

FDA Chief and HHS Secretary Cite Prescription Drug Prices as Top Priorities for Agencies; President Trump Scheduled to Speak on Issue on May 11, 2018.

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All eyes are on the federal government as top officials have recently signaled upcoming actions which could impact the prices of prescription drugs. In the past two weeks, leaders from both the FDA and HHS have made statements signaling that the agencies are focused on reducing prescription drug prices.

In remarks at the Food and Drug Law Institute conference held on May 3, 2018, U.S. Food and Drug Administration Chief Scott Gottlieb suggested that by reexamining the current safe harbor under the anti-kickback statute for drug rebates, list prices for drugs would be closer to negotiated prices and competition may

increase.

Mr. Gottlieb stated that, while “[t]here’s a range of reasons why drug prices are too high” one reason “that’s driving higher and higher list prices, is the system of rebates between payers and manufacturers. And so what if we took on this system directly, by having the federal government reexamine the current safe harbor for drug rebates under the Anti-Kickback Statute?” (The transcript of Mr. Gottlieb’s remarks can be found [here](#)). Mr. Gottlieb appears to be siding with critics of drug rebates who have argued that the practice leads to higher prices for patients because the rebates do not make their way down to patients, and instead, patients pay list prices for the drugs as they meet their out-of-pocket obligations.

Mr. Gottlieb also mentioned some additional upcoming actions to reduce drug prices,

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including a Biosimilars Action Plan that is similar to the FDA's Drug Competition Act Plan (DCAP); additional policies under DCAP to promote generic competition; a comprehensive framework for the regulation of gene therapy; and prioritizing the review of low competition products for generic product applications.

Additionally, Mr. Gottlieb alluded to changes that may be introduced by Secretary of Health and Human Services, Alex Azar, including policies that "will dismantle many of the provisions that shield parts of the drug industry from more vigorous competition" and "a series of changes to the pricing mechanism in [Medicare] Part D."

Days later, on May 9, Alex Azar told members of the American Hospital Association that "HHS is focused on solving a number of the problems that plague drug markets. These include the high list prices set by manufacturers; seniors and government programs overpaying for drugs due to the lack of the latest negotiating tools; rising out-of-pocket costs for consumers; and foreign governments free-riding off of American investments in innovation." Mr. Azar's full speech can be watched [here](#).

President Trump is scheduled to deliver a speech on Friday, May 11, 2018 addressing the steps that the administration plans to take to address drug pricing in the United States. Mr. Azar noted that President Trump wants to go "much, much further" in addressing drug prices than the proposals initially set forth in the President's 2019 Budget.

We will continue to closely monitor these activities which may have a significant impact on all involved in the prescription drug market.

