Drug Reimportation: Sitting in the Middle
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Living in San Diego as I do, I often encounter patients who cross into Mexico to buy their prescription drugs. This practice, which is perhaps even more common in states that border Canada, has culminated in legislation passed by the House of Representatives (H.R. 2427, generally referred to as the “Prescription Drug Reimportation Bill”) that would potentially allow drug wholesalers and pharmacists to reimport drugs from a number of industrialized countries. This legislation, which is currently tied up in considerations surrounding a Medicare reform package and prescription-drug bill, has generated strong feelings among consumers, elected officials, and the pharmaceutical industry. Despite the strong opinions expressed both for and against drug reimportation, the issue is complex, the factual data incomplete, and the consequences unpredictable. As physicians, we sit squarely in the middle of this debate, wanting both affordable medications for our patients as well as continued support for the development of innovative pharmacologic therapies.

The problem that the drug reimportation bill was designed to address directly is easily documented. Drugs constitute approximately 10% of the expenditures of the Center for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA). According to the Consumers Union (1), drug costs have been increasing by 15% to 20% per year, about twice the Consumer Price Index, and are projected to reach $243 billion by 2008. Based on surveys, the majority of individuals 65 years and older expend >10% of their income on health care costs, largely for prescription drugs. Of concern, 17% of all Americans and 42% of uninsured Americans report that they have failed to fill prescriptions for financial reasons. As drug prices continue to rise, these problems can be expected to increase.

While the escalating costs of prescribed pharmaceuticals in the U.S. is problem enough by itself, it is magnified by the fact that the prices paid by citizens of other industrialized countries are less. Hard data on the cost differences between the U.S. and other countries are lacking, but these differences have been estimated to be as high as 35% for non-generic drugs. A recent survey conducted by the Associated Press found that 10 of the most-prescribed drugs were 33% to 80% cheaper in Canada than in the U.S. (2). Lipitor, for instance, was 37% cheaper in Canada. The reduced cost of pharmaceuticals in other countries is attributable to price controls, a concept that is antithetical to our capitalist system. Given these price controls, pharmaceutical companies derive minimal profits overseas and must recoup their development expenses and generate their profits from the U.S. Although the American people have considerable compassion and generosity, and are willing to subsidize medications for developing countries, it does not seem reasonable that citizens of industrialized countries with a standard of living comparable to our own should receive subsidies.

The proposed solution to the foregoing problems was the prescription drug reimportation bill introduced by Representative Gil Gutknecht of Minnesota. This bill would extend the right to reimport drugs from pharmaceutical companies to wholesalers and pharmacists. The legislation restricts the countries from which drugs could be imported and stipulates that reimportation be contingent upon the Food and Drug Administration’s (FDA) ability to ensure the safety of the process and upon the provision of proof of cost savings—efforts for which funding was not provided. The bill estimated that Americans could save hundreds of billions of dollars per year—a figure that is debated.

It is not surprising that opponents of reimportation rapidly delineated its limitations. The most obvious issue deals with safety, and the FDA commissioner himself indicated that his agency could not guarantee the safety, purity, and efficacy of imported drugs. No safety issues have been encountered thus far with the current level of importation, but the scale of importation anticipated by the legislation would make products susceptible to major modification. The actual savings that would accrue were called into question, particularly with regard to generics and to the add-on costs entailed in administering the process and retailing the drugs. From a conceptual standpoint, many objected to the fact that reimportation would, in essence, subject the U.S. to the price controls and pharmaceutical policies of a foreign government. However, of perhaps greatest consequence, reduced U.S. profits for prescribed drugs could eliminate the funds necessary to support the expensive drug discovery and development effort of the pharmaceutical industry. Clearly, we in cardiology have benefited as much as anyone from the continuous stream of effective new agents flowing from the pharmaceutical pipeline as a result of heavy investment in research and development (R and D). Any threat to this process could have a major negative impact on the health of society.

Two issues loom in the background of the debate regarding reimportation, and they act to color all the interchange.
The first is the profitability of the pharmaceutical industry. The pharmaceutical industry has been the most profitable business in the American economy for the past 10 years. Although drug companies are among the leaders in spending on R and D, they also devote substantial dollars to marketing and advertising, of which direct-to-consumer media advertising is a prime example. In their own defense, pharmaceutical executives point out that it currently costs approximately $800 million to bring a drug to market and that only 3 of 10 new drugs ever return the investment in development. Nevertheless, the escalating costs of drugs combined with the robust profits of pharmaceutical companies create the impression that drug prices could be reduced without a detrimental effect on the industry. The second issue is the general concept of price controls. Majority opinion favors free market control as the optimal method of determining the value of goods and services. Even most advocates of drug reimportation foresee it as a method of equalizing prices in the industrial world rather than as price controls. Thus, in a sense, reimportation serves as a surrogate issue for questions regarding the very nature of our capitalist system.

Much of the disagreement over drug reimportation relates to uncertainty concerning what consequences will follow. Under one pessimistic scenario, industry profits will plummet, R and D will cease, and no new drugs will be introduced. A proportionately optimistic view is that companies will no longer sell to other countries at low prices, foreign governments will be forced to drop price controls to provide their citizens life-saving pharmaceuticals, and inequities in drug prices will be eliminated throughout the industrialized world. Your position on this issue depends on which of these scenarios you think will occur. The problem is, of course, that no one can predict with certainty.

Where does all this leave cardiologists? Clearly, we have vested interests on both sides of the issue. It is of paramount importance that prescription drugs be readily affordable to our patients. Any action that we can take to achieve this goal is mandatory. The solution should also address the inequities of current international drug prices. Similarly, we must ensure that our productive pharmaceutical industry has sufficient financial support to continue to bring new therapeutic agents to market. It would be catastrophic to kill the goose that laid the golden egg. So we sit in the middle. Personally, I believe that reimportation is a distraction from the major problem, which is the need to provide proven drugs to every patient who requires them. If the only way to accomplish this within existing resources is to negotiate price reductions, then the government should take this on directly, not through reimportation. However, even with substantial price reductions, through negotiations or reimportation, some patients will still be unable to afford drugs. Therefore, I believe the only sure solution is a prescription-drug benefit that provides all patients with the drugs we determine they need. We may be in the middle on reimportation, but there should be no doubts about the desirability of a reasonable, nonintrusive prescription drug benefit package.

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REFERENCES