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# Biden Administration Takes Aim at Rising Drug Prices through its Executive Order on Promoting Competition

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On Friday, July 9, 2021, President Biden released an Executive Order "to promote competition in the American economy" and to "to reduce the trend of corporate consolidation" (the "Order"). As part of this Order, the Biden Administration specifically targets competition in the pharmaceutical industry and sets forth policies to combat the high cost of prescription drugs. As the Administration's first major policy initiative on drug pricing, this Order may serve as a preview of the Administration's drug pricing reform agenda.

## Canadian Drug Importation

Among the more controversial provisions, the Order supports importing drugs from Canada as an effort to reduce prescription drug costs. The Order calls on the Food and Drug Administration (FDA) to work with States seeking to import drugs under Section 804 of the Federal Food, Drug, and Cosmetic Act, known as the Section 804 Importation Program (SIP). FDA, under the Trump administration, previously implemented regulations and guidance to States and other entities seeking to import drugs from Canada through the SIP. In November 2020, Florida submitted a proposal to FDA to begin the importation of a limited number of drugs.

## HHS Plan to Address Drug Pricing

Rather than calling on Congress to address drug pricing, President Biden is requesting that the Department of Health and Human Services (HHS) develop a plan to address drug pricing by the end of the summer (Drug Pricing Plan). Specifically, within 45 days of the release of the Order, the HHS Secretary must develop and submit to the White House, a Drug Pricing Plan to:

- Continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains;
- Reduce the prices paid by the Federal Government for such drugs; and
- Address the recurrent problem of price gouging.

## Provisions Related to Generics and Biosimilars

The Order also includes multiple provisions to increase the availability of generics and biosimilars. It specifically encourages the Federal Trade Commission to use its rulemaking authority to combat unfair anticompetitive conduct. In the Order's press release, the Administration makes it clear that they are targeting "pay for delay" arrangements or other agreements to delay the market entry of generic drugs or biosimilars.

The Order also calls on the FDA to:

- Improve the approval framework for generic drugs and biosimilars by making it more transparent, efficient, and predictable;
- Update the regulations related to Biologics License Applications to clarify existing requirements and procedures;
- Develop and provide educational materials to help the public understand biosimilars and interchangeable products;
- Continue implementing the CREATE Act by issuing Covered Product Authorizations (CPAs), which assist product developers in obtaining brand-drug samples; and
- Within 45 days, write a letter to the U.S. Patent and Trademark Office outlining the FDA's concerns with the patent system that may "unjustifiably delay generic drug and biosimilar competition."

In addition to the specific policies outlined above, the Order states upfront that it supports "aggressive legislative reforms, including allowing Medicare to negotiate drug prices." Granting HHS the power to directly negotiate prices with pharmaceutical manufacturers is a controversial measure that is supported by many Democratic lawmakers.

With HHS' Drug Pricing Plan and FDA's patent letter to the U.S. Patent and Trademark Office due by the end of the summer, and Congress navigating a path toward drug pricing legislation, drug pricing reform will continue to be a priority for the Administration and Congress.



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