Testimony of

The Honorable Byron Dorgan

July 14, 2004

Testimony of U.S. Senator Byron L. Dorgan
Senate Judiciary Committee Hearing on "Examining the Implications
Of Drug Importation"
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Chairman Hatch, Ranking Member Leahy, and other Members of the Judiciary Committee, I want to thank you for having this hearing on the important issue of prescription drug importation and for granting me the courtesy of testifying before you today. 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.

More recently, I have introduced S. 2328, the Pharmaceutical Market Access and Drug Safety Act, the only bipartisan drug importation bill before the Senate. I am pleased to be joined in sponsoring this bill by Senators Snowe, Kennedy, McCain, Daschle, Lott, Stabenow and others, and I'm glad to note that many Members of the Judiciary Committee are cosponsors of this bipartisan legislation.

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.

American consumers are desperate for the lower-priced prescription drugs that the Pharmaceutical Market Access and Drug Safety Act would provide, and I intend to continue fighting for an opportunity to bring my legislation before the full Senate. I am very disappointed that I was not given an opportunity to offer my amendment on drug importation to the Class Action reform legislation when it was before the Senate last week. I was likewise very disappointed to read in yesterday's Washington Post that Majority Leader Frist said it is unlikely the Senate will consider drug importation legislation before adjourning this fall. That is unacceptable to me.

Having said that, I am encouraged to hear that HELP Committee Chairman Gregg plans to hold a mark-up on drug importation legislation next week.

Confronting the Safety Issues

I have worked very hard with Senators Snowe, Kennedy, 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 dosages, 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. The bipartisan bill 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.

My bipartisan 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, the bipartisan bill 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, Europe, 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 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 drug 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 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 provisions that are not included in Senator Gregg's bill 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, the bipartisan 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, dosage form, 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.

? 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 bipartisan bill may be unconstitutional. 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

In closing, the Senate must - and I hope will -- act promptly to pass the bipartisan Dorgan-Snowe bill. The House of Representatives has already passed strong bipartisan legislation, the Pharmaceutical Market Access Act, last summer by a wide bipartisan vote. Now it is our turn.