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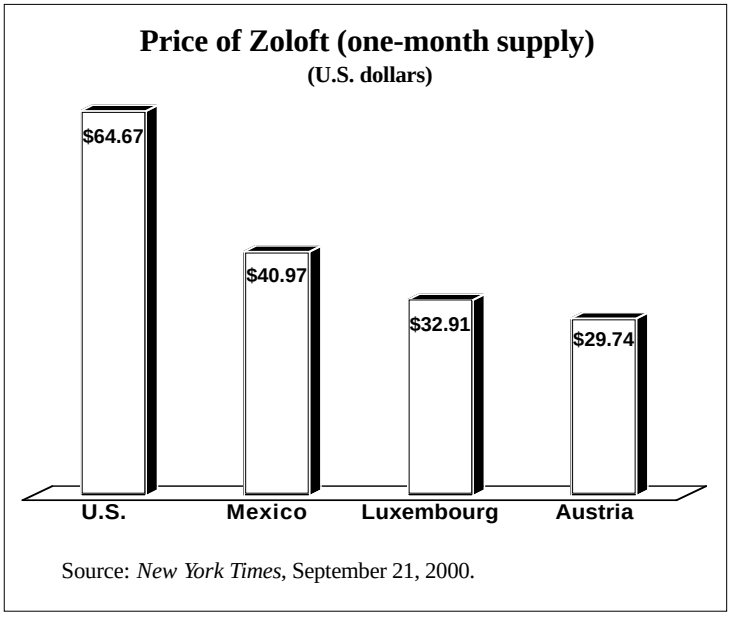
Reimporting Prescription Drugs

By Robert Goldberg

Physicians and patients in the United States have better access to innovative treatments than do those in any other developed country. And the U.S. has become the world leader in biotechnology, including the development and manufacture of new drugs. The main reason is the lack of price controls. In almost every other industrialized country, choice of and access to the most effective new drugs are limited by drug price controls and other government restrictions.

Although Americans derive enormous benefits from our relatively free market for prescription drugs, many think it is unfair that prices in this country are often substantially higher than prices for the same drugs in other countries. [See the figure.] In response to this concern, bills have been introduced in both the House and the Senate to allow wholesalers and pharmacies to import any prescription drug approved by the Food and Drug Administration. These bills would overturn the Prescription Drug Marketing Act of 1988, passed ostensibly to protect American patients from adulterated and counterfeit drugs and drugs that may have lost their potency during foreign handling and shipping. Several states, including Maine and Vermont, have proposed similar measures, but these laws have been challenged as conflicting with the 1988 legislation.



Source: *New York Times*, September 21, 2000.

Goals of the Legislators. The idea of the proposed legislation is to allow Americans to take advantage of lower prices in other countries for drugs, many of them manufactured in the United States. If passed, these laws would allow a pharmacy, say in an African country, that obtains drugs from a U.S. drug maker to ship those drugs back to the U.S. and sell them to U.S. consumers. However, once the drug came back to this country, the foreign pharmacy would be competing against its own U.S. supplier. So wouldn't the U.S. drug maker insist as part of its contract that the foreign pharmacist not ship those drugs back to the United States? Of course it would. And that's why, if the proposed laws have any impact at all, there will be problems.

Likely Response of Drug Manufacturers. AIDS drugs like AZT are sold in South Africa at 10 percent of the U.S. price. (Note: This price barely covers the costs of production and contributes nothing to the cost of developing the drug.) If Americans had unlimited access to cheaper drugs sold in South Africa, there would be one of two consequences, both of them bad:

- Either the U.S. price would fall to the South African price — which would preclude the manufacturers' recouping the sometimes vast sums spent for research and development,
- Or the South African price would rise to the U.S. price — which would preclude South Africans from having the drugs at prices they could afford.

But these consequences are unlikely. American drug companies would add a provision to their contracts prohibiting reimportation (if they haven't already); and they would go to great lengths to ensure that the contracts were enforced.

Thus, the only way the legislative goals could be attained is if the contracts were breached. And because contract monitoring is imperfect, it seems likely that some drugs will still be reimported by contract breakers. But if these importers are willing to break the civil law, can they be trusted to obey the criminal law?

The Problem of Safety. It follows that reputable suppliers would not reimport drugs. And if the law makes it easier for disreputable suppliers to import, that could exacerbate a safety problem that already exists in the international drug market.

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- The Log Cabin AIDS Policy Institute reports that AIDS patients in the 1980s fell victim to adulterated bootleg HIV drugs from overseas when FDA licensing of critical new medicines was slow.
- In 1996 people died from a generic epilepsy drug made from imported bulk substances that slipped by FDA inspection.
- The World Health Organization estimates that about 8 percent of bulk drugs imported to the United States are counterfeit, unapproved or substandard, and the FDA has told Congress it has little information about such shipments at this low level.

Indeed, the FDA has admitted that it lacks the ability to track bulk products, let alone finished goods, at present levels at port of entry. It would require hundreds of millions of dollars, years of planning and additional staff to monitor large-scale importation. Eleven former FDA commissioners have sent a letter to Congress opposing widespread importation as a public health threat.

Why Consumers Would Not Benefit. Backers of reimportation make the implicit assumption that cheaper prices for drugs obtained in other countries will be passed along to the American consumer. They might be — if there were many importers and large quantities were imported. However, with few importers and small quantities, the price break likely will become a middleman profit instead of a patient boon.

Britain has found that, even with many drug importers, middle men rather than consumers reap the benefit of price differences — ironically because of price controls on drugs. Britain's *Sunday Times* recently reported that British importers buy cheap drugs in countries such as Greece, Italy and Spain, then sell them to wholesalers, who pass on savings to pharmacies. Because of price controls, pharmacies are reimbursed by the National Health Service at the agreed national price — often more than double the import cost. New figures from the Medicines Control Agency show that 1,392 such importers have set up in business in the past year, while only a handful operated in the early 1990s. The new industry is believed to be worth up to 1 billion British pounds. Industry analysts and British drug companies say this gray market is cutting pharmaceutical profits on some brands by up to 50 percent, threatening jobs in the drug industry and squeezing the amount of funds for research.

Importation's Impact on Access to New Medicines and Innovation. The ultimate goal of drug importation supporters is to establish the same prices for drugs in the United States and abroad. Since this effort to control prices is doomed for the reasons cited above, the next step surely will be a call for direct controls on prescription drug prices in the U.S. But however imposed, price controls will do damage.

For example, to maintain higher prices to pay for the expensive research and development that produces innovative products, biotech and pharmaceutical companies might initially delay launching new products overseas because of the risk of driving down prices globally. This would delay access to important new medications and reduce investment in innovation.

Nearly one-third of the biotech products sold in the United States today are unavailable in Canada because government price controls simply make them unprofitable to sell there. Paul Abrams, CEO of NeoRx, a biotech company developing cancer drugs, has suggested in congressional testimony that U.S. companies might stop sales to Canada of many of the biotech products that *are* available there if they could be reimported to the United States.

The United States, with no widespread price controls on drugs, now develops a high percentage of the world's most innovative drugs — 45 percent of all those marketed worldwide in the 1990s. By contrast, thanks to price controls, France has some of the lowest drug prices in Europe — and one of the worst records in developing innovative products that can compete globally. In the wake of a series of drug price restrictions in Britain, which had three of the 10 best-selling new products worldwide in 1988, that country today has none.

Conclusion. Imposing price controls on prescription drugs, either directly or indirectly, has few pluses and many minuses. The minuses include threats to the flow of lifesaving drugs at low prices to poor countries and to the safety of the U.S. prescription drug supply. Further, it is far from certain that consumers would see savings. Rather, there is ample evidence that price controls would drastically slow the innovative development of new or improved drugs and undermine investment in new scientific opportunities.

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