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FDA Finalizes Rule and Guidance to Implement Safe Importation Action Plan Aimed at Lowering Prescription Drug Prices

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On September 24, 2020, FDA announced[1] that it was taking action to help lower prescription drug prices by issuing a final rule[2] and a final guidance[3] aimed at facilitating the safe importation of certain prescription drugs. Effective November 30, 2020, these actions carry out the Trump Administration's Safe Importation Action Plan,[4] as directed by President Trump in an Executive Order issued on July 24, 2020.[5] These actions were touted by the President during the presidential debate on September 30, 2020, when, in response to a question about health care he stated, "I'm cutting drug prices. . . . Drug prices will be coming down 80 or 90 percent."[6]

As we have described in detail in previous client alerts, the Safe Importation Action Plan, which was released in July 2019, promised two pathways to facilitate drug importation. With the finalization of the drug importation rule and guidance, FDA has now brought these two pathways to fruition.

The first pathway, implemented through FDA's final rule, allows states (including the District of Columbia and territories) to seek FDA approval to establish an importation program under which the state would import prescription drugs from Canada.[7] These importation programs (referred to as "Section 804 Importation Programs" or "SIPs") may also be cosponsored by an Indian tribe, pharmacist, or wholesaler, and will be managed by the respective sponsor (and any co-sponsor) who will be authorized by FDA to facilitate the importation of certain eligible prescription drugs (i.e., drugs that are approved in Canada and meet the conditions of an FDA-approved drug application, including labeling).[8]

The second pathway, implemented through FDA's final guidance, provides procedures for a drug manufacturer to obtain a National Drug Code ("NDC") number for certain FDA-approved prescription drugs, including biological products and combination products, that were

originally manufactured and intended for sale in a foreign country (i.e., "multi-market approved products" or "MMA products").[9] MMA products imported under this pathway could be made available to patients in a variety of settings, including hospitals, health care providers' offices, and licensed pharmacies, and would include the FDA-approved labeling (including full prescribing information).[10]

These two pathways for drug importation are not yet in effect, and significant statutory and logistical hurdles remain that could render them ineffective. Our assessment of the key challenges these pathways likely will face in successfully lowering the cost of prescription drugs in the United States is set forth below.

KEY CHALLENGES TO SUCCESSFUL IMPLEMENTATION OF NEW DRUG IMPORTATION PATHWAYS

Many of the challenges we have described in our previous client alerts on these drug importation pathways remain unaddressed by the final rule and final guidance, including:

- The legality of the final rule is questionable: We have significant concerns that FDA does not have statutory authority to implement the Final Rule because the U.S. Department of Health and Human Services ("HHS") cannot make the required cost reduction certification. FDA can only implement Section 804 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") if HHS certifies that implementation of the law (1) will "pose no additional risk" to the public health, and (2) will "result in a significant reduction in the cost of covered products to the American consumer."[11] We do not believe HHS has made or can make the required cost reduction certification, given that the final rule explicitly states that

  > we are unable to estimate the cost savings from this final rule because we lack information about the likely size and scope of SIPs, the specific eligible prescription drugs that may be imported, and the degree to which these imported drug products will be less expensive than non-imported drugs available in the United States, and while eligible prescription drugs are produced by U.S.-based drug manufacturers.[12]

  Additionally, states are not authorized importers under Section 804 of the FD&C Act. Indeed, Section 804 provides that the "Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. As such, HHS cannot authorize a SIP sponsored by a state."[13]

- The Canadian government has expressed reluctance: The Canadian government has made clear that it would not allow U.S. demand for inexpensive prescription drugs to be met in a way that results in drug shortages for Canadians. As a result, the volume of drugs that Canada can supply, at least in the short term, until manufacturers are able to ramp up operations, may be limited. Additionally, the testing and relabeling requirements imposed by the final rule would potentially increase the cost of drugs being imported.[14] Without buy-in from the Canadian government, there is little reason to believe that significant cost-savings for U.S. patients will be realized.

- It will be difficult or impracticable for foreign sellers and U.S. importers to comply with DSCSA requirements: Requirements imposed under the Drug Supply Chain Security Act ("DSCSA") are onerous and technically challenging to implement—indeed, it has taken U.S. supply chain stakeholders years to begin to implement them. As such, foreign sellers and importers not familiar with DSCSA requirements may not be willing or able to meet these requirements, at least in the near term.

- Government price reporting and federal reimbursement implications: Neither the final rule nor the final guidance addresses how the importation pathways would affect price reporting or Federal reimbursement, which is

unsurprising, given that they were issued by FDA, not HHS's Centers for Medicare & Medicaid Services ("CMS"). Manufacturers should consider how these drug importation pathways would affect the sale, use, reimbursement, and rebating of imported medications.[15]

Given these challenges, we anticipate that the actions by FDA to issue the final rule and the final guidance will not be the last word on the Trump Administration's push for prescription drug importation.

[1] *See* FDA, *FDA Takes Actions to Help Lower U.S. Prescription Drug Prices* (Sep. 24, 2020).
[2] *See* FDA, Final Rule, *Importation of Prescription Drugs*, 85 Fed. Reg. 62,094 (Oct. 1, 2020) [hereinafter "*Drug Importation Final Rule*"].
[3] *See* FDA, Guidance for Industry, *Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (Sep. 2020) ["hereinafter "*Drug Importation Final Guidance*"].
[4] *See* FDA, *FDA Safe Importation Action Plan* (2019).
[5] *See* Executive Order 13938, *Increasing Drug Importation To Lower Prices for American Patients*, 85 Fed. Reg. 45,757 (July 29, 2020).
[6] Janet E. Silver, "Drug plan touted by Trump in presidential debate hangs on Canadian insulin," *iPolitics* (Sep. 30, 2020), https://ipolitics.ca/2020/09/30/drug-plan-touted-by-trump-in-presidential-debate-hangs-on-canadian-insulin/.
[7] *See Drug Importation Final Rule*, 85 Fed. Reg. at 62,094-95.
[8] *See id*.
[9] *See Drug Importation Final Guidance* at 1-2.
[10] *See id*. at 3-6; *see also* FDA, *FDA Takes Actions to Help Lower U.S. Prescription Drug Prices* (Sep. 24, 2020).
[11] 21 U.S.C. § 384(l)(1)(A), (B).
[12] *Drug Importation Final Rule*, 85 Fed. Reg. at 62,095-96; see also King & Spalding, LLP, Client Alert, *FDA Issues Proposed Rule and Draft Guidance on Drug Importation* (Jan. 7, 2020); King & Spalding LLP, Client Alert, *A Gimmick No More? HHS Moves to Authorize Prescription Drug Importation* (Aug. 6, 2019).
[13] King & Spalding, LLP, Client Alert, *FDA Issues Proposed Rule and Draft Guidance on Drug Importation* (Jan. 7, 2020).
[14] *See* King & Spalding, LLP, Client Alert, *Trump Administration Continues to Promote Drug Importation as a Way to Lower the Cost of Prescription Drugs* (July 30, 2020).
[15] *See* L. Dwyer, J. Shakow, S. Lundy, P. Leininger, & K. Sampson, "HHS Drug Import Proposal is Unlikely to Succeed," *Law360* (Jan. 16, 2020).