Ban-Busting Bill: Senate May Pass Legislation Permitting Drug Importation

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Look for the Senate to do this summer what it could not do last year: pass a bill permitting wholesalers to import drugs from developing countries, where their prices are far below those in the U.S.

By the end of April, the way will be cleared for the Pharmaceutical Market Access & Drug Safety Act of 2005 (Section 334/H.R. 700) to come to the Senate floor. That is the deadline set by Senate Majority Leader Bill Frist (R-Tenn.) for the Senate Health, Education, Labor, and Pensions (HELP) Committee to hold hearings on Section 334. No hearings were held in 2004, and Senator Frist, after promising to allow Senate advocates to bring the bill to the floor for a vote, reneged at the end of the session.

But 2005 will be different for a number of reasons. Senator Frist and Senate HELP Chairman Mike Enzi (R-Wyo.) have agreed to hold hearings, although they have not necessarily agreed to allow a committee vote on Section 334 when those hearings take place. There will be plenty of pressure on these two senators to stand aside and let the full Senate vote on the bill, which President Bush opposes.

First, the House passed the 2003–2004 version of H.R. 700 by a vote of 243 to 186 in July 2003. It waited and waited for Senate action, which never came. The House will again pass the bill in 2005.

Second, escalating estimates of the cost of the new Medicare outpatient drug benefit, which starts on January 1, 2006, has put intense pressure on Congress to find ways to decrease the cost of drugs to Medicare. Federal price controls on drugs are out of the question. So, too, apparently, is a revision to the Medicare Modernization Act of 2003 that would allow the federal government to negotiate drug prices with drug manufacturers. That leaves allowing the importation of drugs produced by Pfizer, Merck, GlaxoSmithKline (GSK), and other manufacturers from Europe and Canada, where they are sold for considerably lower prices.

Third, Senate advocates of Section 334 are prepared to deal with any maneuvering by Senator Frist. “We’re not relying on a similar promise this year,” notes Barry Piatt, spokesman for Senator Byron Dorgan (D-North Dakota), one of the co-sponsors of the bill along with Senator Olympia Snowe (R-Maine). “The bill will come up for a vote, and there is easily a majority for it.”

The Doğan–Snowe bill already has nearly 30 co-sponsors. Two other factors will come into play. Given the headlines about unsafe drugs manufactured here in the U.S. and about the Food and Drug Administration’s (FDA’s) spotty approval and monitoring system, it is difficult to argue against drug importation on the basis of concerns about the safety of the European and Canadian drug supply.

The latest evidence is the FDA’s seizure of two GSK drugs that are manufactured in Puerto Rico. GSK had voluntarily recalled some of the affected lots of controlled-release paroxetine (Paxil® CR) and rosiglitazone maleate/metformin HCl (Avandamet®), but not all of them, forcing the FDA to step in. The FDA alleged that GSK had failed to meet U.S. standards for product safety, strength, quality, and purity.

In contrast, there is evidence that drug importation within Europe has worked out fine. At Senate hearings in February 2005, Peter Rost, a Pfizer vice president who must have been taking his professional life in his hands, testified on behalf of drug importation. He referred to his experiences working in Europe.

“I believe that getting a drug from Europe is actually safer than getting it in the U.S.,” he said. “The German Federal Health Ministry has verified that not one single confirmed case of a counterfeit medicine has ever come through the parallel trade chain. The UK [United Kingdom] regulatory authority has described the level of pharmaceutical counterfeiting as ‘virtually undetectable.’”

Even Richard Carmona, the U.S. Surgeon General, who headed the Bush administration task force, which came out against drug importation in 2004, says that it might be a different story if anti-counterfeiting technologies were available to ensure the integrity of the distribution chain. Well, those technologies are available. By the end of 2005, Pfizer will have radiofrequency identification (RFID) tags on 30-count and 100-count bottles of sildenafil (Viagra®) sold in the U.S., according to Peggy Staver, Pfizer’s director of trade product integrity. Purdue Pharma L.P. in Stamford, Connecticut, is already tagging bottles of oxycodone (OxyContin®) and hydromorphone (Palladone™) that are being shipped to two of its largest customers, Wal-Mart and H.D. Smith Wholesale Drug Co., the seventh-largest drug wholesaler in the U.S.

Drug importation into the U.S. will occur, and it should. If prices aren’t as low as promised or if the chain of custody is compromised, the marketplace will react negatively and will adjust accordingly. But at least the market—and more important, consumers—will have a chance to benefit.

Note: The views expressed here are those of the author and do not necessarily reflect those of P&T.