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FDA

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Reimportation of U.S. Pharmaceuticals Exported to Canada: Senator Dorgan introduces a bill in U.S. Congress

On April 24, U.S. Senator Dorgan (D-ND) introduced a bill (S. 2244) intended to help U.S. consumers to save money on prescription drugs by allowing drugs exported from the United States to Canada to be reimported. Co-sponsors of S. 2244, entitled the "Medicine Equity and Drug Safety Act II," include Senators Collins (R-ME), Jeffords (I-VT), Levin (D-MI), Snowe (R-ME), Stabenow (D-MI), and Wellstone (D-MN). The sponsors reportedly hope to attach S. 2244, dubbed the "Canada-only bill," to other legislation moving through U.S. Congress this year.

On October 28, 2000, the Medicine Equity and Drug Safety Act of 2000 (MEDS Act) was signed into law as part of the annual U.S. Food and Drug Administration (FDA) appropriations act (Pub.L. 106-387). However, the MEDS Act has never become operational because it included a requirement that the U.S. Secretary of Health and Human Services (HHS) determine that implementation would "pose no additional risk to the public's health and safety" and "result in a significant reduction" in prescription drug costs for U.S. consumers.

On July 9, 2001, HHS Secretary Tommy Thompson informed Senator Jeffords in a letter that he could not make such a determination. He thus reached the same conclusion as had former HHS Secretary Donna Shalala. Citing an analysis by FDA on the safety issues and an analysis by his planning office on the cost issues, Secretary Thompson decided not to "sacrifice public safety for uncertain and speculative cost savings." Members of Congress, particularly from northern border states, have continued to try drafting drug reimportation legislation to deliver the desired cost savings while addressing HHS's concerns. Of course, the issue is tied to a broader debate about drug prices and a drug benefit under Medicare.

The Dorgan Bill

S. 2244--like the current MEDS Act--allows reimportation only of drugs approved by FDA, manufactured in the United States, and compliant with all FDA requirements. While S. 2244 would apply only to reimportation of drugs exported from the United States to Canada, the MEDS Act would authorize reimportations also of drugs exported from the United States to certain European countries, Japan, Australia, New Zealand, and South Africa. S. 2244 has detailed requirements for registration, recordkeeping and reporting by importers and exporters as well as a laboratory testing requirement for all imports. However, the sponsors of S. 2244 omitted the MEDS Act requirement that HHS make a determination prior to implementation, so it will be important for the Executive Branch (and the private sector) to continue to express their views on the legislation through the means that normally apply to legislative proposals prior to enactment.

Interested companies should be monitoring carefully the Congressional consideration of S. 2244 and particularly the following issues:

1. Does S. 2244 respond to the HHS/FDA criticisms of the MEDS Act? (See analysis below.)
2. Is it true, as the bill's sponsors say, that Canada's drug distribution system is so comparable to that of the United States that HHS/FDA need have no fear that enactment of S. 2244 would undermine the U.S. drug safety system?
3. Even if the Canadian drug distribution system matches that of the United States, might our northern neighbor's system be overwhelmed if drug sellers in other countries seek access to the U.S. market by transshipments through Canada?
4. With all the other demands on Canadian and U.S. authorities, separately and jointly, that the North American homeland security effort entails, is it realistic to expect governmental resources on either side of the border to oversee the complex regulatory system that S. 2244 would require? Even before the events of September 11, FDA officials had expressed concern about whether Canada could guard against transshipments through its vast territory of drugs originating elsewhere and destined for the United States.

We are not the only ones watching this bill with interest and wondering about alternatives. When questioned recently by one of the sponsors about whether he might support a Canada-only bill, Secretary Thompson replied that such legislation could require FDA to divert resources away from scrutiny of food imports, and he suggested as an alternative a new effort to improve Medicare.

The MEDS Act vs. the Dorgan Bill

Secretary Thompson's July 9, 2001, letter cited a number of concerns regarding the MEDS Act. What follows is a brief summary of whether the Dorgan bill addresses his concerns:

Secretary Thompson: It would be impossible to ensure that the MEDS Act would result in no loss of protection for the drugs supplied to the American people through the current closed drug distribution system. Most retail stores, hospitals and other outlets obtain drugs either directly from the drug manufacturer or from a small number of large wholesalers, under FDA and state oversight, with only original drug manufacturers allowed to reimport FDA-approved drugs.

The Dorgan Bill: Sponsors of S. 2244 claim that, because Canada has the same type of closed distribution system, the bill responds, without further proof, to this objection.

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Secretary Thompson: HHS/FDA said that the MEDS Act would open up the closed U.S. distribution system to allow any pharmacist or wholesaler to reimport drugs from abroad, which could result in significant growth in imported commercial drug shipments. Pointing out that FDA and the states do not oversee the drug distribution chain outside the United States, Secretary Thompson said that the MEDS Act "would increase the likelihood that the shelves of pharmacies in towns and communities across the nation would include counterfeit drugs, cheap foreign copies of FDA-approved drugs, expired drugs, contaminated drugs, and drugs stored under inappropriate and unsafe conditions."

The Dorgan Bill: S. 2244 limits the bill's coverage to drugs exported to and reimported from Canada. Only those importers and exporters who register with the FDA would be able to take advantage of the bill. However, all of FDA's previous objections about its inability to oversee drug distribution outside U.S. territory would still be applicable.

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Secretary Thompson: The HHS/FDA said that the MEDS Act's requirements for chain-of-custody documentation and sampling and testing of imported drugs are no substitute for the strong protections of the current distribution system.

The Dorgan Bill: The FDA might still say it cannot ensure, under S. 2244, that the reimported drugs would be as safe as those currently found in U.S. pharmacies. The chain of custody is difficult to maintain; documentation can be falsified; end-product testing cannot substitute for in- process controls, sampling and testing cannot detect all potential counterfeit or substandard drug products; and relabeling of reimported products could introduce errors and mix-ups.

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Secretary Thompson: The HHS also found insufficient information to demonstrate that the law would reduce drug costs significantly. The HHS Office of Planning and Evaluation concluded there are significant disincentives to reimportation under the MEDS Act. Among these are costs associated with documenting, sampling and testing; the potential relabeling requirements and related costs and risks; possible increased legal liability; costs to wholesalers and pharmacists in managing inventories, and the risk to present and future contractual relationships between all parties involved. Also, lower foreign prices may not translate into lower prices for U.S. consumers.

The Dorgan Bill: Many of these criticisms would apply to S. 2244. The bill includes costly recordkeeping, reporting, registration, and testing requirements that would affect prices of reimported drugs. Interestingly, one of the bill's sponsors is quoted as saying that one purpose of the bill is to encourage the drug industry to offer to U.S. consumers the same prices afforded to Canadian consumers without need for any use of reimportation.

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Secretary Thompson: Secretary Thompson supported "the goal of reducing the cost of prescription drugs in this country [but] no one in this country should be exposed to the potential public health threat identified by the FDA" and that "the expenditure of time and resources in maintaining [MEDS] complex regulatory system…would be of questionable public health value and could drain resources from other beneficial public health programs."

The Dorgan Bill: Obviously, the sponsors would disagree.

If you have any questions regarding the Dorgan Bill or import/export issues generally, please feel free to contact the following Hogan & Hartson L.L.P. attorneys:

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