is the ongoing crisis of opioid addiction. We also continue to face too much avoidable death and disease associated with smoking tobacco; and children are still becoming initiated on, and addicted to, nicotine.

The work we do over the next few years will define how we advance many of these new and transformational technologies that will enable patients to benefit from platforms like gene and cell therapy, while addressing their novel risks and uncertainties. FDA will play an important role in leveraging science-based ways to improve the efficiency and predictability of the development process, while advancing our ability to make sure that new products have been carefully evaluated for safety. When it comes to new areas like regenerative medicine, gene therapy, and digital health, we will be responsible for fully establishing the contemporary regulatory approach for properly evaluating these products, and setting these guidelines in action. In some cases, it is going to require us to modernize our traditional approach to regulation to make sure that our policies are suited to novel challenges.

Already, FDA's ability to harness the full potential of these new opportunities has been enhanced due to recent legislation that gives FDA additional resources and authorities to safely cultivate new technologies and scientific discoveries. This includes the 21st Century Cures Act (Cures Act), and the recently enacted FDA Reauthorization Act of 2017. Making sure we leverage these opportunities and advance these critical policy areas is a big part of our focus in 2018 as we continue to execute across our portfolio of high priority public health obligations, and solidify our fundamental role in protecting consumers from unsafe products and dishonest marketing.

Our Roadmap is not intended to be a traditional strategic plan; and it is not an exhaustive list of the important policies that FDA will initiate and pursue over the coming year. In focusing on these selected efforts, we will optimize our resources to achieve clear deliverables that will yield results over the next two years. Publishing this Roadmap is another way that we aim to provide more transparency about the FDA's policy undertakings to all our stakeholders.

We aim to secure more advantages for society in the form of more efficient risk management, better access to safe products that extend lives, improved nutrition, broader consumer choices, and a lower burden of chronic disease in people and animals. At the same time, we will work to empower patients and providers with better information about the safety and effectiveness of new products, so they can tailor treatments to individual medical needs and preferences.

These goals – and the work we do together in achieving them – go to the heart of our mission of advancing and protecting public health, while maintaining our commitment to the scientific standards that make FDA a recognized global leader, and a gold standard for product review.

Scott Gottlieb, MD

Commissioner of Food and Drugs

Was this helpful?

Yes

No