FDA Statement on the Trump Administration's Plan to Lower Drug Prices

Access to prescription drugs is a matter of public health.

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Statement from FDA Commissioner Scott Gottlieb, MD, on the Trump Administration's plan to lower drug prices

Today is an important day in the Administration's collaborative effort to address the rising cost of drugs. We know that the high list cost of drugs can adversely impact peoples' access to medicines. People rely on medicines to improve their quality of life, manage chronic conditions and treat life-threatening illnesses. Access to prescription drugs is a matter of public health. I applaud President Trump for making this one of the Administration's priorities and introducing a bold plan that puts patients first in advancing actions to address the rising list prices of prescription medicines. The FDA shares the goal of ensuring that American patients have access to quality and affordable care that meets their needs. This is why we're prioritizing actions to encourage the timely development and approval of generics and biosimilars.

To date, we've taken a number of steps as part of our Drug Competition Action Plan (DCAP). We're helping remove barriers to generic drug development and market entry in an effort to spur competition that results in lower drug prices for patients, and greater access.

One key aspect of our role is to strengthen and enhance the overall generic drug review process. We've committed to timelier generic drug reviews to reduce the cycles of review that generic applications typically undergo. In 2017, we approved a record number of generic drug applications—more than 1,000 full or tentative approvals. We expect to beat that goal this year. And although the FDA doesn't have a direct role in drug pricing, by ensuring that regulatory requirements are efficient, predictable and science-based; we can help reduce the time, uncertainty and cost of generic and biosimilar product development.

In addition, we're calling out abuses of the system that impede competition and doing our part to fix them. The agency is committed to adopting strong policies and taking action, when necessary, to reduce gaming of statutory and regulatory requirements to help ensure that drug companies don't use anticompetitive strategies to delay development and approval of important generic

drugs.

Our efforts have included taking significant steps to support complex generic drug development and application review; prioritizing the review of certain generics; publishing a list of off-patent, off-exclusivity branded drugs; and enhancing the efficiency of certain aspects of the submission process for generic drug applicants.

The President made it clear today that we all need to play a role—including the FDA and its sister agencies like the Centers for Medicare & Medicaid Services—to put American patients first by taking bold actions to help patients have access to affordable medicine. The FDA will continue what it started with DCAP by taking new steps to address the significant health challenges we face and extend that momentum to implementing new measures as part of a forthcoming Biosimilar Action Plan that aims to facilitate the development and approval of biosimilars—which will help address patient access to costly biological products that can treat a range of chronic and life-threatening conditions. We will also be taking additional steps to address some of the Risk Evaluation and Mitigation Strategies (REMS) "gaming" abuses that can delay the entry of generic drugs.

These are among some of the new actions that we'll be taking in the coming weeks. The FDA will continue to work to promote drug competition and access for patients, to advance our public health goals.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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