

New York Times Obtains Copy of Draft Executive Order on Drug Prices; FDA Blogs that it is Working to Lift Barriers to Generic Drug Competition

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On June 20, 2017, the New York Times reported that it had obtained a draft proposal of President Trump's Executive Order on drug prices.^[1] The draft Executive Order, which has not been published, has been characterized as focusing on rolling back regulations, with the New York Times reporting that the Executive Order strengthens the pharmaceutical industry's monopoly power overseas and scales back the federal 340B program, a program that allows hospital and clinics that serve low-income populations to receive discounts on drugs from pharmaceutical companies.

One day later, the FDA posted in a blog^[2] that it was working on a "Drug Competition Action Plan" and that it intends to hold a public meeting on July 18, 2017 to solicit input on FDA rules, standards and procedures that create obstacles to generic access. One issue the FDA specifically calls out in the blog post is the use of regulatory or commercial strategies by pharmaceutical companies that create obstacles to the development of generic drugs. Some of these strategies are to limit access to samples of brand name drugs so that generic alternatives cannot be developed. This issue has been raised a number of times recently. For example, the issue was discussed in a June 19, 2017 letter Senate Chuck Grassley (R-Iowa), chairman of the Senate Judiciary Committee, sent to FDA Commissioner Scott Gottlieb^[3]. Senator Grassley asked Mr. Gottlieb to consider ideas proposed in the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act^[4] to solve the problem. The issue was also discussed at the June 13, 2017 Senate Health, Education, Labor and Pensions Committee hearing on prescription drug pricing and prescription drug supply-chain.^[5]

We do not know yet how the Executive Order will impact the 340B program. However, changes to the 340B program could have a substantial financial impact on hospital and clinics currently enrolled in the program, as well as on contract pharmacies and others

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who provide services related to the 340B program. Other proposed changes by the Trump Administration and the FDA will likely impact the entire pharmaceutical supply-chain and are being closely watched by the industry. We will continue to monitor these changes and update our blog as they occur.

[1] <https://www.nytimes.com/2017/06/20/health/draft-order-on-drug-prices-proposes-easing-regulations.html>

[2] <https://blogs.fda.gov/fdavoices/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/>

[3] <https://www.judiciary.senate.gov/imo/media/doc/2017-06-19%20CEG%20to%20FDA%20-%20Affordable%20Prescription%20Medication.pdf>

[4] <https://www.congress.gov/115/bills/s974/BILLS-115s974is.pdf>

[5] <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-how-the-drug-delivery-system-affects-what-patients-pay>