

Reprint

Congress Fiddles While Reimportation Issue Burns

By John Mack

Several drug re-importation bills are currently being considered in Congress (see TABLE 1 for bills in the House).

Two Senate bills, the Pharmaceutical Market Access and Drug Safety Act of 2004 (S.2328) and the Safe IMPORT Act of 2004 (S.2493), are likely to meet head-to-head in conference committee. While neither may make it out alive in this session of Congress, the issue of re-importation, however, is not likely to go away. A comparison of the provisions of these bills illustrates where the lines on the policy debate are being drawn.

The Senate Contenders

The Pharmaceutical Market Access and Drug Safety Act of 2004 (**S.2328**) is a bipartisan bill sponsored in the Senate by Republicans John McCain (R-AZ) and Olympia Snowe (R-ME) and Democrats Edward Kennedy (D-MA) and Byron Dorgan (D-ND).

The Safe IMPORT Act of 2004 (**S.2493**) was introduced by Sen. Judd Gregg, R-N.H. and is cosponsored by Republications such Sen. Trent Lott (R-MS), Jeff Sessions (R-AL), and Susan Collins (R-ME).

TABLE 1: Drug Importation Bills in Congress (blue=Republican, yellow=Democrat)

Bill No.	Title	Sponsor	Last Major Action
H.R.2769 (House)	To permit commercial importation of prescription drugs from Canada, and for other purposes. AKA: Save Our Seniors Act of 2003	Rep Emerson, Jo Ann [R. MO] (introduced 7/17/2003)	8/8/2003 Referred to House Subcommittee on Health
H.R.3710 (House)	To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs.	Rep Wexler, Robert [D. FL] (introduced 1/20/2004)	2/3/2004 Referred to House Subcommittee on Health
H.R.4790 (House)	To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes. AKA: Drug Importation Promotion and Safety Act	Rep John, Christopher [D. LA] (introduced 7/9/2004)	7/19/2004 Referred to House Subcommittee on Health
H.R.4923 (House)	To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes. AKA: Drug Importation Promotion and Safety Act	Rep Bradley, Jeb [R. NH] (introduced 7/22/2004)	7/22/2004 Referred to House Committee on Energy and Commerce.
S.2328 (Senate)	A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes. AKA: Pharmaceutical Market Access and Drug Safety Act of 2004	Sen Dorgan, Byron L. [D. ND] (introduced 4/21/2004)	7/14/2004 Status: Committee on the Judiciary. Hearings held.
S.2493 (Senate)	A bill to amend the Federal Food, Drug, and Cosmetic Act to protect the public health from the unsafe importation of prescription drugs and from counterfeit prescription drugs, and for other purposes. AKA: Safe IMPORT Act of 2004	Sen Gregg, Judd [R. NH] (introduced 6/2/2004)	6/2/2004 Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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Comparing Provisions

S.2328 would allow the importation of prescription drugs by registered exporters or registered importers from Canada within 90 days of passage of the Act and from Australia, European Union countries, Japan, New Zealand, or Switzerland within one year.

S.2493 also permits importation from Canada and EU members and other countries approved by the Secretary of Health and Human Services. However, under S.2493, the FDA would have one year to create a system allowing the reimportation.

S.2493 would limit personal importation to FDA-approved drugs manufactured in FDA-approved facilities.

S.2328 would allow drugs to be imported that have the same active ingredients as an FDA-approved drug produced by the same manufacturer. That is, relabeled US FDA-approved drugs would be OK to re-import to the US.

S.2493 would retain the current law prohibiting reimportation of relabeled US FDA-approved drugs. The bill creates an FDA regulatory system for imported drugs that gives the FDA authority to track and inspect imported drugs (as does S.2493), but also to limit ports of entry for imported drugs and impose other conditions upon importers and exporters.

S.2328 would prohibit drug manufacturers from preventing importation by engaging in behavior such as charging higher prices or limiting supplies to registered exporters and importers. Pfizer, GlaxoSmithKline and several other pharma companies have already limited supplies of their drugs to Canadian pharmacies they suspect may be involved in re-importation.

S.2493 would not prohibit drug companies from punishing Canadian reimportation outlets by limiting their supplies or charging them higher prices.

S.2328 would impose one-time registration fees on importers and exporters and allow inspection fees of up to 1% of the total drugs imported annually

S.2493 would require drug importers to pay annual fee determined by the Secretary. It would also require Internet pharmacies to pay an initial \$5,000 licensing fee and a yearly fee thereafter set by the Secretary.

Pharma's Position

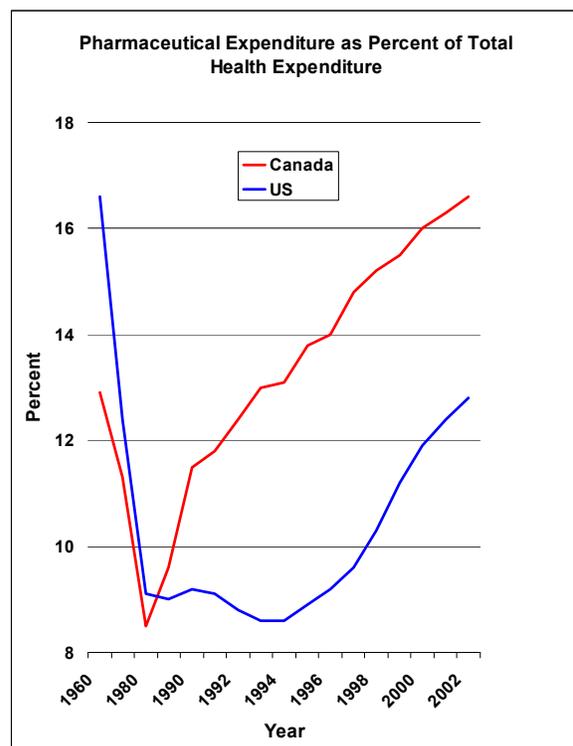
The pharma industry officially opposes both bills.

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's leading pharmaceutical research and biotechnology companies, claims that S.2328 "poses serious patient safety risks."

PhRMA was a bit less harsh in its opposing statement to S.2493. Alan F. Holmer, President and CEO of PhRMA said "While we believe the legislation introduced today by Senator Gregg ... is, in some aspects, more responsible than other importation bills, we respectfully believe that importation is not a solution to the problems of access and affordability to medicines because of the significant safety risks importation poses."

While Congress fiddles as the issue burns, a number of states including Illinois, Minnesota, Wisconsin, and New Hampshire have already enacted legislation to help residents import drugs from Canada and Europe.

Pharma Marketing News



Source: Total expenditure on pharmaceuticals and other medical non-durables, % of total expenditure on health. OECD Health Data 2004

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