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## For Price Break on Drugs, Congress Looks to Canada

By ROBERT PEAR

**W**ASHINGTON, Sept. 8 — Congress is taking steps to allow imports of prescription drugs from Canada, in the hope of giving American consumers access to lower-priced medicines.

The Food and Drug Administration and drug companies oppose the legislation, but many lawmakers said they know of no serious safety hazards with Canadian imports.

"It would be very hard for anyone to make a credible case that there is a risk in importing drugs from Canada," said Senator Byron L. Dorgan, Democrat of North Dakota, who is leading efforts to relax restrictions on such imports.

A law adopted last year allowed pharmacists, drug wholesalers and distributors to import low-priced prescription drugs from 26 countries including Canada, Japan, Israel and members of the European Union.

But the law gave broad discretion to the secretary of health and human services. The Bush administration and the Clinton administration both refused to issue rules to carry out the law. They said they could not certify that the import plan would be safe and would save money for consumers.

In an interview, Mr. Dorgan said, "We are narrowing the bill this year to focus on imports from Canada as a first step."

The broader proposal was included in a spending bill approved last year by votes of 86 to 8 in the Senate and 340 to 175 in the House. A measure dealing just with Canada could pass even more easily, Mr. Dorgan and other lawmakers said.

In July, by a vote of 324 to 101, the House approved a bill that would make it easier for people to import low-cost prescription drugs for their own use. Mr. Dorgan plans to offer his proposal on the Senate floor this month.

Proposals to allow drug imports appeared unexpectedly on the House floor last year without much study or analysis by the committees that usually handle health care legislation.

The idea has attracted serious attention in recent weeks as the federal budget surplus has shrunk, making it more difficult for Congress to add drug benefits to Medicare, the federal health program for the elderly and the disabled.

Senators James M. Jeffords, independent of Vermont, and Debbie Stabenow, Democrat of Michigan, are working closely with Mr. Dorgan to push legislation through the Senate.

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Drug costs were one of the top issues in Ms. Stabenow's campaign last year. She organized bus trips to Canada for Michigan voters who wanted to buy prescription drugs at the lower prices available there. Prescription drugs are subject to price controls in Canada, as in many industrial countries.

The bill Mr. Dorgan and his colleagues are drafting, like the one enacted last year, says that imported drugs must comply with all the safety and labeling requirements that apply to drugs made and distributed in the United States. Each batch of imported drugs would have to be tested for purity, to make sure it was not adulterated or misbranded.

Stephen L. Giroux of Middleport, N.Y., a pharmacist who owns three drugstores about 40 miles from the Canadian border, said, "I would be totally confident and comfortable buying products from Canadian suppliers."

At a Senate hearing this week, William K. Hubbard, senior associate commissioner of the Food and Drug Administration, said he "would have a relatively high degree of confidence" in drugs purchased in Canada. But he said that large-scale imports from Canada would pose immense challenges to the F.D.A.

Drug manufacturers and distributors said they now had virtually complete control over the custody of prescription drugs, from the factory floor to the retail pharmacy. But after drugs leave the United States, they said, they could not be sure of the conditions under which the drugs are stored and handled.

Canada has a sophisticated system for regulating drugs. But Mr. Hubbard said he could not give assurances about the safety of products imported from Canada because

"Once a drug goes into the Canadian market, it's outside F.D.A. jurisdiction," Mr. Hubbard said, adding that "all sorts of malevolent things" could happen to drugs there.

Senator Dorgan said he considers the drug-import bill a tool to "put pressure on drug companies to lower their prices."

Congressional aides who have visited Canada and studied the pharmaceutical market there said it was unrealistic to think that the United States could solve its problems by

Canada has a population of 31 million, compared with the United States' population of 285 million.

Alan Sager, a professor at the Boston University School of Public Health, said drug makers could try to thwart Mr. Dorgan's bill by limiting the supply of drugs available in Canada for export to the United States.

Drug companies would, in effect, be competing with themselves if they sold large amounts of drugs in Canada, only to see the products shipped to the United States for sale here at discount prices.

Mary R. Grealy, president of the Health Care Leadership Council, a coalition of chief executives from large health care companies, said Canada could become "a trans-shipment point" for counterfeit drugs being sent to the United States from

third-world countries. "You don't know where drugs in Canada came from," she said. "They could have been made or stored in third-world countries with no regulation at all."

Federal law says that a prescription drug made in the United States and exported may not be imported to the United States except by the manufacturer. The law, adopted in 1988, sought to end a "gray market" for drugs that were counterfeit, adulterated or too old to be used safely.

The 1988 law, drafted by Representative John D. Dingell, Democrat of Michigan, was widely seen as a consumer protection measure. Congressional investigators had documented many cases in which counterfeit drugs, including birth control pills, had been imported.

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