

Hearing Date: April 19, 2005, 10:00 am

Location: SD430

Witness:

Senator Byron Dorgan
North Dakota

Testimony

Chairman Enzi, Ranking Member Kennedy, and other Members of the HELP Committee, I want to thank you for having this legislative hearing on S. 334, the bipartisan prescription drug importation bill that I have sponsored along with Senators Snowe, Grassley, Kennedy, McCain, Stabenow, and many others. I especially want to express my appreciation to Majority Leader Frist and Chairman Enzi for meeting the commitment they made to Senator Snowe and me to hold this hearing specifically on our bill.

As my colleagues know, this is an issue that I have been working on for quite some time. In fact, I introduced the very first prescription drug re-importation legislation in the Senate back in 1999, and the first Senate vote on this issue was way back in 2000 on an amendment Senator Jeffords and I offered to an Agriculture Appropriations bill.

Most recently, I have introduced S. 334, the Pharmaceutical Market Access and Drug Safety Act. This bill currently has 31 cosponsors from across the political spectrum, including, I'm pleased to note, a number of Members of this Committee.

In short, my bipartisan bill would allow American consumers, pharmacies and drug wholesalers to import FDA-approved prescription drugs at the substantially lower prices available on the world market. Many studies have confirmed what millions of Americans already know – the same prescription drugs cost significantly less in Canada, Europe, and other developed countries than they do here in the United States. And in fact, the Congressional Budget Office has confirmed that brand-name drugs cost, on average, 35 to 55 percent less in other industrialized nations than they do in the United States.

Unfortunately, the price discrepancy for prescription drugs between the United States only continues to get worse, even despite the weakening of the American dollar. Drug prices continue to rise at a rate much higher than inflation – a study released just last week by AARP has found that brand-name prescription drug prices went up an average of 7 percent just in the last year. Clearly, Congress must act to inject some competition into the pharmaceutical marketplace in order to put downward pressure on drug prices.

Confronting the Safety Issues

I have worked very hard with Senators Snowe, Kennedy, Grassley, McCain and others to assure the safety of drugs imported under our legislation.

Unfortunately, there exists in the United States a situation today whereby American citizens are resorting to potentially unsafe measures in order to afford their medicines – including cutting pills in half, skipping doses, and ordering drugs from possibly rogue foreign and domestic Internet pharmacies. In fact, the amount of potentially unsafe drugs coming into the country has exploded because people who can't afford high U.S. prices have been buying their medications over the Internet under a system that is virtually unregulated by the Food and Drug Administration (FDA).

Mr. Chairman, not acting on drug importation legislation is a far greater safety hazard than acting on this bill would be. S. 334 will empower consumers to purchase safe, approved prescription medicines from Canadian pharmacies via mail-order or the Internet under a regulated program. Consumers who choose this option will be assured that they are dealing with a legitimate, licensed Canadian pharmacy that is registered and inspected by the FDA. The FDA will post the list of approved Canadian pharmacies on its website and through a toll-free number, so Americans can readily check to see if they are dealing with a legitimate pharmacy and not a rogue website.

The Dorgan-Snowe bill also creates a closed system of commercial drug importation that ensures the safety of imported drugs from the point of manufacture to the drugstore shelf. Again, S. 334 includes a range of safety features. First of all, only FDA-approved drugs made in FDA-inspected facilities can be imported under the Dorgan-Snowe bill. Moreover, commercial importation by pharmacists and wholesalers could only occur from a limited number of countries – Canada, some European countries, Japan, Australia, New Zealand, and Switzerland – that have drug regulatory systems comparable to our own. And only U.S. licensed pharmacies and drug wholesalers that register with the FDA can import prescription drugs. Registered pharmacies and drug wholesalers would be required to maintain the pedigree of imported medicines all the way back to the FDA-inspected manufacturing plant. Finally, registered importers would be subject to frequent, random FDA inspection and could have their registration suspended or terminated if they don't comply with the bill's requirements.

Perhaps most importantly, the bipartisan bill enables American consumers to stay at home and use their local pharmacy, while still benefiting from lower drug prices. This would ensure that pharmacists could coordinate their patients' pharmaceutical care and help to prevent adverse drug interactions.

Let me make one final point about safety: Some have suggested that we should rely on a requirement that the Health and Human Services Secretary should certify to the safety of imported medicines before importation legislation be implemented. As I mentioned earlier, we currently have an unsafe system whereby as many as 5 million packages containing drugs come into the United States with virtually no regulation. We cannot allow this unsafe situation to continue, and that is what a Secretarial certification requirement would cause.

Closing Loopholes

It is also very important that drug importation legislation include provisions that would prevent drug companies from exploiting loopholes to shut down drug importation and prevent consumers from saving money. The Dorgan-Snowe bill includes a number of necessary provisions to close these loopholes.

The situation in Canada is evidence that the provisions in the bipartisan bill are vitally needed to ensure real savings for American consumers. The drug companies have already demonstrated in Canada that, if they cannot shut down importation by lobbying Congress, they will take steps to do so by backdoor methods.

More specifically, our bill:

- Prevents drug companies from taking actions, such as discriminating against a foreign pharmacy or wholesaler that exports drugs to the U.S. by shutting off their drug supply, that would thwart drug importation. Such an action would be an unfair and discriminatory practice, subject to treble economic damages.
- Prevents a drug manufacturer from blocking importation of drugs in more subtle ways, such as by changing the color, an inactive ingredient, or place of manufacture of the drug so that it is no longer FDA-approved. Drug manufacturers that make these kinds of changes would be required to notify the FDA, and the FDA would be given the authority to approve these changes, if approval is warranted. In other words, our bill ensures that all imported drugs will be FDA-approved, while also ensuring there will be drugs to import.
- Protects pharmacies, wholesalers, and individuals from patent damages arising from the importation of drugs.

Opponents of drug importation have alleged that some of the provisions in the Dorgan-Snowe bill may be unconstitutional. Most of these claims seem to be based on a notion that our non-discrimination provisions would somehow force a drug company to sell a drug for a price that it doesn't want to accept in a country where it doesn't want to sell it. Our bill language specifically makes clear, on page 78, that nothing "shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country." Moreover, our bill only allows importation from other major industrialized nations, and I don't think any of us believe the drug industry is actually selling its products for a loss in these countries. In other words, the drug companies have already voluntarily sold their medicines for a profit once, so importing them for the benefit of American consumers does not in any way violate the drug industry's Constitutional rights.

Regrettably, it is not terribly surprising that the drug industry would make this claim – the drug industry always argues that legislation to reduce the cost of medicines for consumers violates the Constitution. However, objective legal authorities tell me the bipartisan bill is constitutional.

Conclusion

Let me make one final point: Within the Europe Union, they have had a thriving trade in prescription drugs called “parallel trade” for the past two decades. We have heard testimony previously before other hearings that this trade occurs routinely with no safety problems whatsoever and with substantial savings to European governments and consumers. As Dr. Peter Rost, a pharmaceutical company executive who has endorsed S.334 has pointed out: “During my time responsible for a region in northern Europe, I never once – not once – heard the drug industry, regulatory agencies, the government, or anyone else saying that this practice was unsafe. And personally, I think it is outright derogatory to claim that Americans would not be able to handle reimportation of drugs, when the rest of the educated world can do this.”

In closing, the Senate must – and I hope will -- act promptly to pass the bipartisan Dorgan-Snowe bill. This hearing is an important step towards Senate passage of strong, beneficial drug importation legislation, and I thank the Chairman once again for holding it. I have no doubt that we have the votes in the Senate to pass my bill, and I intend to push aggressively for a vote on it soon.

I’d be pleased to answer any questions the Committee Members may have.