

Trump Administration Announces Executive Action Intended to Use Cross-Border Market Forces to Impact Drug Pricing in the U.S. Market

JULY 28, 2020

On July 24, 2020, at a press conference in Washington, DC, President Donald J. Trump (hereinafter “Trump Administration” or “Administration”) announced three executive orders and one anticipated executive order aimed at reducing U.S. drug prices for consumers. One of the orders, as well as a second anticipated order, concerns the international drug market and would use international market forces to influence drug pricing for United States residents. The Administration’s announcement comes one day after Health and Human Services (“HHS”) Secretary Alex Azar announced on Twitter a 90-day continuation of the COVID-19 Public Health Emergency until October 23, 2020. The executive policies, if effectuated as currently formulated, are likely to have a substantial impact on the pharmaceutical industry well beyond products relevant to the therapeutic fight against the COVID-19 pandemic.

In the first order, the Administration announced its “Executive Order on Increasing Drug Importation to Lower Prices for American Patients.” As described, the order will allow states, wholesalers, and pharmacies to safely import prescription drugs from Canada and other countries where the price for identical prescription drugs is ostensibly lower. Over time, the order seeks to reduce trade barriers and increase the exchange of drugs across the border. The executive order’s efficacy is premised upon the idea that augmented trade will increase competition and lead to lower prices in the United States.

By its terms, the order authorizes the Secretary of HHS to take action to expand safe access to lower-cost imported prescription drugs by: (1) facilitating grants to individuals and waivers on the prohibition of importation of prescription drugs pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. 384(j)(2);¹ (2) authorizing re-importation of insulin products where the Secretary of HHS deems them required for emergency medical use pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d); and (3) completing the rulemaking process to implement section 804(b) through (h) of the FDCA, 21 U.S.C. 384(b) through (h), and allow importation of certain prescription drugs from Canada.

In effect, the executive order is a continuation of importation proposals from the Administration either stalled or abandoned during the rulemaking process. See “Importation of Prescription Drugs: A Proposed Rule by the Food and Drug Administration on 12/23/2019” *available at* <https://www.federalregister.gov/documents/2019/12/23/2019-27474/importation-of-prescription-drugs>. There, as here, HHS’s rulemaking is open to public comment.

Relatedly, Friday, President Trump telegraphed the imminent arrival of another executive order aimed at decreasing Medicare drug prices through the use of data on drug pricing in international markets. Prior media reports regarding the so-called “International Price Index” model have circulated widely over the past 18 months. While the President did not elaborate substantially on the current details of the IPI model, he acknowledged that the structure of the final form of his executive order was still the subject of negotiation with the industry. Pharmaceutical leaders are expected to meet with the President as early as Tuesday, July 28, 2020. However, the President has said that if no agreement is met, he plans to effectuate the international price indexing order by August 25, 2020. Stay tuned.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

For further information or questions on the Administration’s executive orders and plan for implementation, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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¹ Provided that importation does not pose additional risk to public safety and does indeed result in lower costs to U.S. patients.

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