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In Policy Reversal, HHS and FDA Propose Plan to Import Foreign Drugs

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On July 31, 2019, the U.S. **Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA)** jointly published a proposal, called the Safe Importation Action Plan, to allow certain entities to import drugs from foreign entities. While this development was not a surprise given President Trump's campaign promises to lower drug prices by, among other things, removing barriers to drug product importation, it represents a stark departure from prior agency positions that the importation of drugs could not be adequately verified as safe and would not lead to significant cost reductions.

The Plan

The Safe Importation Action Plan proposes two separate pathways for importing drug products.

Pathway 1:

This pathway offers individual states, drug wholesalers, or pharmacists the opportunity to submit plans for demonstration projects to HHS explaining how the entity would import drugs from Canada to ensure safety and a significant reduction in the cost of the covered drugs to the consumer. HHS and FDA will first need to publish a Notice of Proposed Rulemaking to authorize the demonstration plans and importation from Canada under Sections 804(b)-(h) of the Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 384(b)-(h)). The action plan describes fairly broad restrictions on the types of drugs that may be imported from Canada under this pathway, as the drugs must be already approved by FDA and must be made with active pharmaceutical ingredients (API) manufactured at facilities that also produce API for FDA-approved versions of the drugs. In addition, the imported drugs cannot be controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, certain parenteral drugs, or any drug subject to an FDA-mandated risk evaluation and mitigation strategy (REMS).

Pathway 2:

The second pathway would allow a manufacturer of FDA-approved drugs to import into the U.S. versions of such drugs that the manufacturer sells in foreign countries. If the manufacturer can demonstrate to FDA that the foreign version of the drug is identical to the version sold in the U.S., the

manufacturer would be permitted to label the foreign version for sale in the U.S. under a different NDC number. The plan proposes that FDA would authorize manufacturers to utilize this importation pathway through Section 801(d) of the FDCA (21 U.S.C. § 381(d)) and subject to additional guidance from the agency.

Will This Plan Actually Bring Drug Prices Down?

Although importing drugs from foreign countries has long been touted as a potential way to lower drug prices in the U.S., it is far from clear that these two proposed “safe” importation pathways will significantly lower costs or will be utilized by the entities for which they are designed.

Under the terms of Section 804 of the FDCA and Pathway 1, states, wholesalers, and pharmacists would be required to certify that the importation of Canadian drugs poses no additional risk to the U.S. public health or safety and will result in significant cost reductions ultimately realized by the consumer. Proposing a demonstration project that could allow such certification will take extensive resources and time, potentially vitiating the savings to the proposing entity, as well as to the consumer. Pathway 1 is also subject to the federal rulemaking process, which includes a required notice and comment period. This means that even if HHS and FDA commit to following through with the plan, it will take years to finalize the regulations and, only then, could states, wholesalers, and pharmacists begin submitting plans for demonstration projects that could presumably also take years to complete. Furthermore, the restrictions on the types of drugs that may be imported through this pathway eliminate the most expensive types of drugs (i.e., biologics and infused drugs), meaning that no savings on those expensive categories of drugs will be realized through this plan.

While states, wholesalers, and pharmacists may have some incentive to follow through with plans to use Pathway 1, once it’s available, there does not appear to be clear incentive for manufacturers to make use of Pathway 2. Many of the large drug manufacturers have subsidiaries that manufacture generic versions of their own drugs or produce (or permit third parties to produce) authorized generics, which can be marketed and sold separately from branded versions under different NDC numbers and at significantly reduced costs. In the Safe Importation Action Plan, HHS and FDA claim that manufacturers might use Pathway 2 to avoid restrictions imposed by current supply agreements and to offer such drugs to consumers at lower costs. However, it is important to note that industry trade groups PhRMA and BIO have already voiced strong objections to the plan, so it is reasonable to expect that most manufacturers may choose to ignore Pathway 2.

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