



Sen. Sanders Introduces Drug Importation Bill on Feb. 28

On Feb. 28, Sen. Bernie Sanders, I-Vt., introduced S. 469, The Affordable and Safe Prescription Drug Importation Act, which would amend the Federal Food, Drug and Cosmetic Act to allow importation of drugs from Canada and possibly other countries. The bill's 19 original co-sponsors include Sens. Cory Booker, D-N.J., and Bob Casey, D-Pa., both of whom voted against a drug importation amendment that Sen. Sanders offered during the January budget resolution debate. The bill has been referred to the Senate Committee on Health, Education, Labor and Pensions and currently has 20 co-sponsors.

Initial Importation From Canada With Possibility for Expansion. S. 469 directs the Department of Health and Human Services (HHS) Secretary to promulgate regulations within 180 days of enactment permitting the importation of prescription drugs by individuals, wholesalers and pharmacies. For the first two years, importation would be permitted only from Canada but could then be expanded to include other countries that are members of the Organisation for Economic Co-operation and Development and have standards similar to those in the United States for regulation of prescription drugs.

Regulation of Foreign Sellers. Foreign sellers, including foreign pharmacies and wholesale distributors, would be required to be certified by the HHS Secretary and could purchase drugs for import into the United States only from Food and Drug Administration-inspected manufacturers.

Standards and Limits on Drugs for Import. Drugs eligible for importation would be required to have the same active ingredient, route of administration and strength as a prescription drug approved in the United States. While individuals would be permitted to purchase a 90-day personal supply pursuant to a valid prescription issued by a U.S.-based provider, certain types of drugs, such as biologics and insulin, could be imported only by wholesalers or pharmacies. Additionally, controlled substances, compound drugs and anesthetic drugs inhaled during surgery would be prohibited for import entirely.

Other relevant provisions of the bill are outlined below:

- The bill would require several supply chain security measures, including importation tracing, and would require importers to submit biannual reports to the HHS Secretary with information about the importation of qualified prescription drugs.

- The HHS Secretary would have the authority to suspend importation of a specific drug or a certified foreign seller for patterns of importation of counterfeit or recalled drugs, or other related violations.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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