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FDA Announces Plans Aimed at Importing Cheaper Prescription Drugs

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The Food and Drug Administration is going to create guidance for manufacturers who seek to import prescription drugs that usually go to foreign markets, but are not currently able to do so because their distribution contracts for U.S. drugs are locked in at higher prices. This is one of two "pathways" on drug importation announced by the Department of Health and Human Services July 31.

The announcement follows multiple state-level efforts to allow for drug importation programs, which would be likely helped along by these federal programs, said Benjamin England, a former FDA lawyer and the founder of Benjamin L. England & Associates and FDAimports.com. "This is not complicated and is merely an extension of the already existing international prescription drug distribution system," he said.

Manufacturers would use a new National Drug Code, which might allow them to get around their distribution contracts. "To use this pathway, the manufacturer or entity authorized by the manufacturer would establish with the FDA that the foreign version is the same as the U.S. version and appropriately label the drug for sale in the U.S.," HHS said. "This pathway could be particularly helpful to patients with significantly high cost prescription drugs. This would potentially include medications like insulin used to treat diabetes, as well as those used to treat rheumatoid arthritis, cardiovascular disorders, and cancer," the agency said. Infused and injected drugs tend to have higher prices than pills.

The Healthcare Distribution Alliance, which represents the distribution companies that would lose revenue if manufacturers pursued this strategy, issued a statement condemning the proposal. “Pharmaceutical distributors support efforts to address the high cost of prescription drugs. But we firmly believe the administration should focus on policies that maintain the same high standards of safety that Americans have come to rely on. Importation runs directly counter to the efforts of many regulators, the pharmaceutical industry and congressional intent -- and is simply not worth the risk.”

Senate Finance Committee Chuck Grassley, R-Iowa, told reporters July 31 that he supports the proposal.

HHS said it is not sure that costs to consumers would be lowered with this work-around, so it is also planning for a notice of proposed rulemaking to authorize demonstration projects developed by states, wholesalers or pharmacists to import certain drugs from Canada. The proposal would "implement Section 804 of the Food Drug and Cosmetic Act (FDCA) authorizing the importation and reimportation from Canada of prescription drugs that are FDA-approved, properly labeled, and

unadulterated that will be at least as safe as the higher cost prescription drugs distributed through the normal U.S. distribution channels," England said in an email.

The department would review these plans, and there would be conditions "to ensure the importation poses no additional risk to the public's health and safety," the agency said. These pilot projects could not import infused drugs, biologic products, controlled substances, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs. The rule would also exclude any drug subject to a risk evaluation and mitigation strategy. The proposal "essentially extends the already existing regulatory construct that protects the prescription drug supply in the U.S. today out into the international supply chain, through Canada," England said.

The Section 804 component would mark the first time the HHS secretary has used that authority since it was put into place in 2003, and will require a safety and price reduction certification from the HHS secretary to Congress, England said. The prescription drug wholesale distribution system "already relies on the pedigree system under the Drug Supply Chain Security Act of 2013 (DSCSA) and so must a Section 804 importation program," England said. "The added safety measure under Section 804 is the documentation and testing regime necessary to ensure the drugs obtained in the Canadian market are actually the FDA-approved drugs that are properly labeled and have not degraded (become adulterated) while in transit. Therefore, drugs imported under Section 804 are actually safer (or at least there is a testing regime to indicate safety) than all the other drugs currently imported under the existing system."

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