December 21, 2020

FDA Sued Over Final Rule Permitting Importation of Prescription Drugs from Canada

On November 23, a group of pharmaceutical watchdogs sued the Department of Health and Human Services (DHHS) and the Food & Drug Administration (FDA), seeking to enjoin a final rule implemented on September 25, (Rule). The Rule permitted the importation of certain prescription drugs originally sold in Canada into the United States for resale, so long as the drugs were: (1) similar to FDA-approved drug or their derivatives; (2) labeled with a notation that they were prescription drugs made in and imported from Canada; and (3) underwent marginal testing at the U.S. border prior to entry.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) delegates to the DHHS and FDA the power to develop regulations that govern the importation of prescription drugs made in Canada if the regulations: (1) pose no additional risk to the public's health and safety, and (2) result in a significant reduction in the cost of prescriptions to the American consumer. The plaintiffs allege that the Rule failed to comply with such existing drug safety requirements for imports, pursuant to the FD&C Act.

Importation of drugs from Canada has long been presented as an option for cost savings for American consumers because Canada sells many branded drugs at prices far below U.S. prices. Though the Rule was set to go into effect on November 30, the pending lawsuit threatens to delay its implementation.

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