



The High Price of Cheap Drugs

By John E. Calfee

Congress is considering whether to allow pharmaceuticals exported by American manufacturers to be reimported into the United States. Reimportation would mean importing foreign price controls, which would destroy the pricing structure of the U.S. drug market and have disastrous consequences for future drug research and development.

A vote is imminent in the House of Representatives on whether to vastly expand the importation of prescription drugs from a long list of nations including Canada, all of the European Union, Eastern European nations to be admitted to the EU in 2004, Israel, and South Africa. The House vote is an up-or-down one with no opportunity for amendments. It was part of the deal that got a Medicare drug benefit passed by one vote earlier this month. If passed, the House importation measure, which includes the reimportation of drugs exported from the United States, will presumably be a non-negotiable item in the conference deliberations with the Senate over a Medicare drug benefit.

The House's importation measure is supported by a bipartisan coalition that wants U.S. prices to match prices in Canada or other nations that control drug prices. This is a pretty radical change, and it merits some careful thought.

Foreign Price Controls

Essentially, the coalition wants our drug prices to be set by the PMPRB or one of its sister agencies. The PMPRB, whose full name is the Patented

Medicine Prices Review Board, is a creature of the Canadian government. It dictates the maximum price that can be charged for a new drug when it is introduced into Canada. The individual provinces then keep prices from rising with inflation (or with changes in exchange rates), so that prices steadily fall behind free-market levels.

The PMPRB does not work alone. It links Canadian price ceilings to European controls. Each European nation has its own price control system, and there are lots of links among those systems. The Netherlands, for example, sets prices at the average price in Belgium, France, Germany, and the United Kingdom. Portugal demands the lowest price in France, Italy, or Spain. Greece wants the lowest price in Europe, period.

Those price controls prevent innovative pharmaceutical firms from reaping free-market rewards anywhere but in the United States. That is one reason why the world pharmaceutical industry, which twenty years ago was mostly based in Europe, has largely relocated to the United States. American manufacturers now account for seven of the top ten worldwide best-selling medicines, and fifteen of the top twenty. This reflects a large and growing disparity in research and development expenditures. In 1990, European pharmaceutical firms outspent American firms on R&D by approximately 8 billion euros to 5 billion euros (\$7 billion to \$4.3 billion). In 2000, U.S. firms outspent European firms by 24 billion euros to 17 billion euros

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(\$20.9 billion to \$14.8 billion). Even traditional European firms, notably GlaxoSmithKline and Novartis, have moved many of their most essential operations to the United States.

After years of looking the other way, the European Commission is sufficiently alarmed by these trends to propose relaxing price controls in order to rejuvenate its pharmaceutical industry, especially the biotechnology sector.

But in the meantime, a lot of drugs are substantially cheaper in Canada and Europe than in the United States. That is why Republican congressmen Gil Gutknecht and Dan Burton want Congress to pass a law so that drugs shipped to Canada or Europe or South Africa can be imported into the United States for sale at foreign prices.

The law would leave the Food and Drug Administration with almost no authority to check the safety of these imports. Wholesalers would have to do their own testing, but pharmacies and “qualifying individuals” (who could resell to others) would face no such requirement. This bothers the FDA, because it thinks mass importation will drastically increase the traffic in counterfeit drugs. Counterfeits are already a problem even though imports are now only a tiny fraction of what they will be if the House bill does what its proponents want it to do.

Importation advocates do not worry about safety because they think the mere threat of importation will push down prices in the United States by at least 30 percent, according to a recent op-ed by Rep. Burton. They think this is competition and free trade at work. The fact that a group of Canadian or European bureaucrats would be setting drug prices for the entire U.S. economy seems to elude them.

Likely Consequences

What would this law actually do? For one thing, Burton, Gutknecht, and their allies might not get the low prices they want even if Congress passes their law. Foreign price controls are anything but a free-market institution, and the Canadian price structure, for example, cannot be imported like a piece of equipment. Prices will not drop in the United States unless foreign drugs really will be imported in large volumes. Importation from Canada alone will not do the trick because the Canadian market is tiny, about 5 percent of the U.S. market in terms of revenues. When Canadian pharmaceutical wholesalers ask Pfizer, Merck, and their competitors to ship them ten times the usual volumes of Lipitor and Zocor and other

blockbuster drugs, with the obvious intention of shipping them right back to the United States, any manufacturer with a decent regard for its shareholders will refuse. Why sacrifice billions of dollars in U.S. sales to maintain sales in a market one-twentieth the size?

If that were the end of the story, events would follow a simple course. Canadian authorities, who understand the importation logic as well as anyone, would have to reassess their price ceilings or leave their citizens short of the best pharmaceuticals. At some point, it would become clear that Canadian drug importation would not bring the low U.S. prices its advocates want, although it might put a good number of patients at risk if importation—including importation of counterfeits—were to ramp up before prices adjusted. Prices in Canada, meanwhile, would rise.

But the House bill is not limited to Canada. There is also France, Italy, the Netherlands, Portugal, and Greece, not to mention Israel and South Africa and soon, Hungary and the Czech Republic, and on and on. That makes for a lot of places from which to ship drugs that can be purchased for a lot less than they cost here.

Two scenarios could play out, one bad and the other worse. In the first scenario, drug manufacturers would again simply refuse to ship huge volumes of drugs to small foreign countries in order for the drugs to be shipped back and cripple profits at home, where the drugs were invented. If that happened (and I think it would), our European friends would probably have a political fit. They would face the prospect of either going without American drugs or raising their own price ceilings—and with them the costs of their fiscally strapped socialist health care systems. From their point of view, the importation plan would be a clever way to force U.S. drug prices on Europeans. They would want very much to prevent that. An international demand for drug price controls in the United States (not just in Europe) would become a centerpiece of international diplomacy. And we might cave in, pushed by the same politicians who want importation. Our record of standing alone in the face of unanimous international pressure is not exactly unmarked by failure.

In scenario two, Burton and Gutknecht would win in the short run. Importation would rapidly escalate to massive volumes from Canada and Europe, maybe from South Africa and elsewhere. The process would resemble the “parallel trade” now engulfing European drug markets as products with Greek or Spanish labels flow to patients in Germany and Britain. Drug prices would drop here,

limited only by fears of counterfeiting, dilution, or inadequate storage. Wholesalers, pharmacies, managed care organizations, and other large-volume dealers would feel intense price pressure from the imports, and the U.S. pricing structure would gradually collapse, just as congressmen Gutknecht and Burton now pray and predict.

Either way, price controls would end up suppressing innovation here, just as they have done abroad. It is one thing for the Canadians and Europeans to free-ride on American R&D, but we cannot free-ride on ourselves. The system that gave us the drugs the whole world wants would be hobbled just when researchers are finally glimpsing pathways to cures for Alzheimer's, cancer, and other killers. The hundreds of biotechnology firms searching for these cures would know that if and when one of them discovers the elusive solution that no one else could find, it will face the prospect of price ceilings set by a government agency intent upon cutting costs.

Given that the expensive part—all the laboratory work and the years of clinical trials—had already been paid for, the manufacturer of a breakthrough drug would have no choice but to take whatever deal it could get as long as the price covered manufacturing and distribution, without consideration for the expensive failures littering the path to success. The market would understand with perfect clarity that the days of free-market rewards for high-risk-high-payoff research were over. The implications for future drug research are both obvious and depressing.

Congress should dismiss all possibility of these scenarios by rejecting the drug importation legislation. It should not fall into the trap of thinking that as long as controls over U.S. prices were introduced by the government of a foreign country, we would still have a free market. We would not have a free market, and we would not get the benefits of one.