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The Grim Economics of Pharmaceutical Importation

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Political pressure has been mounting to give Americans access to prescription drugs from price-controlled nations, yet any legislation needs to take into consideration the likely effects of allowing unrestricted pharmaceutical importation to and from the United States in terms of patient safety and drug prices both at home and abroad.

Years of simmering debate about international prescription-drug prices have suddenly escalated into a political firestorm. Back in 2000, Congress passed the Medicine Equity and Drug Safety (MEDS) Act to permit free importation of prescription drugs from developed nations.[1] The goal was to exploit government price controls in Canada, Europe, and elsewhere. But the MEDS Act required the secretary of health and human services to certify that implementing the law would cut prices without risking safety. Neither Democrat Donna Shalala nor Republican Tommy Thompson would do that, and the law never took effect.

This left matters where they had been since the Prescription Drug Marketing Act was passed in 1987: the Food and Drug Administration would look the other way when individuals imported small amounts of prescription drugs for personal use, but only pharmaceutical manufacturers could import unlimited quantities.

Since 2000, however, political pressure for importation from price-controlled nations has mounted with extraordinary speed. H.R. 1 and S. 1, the House and Senate bills to reform Medicare and add a prescription-drug benefit, would also permit drug importation from Canada. Modeled after the MEDS Act of 2000, H.R. 1 and S. 1 and would again require HHS certification of drug safety and lower costs. Another bill is much more ambitious. H.R. 2427 would permit importation from more than twenty nations without requiring HHS certification. Sponsored by a conservative Republican (Gil Gutknecht) and a liberal Democrat (Rahm Emanuel), H.R. 2427 easily passed the House with substantial bipartisan support.

State and local governments are also getting into the act. Governors and mayors in Illinois, Iowa, Massachusetts, Minnesota, and West Virginia, recently joined by Mayor Bloomberg of New York, want their employee health plans to include drugs from Canada. Some state employees are already receiving drugs through these plans. This development creates a significant gap in existing prohibitions on large-scale importation, because the FDA recently made clear that it would not prosecute state governments involved in importation for their employees.[2]

Public sentiment appears overwhelmingly in favor of importation. In an October 9, 2003, *Wall Street Journal*–Harris Interactive survey, for example, 77 percent said they thought it was unreasonable for manufacturers to oppose making Canadian drugs available to Americans over the Internet. AARP supports importation in principle, subject to resolving safety concerns, with

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lower drug prices as its goal. In an October 17, 2003, public appearance at AEI, AARP's John Rother listed pharmaceutical prices, especially disparities between the United States and Canada, as the single most prominent prescription drug issue for AARP members, above passage of a Medicare drug benefit.[3] No wonder that Republican congressman Michael Bilirakis, who opposes importation legislation, told the *New York Times* that never before has he encountered so much harsh criticism from his constituents.

In the meantime, the infrastructure for importing pharmaceuticals under existing law has grown rapidly in size and sophistication as pharmacy chains and Internet pharmacies assume a central role. Unregulated importation from Canada has grown apace. Canada has already experienced internal supply disruptions. The FDA, still bound by the 1987 law, has sued a leading American facilitator of importation from Canada.[4] But the FDA has also indicated that it will not try to stop states and localities from running their own importation programs.

All this has been accompanied by growing public hostility toward the pharmaceutical industry, especially its pricing policies. A good example is the provocatively titled report, "Follow the Money: the Pharmaceutical Industry—the Other Drug Cartel," from the office of the Minnesota attorney general (2003). The news media (with the notable exception of the *Wall Street Journal* and other trade-oriented publications) often provide one-sided accounts with an emphasis on high prices and an almost studied ignorance of the source of breakthrough medical technology. A recent example is the October 9, 2003, NBC evening television news, in which the Springfield, Massachusetts, mayor not only advocated drug importation but urged cities' pension funds to sell their tainted pharmaceutical stocks. Later in that same news program, NBC described the spectacular clinical trial results of a breast cancer drug without mentioning either the firm that developed the drug (Novartis) or the fact that this firm is one that the Springfield mayor thought did not merit a place in municipal pension portfolios.[5]

Safety Concerns

Drug importation proposals are bound to provoke debate over drug safety because the 1987 law they would rescind was passed to protect the safety of imported drugs. Opponents of importation have argued that mass importation will bring in more counterfeit, adulterated, or mishandled pharmaceuticals. There is certainly reason to worry. Recent news reports[6] and the FDA have described a small but worrisome surge in bad drugs. Among the affected drugs are Lipitor, Neurontin, Procrit, and Serostim. Canadian health authorities have made clear they will not be responsible for the safety of imported drugs that are trans-shipped to the United States.[7] In a recent speech, FDA commissioner Mark McClellan outlined the safety problems that importation could bring.[8] Nonetheless, importation advocates vigorously contend that imported drugs will flow through reputable distributors from extremely safe sources in Canada and western Europe.

The safety of imported drugs will probably not be a significant problem in the short run. But if free importation becomes the law for very long, markets here and elsewhere could become sufficiently chaotic to raise a real possibility that dangerous or inferior drugs will enter the U.S. supply line. Working through these problems could be costly in both financial and health terms.

The Economic Dynamics

The overriding issues, however, are economic. Free importation would fail to achieve its intended effects of reducing prices. Instead, it would create a web of market distortions that in turn would generate powerful political forces for domestic price controls.

The Simple Scenario. If Congress passes a law permitting free importation of pharmaceuticals from low-price nations without requiring safety certification from the FDA, events could play out in a relatively straightforward way. The result, however, would not be to reduce U.S. prices anything close to Canadian levels.

Some simple numbers will illustrate why importation cannot push down U.S. prices very far. The immediate problem is that the Canadian market is too small, with revenues of less than 5 percent of U.S. revenues. Now, no one knows exactly how much cheaper Canadian prices are, but importation advocates typically claim that their law would bring U.S. prices down anywhere from 30 to 50 percent. So let's assume that in Canada, drugs sell for two-thirds their U.S. price on average, which is close to the disparity estimated in a new study of international pharmaceutical prices in 1999 by Danzon and Furukawa.[9] What would happen when wholesalers started to order drugs from Canada, at Canadian prices, instead of from U.S. supplies? If wholesalers replaced 15 percent of the U.S. pharmaceutical revenues, they could buy them in

Canada for an amount equal to 10 percent of U.S. revenues. The manufacturers would lose the difference, or 5 percent of current American revenues.

For this to work, manufacturers would have to ship 15 percent of their product to Canada instead of selling it here (the logic works the same way if the drugs were originally imported to the United States from abroad). Would they do that? They stand to lose 5 percent of the U.S. revenues in order to deal with a nation, Canada, that provides no more than that quantity of revenues in the first place. Manufacturers would do just as well to refuse to ship anything at all to Canada. Then there would be no drugs at all to import from Canada at cut-rate prices.

That is what would happen when wholesalers tried to divert only 15 percent of drugs through Canada. Those who lobby on behalf of free importation want to see a lot more than 15 percent of our drugs go through Canadian price controls. A 30 percent diversion would confront manufacturers with a net revenue loss of 10 percent. If the choice were to ship all these drugs to Canada or ship nothing at all, no CEO with a decent respect for his board of directors and his shareholders would hesitate to cut off the Canadians at this point.

And what about the Canadians? They would lose their drug supply. To regain it, Canadian authorities would have to relax their controls. Canadian prices would move upward toward U.S. prices instead of U.S. prices going down.

Also worth mentioning is the physical flow of drugs. Fifteen percent of the U.S. supply represents roughly twice the physical quantity of drugs sold in Canada (taking price differences into account). A 15 percent diversion would therefore triple the total quantity of drugs passing into the Canadian system, with two-thirds of that moving back across the borders to the United States. Today's safety problems would almost certainly multiply several-fold.

This is a simplified scenario, of course, but obvious elaborations illustrate the same market logic. Rather than cutting Canada off completely, manufacturers have started limiting supplies to historical trends.[10] Wholesalers could respond by moving on to European price-controlled nations. But the results would be much the same, as the largest European pharmaceutical market, Germany, is about one-ninth the size of the United States. Wholesalers could also try a shotgun approach, sticking to high-volume drugs with the largest price differentials. Again, shortages would rapidly emerge and regulators would face the same pressure to raise price ceilings. In any case, there is little reason to expect that dramatic price cuts would result in the United States. The greatest change in American prices would come if *all* the large European nations dismantled their price controls. That would allow prices in the wealthiest nations to converge at a single international level, which would presumably be somewhat lower than current prices here and significantly higher than current prices abroad. Again, the new Danzon and Furukawa study is relevant. The authors found differentials on the order of 30 or 40 percent between the U.S. and large European nations. Because those markets in combination are still substantially smaller than the U.S. market, a common U.S.-European price is likely to be closer to prevailing prices here than to the current controlled prices in those nations.

This simple logic has been laid bare over and over again. The editorial page of the *New York Times*, for example, opined that "Nobody really knows what will happen if Congress passes legislation to encourage drug imports. Our own guess is that it could provide a useful nudge to the industry to revise its global pricing policies to spread the burden more fairly."[11] A July 22, 2003, analysis of H.R. 1 and S. 1 by the bipartisan Congressional Budget Office (pp. 52–53) suggested the same outcome:

> Even if the Secretary were to implement these provisions, they would probably not produce substantial savings for the federal government. Manufacturers of brand-name drugs are unlikely to increase their sales in Canada enough to permit a significant share of their United States market to be imported from Canada. Further, Canada's market for prescription drugs is much smaller than that in the United States. If manufacturers were unable to limit the supply of drugs entering the U.S. market from Canada, the likely result would be that brand-name drug prices in Canada would rise much more than the price in the U.S. would decline. [12]

This actually sounds pretty good so far. Sweeping relaxation of price controls would cause the citizens of the world's wealthiest nations, including Canada, western Europe, Australia, New Zealand, and Japan, to contribute more toward research and development for future drugs. This would accelerate drug development generally while reversing a striking tendency in recent years for the United States to bear an increasing and disproportionately large share of the burden. For example, Germany, the world's third-largest economy with a population equal to about 30 percent of the United States', paid less than

5 percent of the worldwide bill for prescription drugs in 2002, while the United States accounted for just under 50 percent.[13] FDA commissioner McClellan, who was an academic economist as well as a physician before joining the FDA, understands this point very well. In a September 25, 2003, speech, McClellan noted:

> In many ways, the economic consequences of overly strict price controls on drugs are no different than violating the patent directly through compulsory licensing to make copies of the drug. Either way, there isn't likely to be a fair payment based on the value of the new-patented product. This year, Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world's third largest economy, Germany, paid less than 5 percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do. [14]

Poorer nations, on the other hand, would suffer. Pharmaceutical firms would find it more difficult to pursue their natural inclination to charge much lower prices in much poorer countries. That strategy only works if cheap drugs stay where they are delivered instead of being shipped on the Europe and then back to the United States.

A More Likely Scenario. The straightforward train of events just described would almost certainly run aground before reaching its logical end in which importation failed to cut American drug prices. In fact, Congress is trying to short-circuit this process. S. 1 includes sweeping provisions to prevent manufacturers from discriminating against wholesalers who service nations with cut-rate prices or import cut-rate drugs to the United States. These prohibitions are remarkable for their intrusiveness and their non-enforceability. They read like second-generation price-control regulations, dictating detailed controls over product supply chains in the attempt to overcome distortions caused by price controls. Essentially, Congress wants to place domestic markets under the influence of foreign price controls, and then it wants to enact a plethora of regulations to keep firms from reacting to the controls that Congress invited.

The full effects of legislation like S. 1, H.R. 1, or H.R. 2427 cannot be predicted, but certain difficulties are inevitable. Manufacturers would face essentially unlimited demand from wholesalers shipping to historically low-priced markets. How much Lipitor should be provided to buyers from Edmonton, Madrid, Athens, or Budapest, when each one will want to arbitrage supplies for the entire U.S. market? At what price should products be sold to these wholesalers?

The provisions of S. 1 also threaten essential market forces by preventing manufacturers from exercising the multiple forms of discrimination necessary to preserve the integrity of their products. It is essential that manufacturers be free to discriminate among wholesalers of varying levels of efficiency, size, ability, proven safety records, and so on. Once importation is unleashed, huge supplies will be released to wholesalers at various prices for shipment to low-price nations and then reshipment back to the United States. Opportunities for arbitrage among more- or less-favored organizations will be pervasive. Long and complex supply chains among wholesalers and across borders will be inevitable. Supply chains in our home market will become vastly more complicated.

We already know something about the consequences of unnecessary complexity in the supply chain, because we are learning new details about a growing trade in counterfeit or imperfect drugs. These problems have been detailed in FDA and Department of Justice litigation and in news stories, most notably the October 19-23 *Washington Post* series mentioned earlier. Some of the episodes described in that series bear examination by anyone preparing to legislate free importation from nations with price controls. Price disparities among shipments to differentially favored buyers (especially price-controlled government agencies such as Medicaid) have caused supplies to be sold and resold among numerous intermediaries. This process not only makes for slippage in safety standards but greatly eases the entry of even cheaper adulterated supplies.[15]

This is not to say that unregulated markets cannot handle complicated supply chains. Many products proceed through complex channels and multiple ownership transfers with no harm whatsoever, because the final retailers (Wal-Mart, Sears, Safeway, et al.) and their chosen wholesalers face overwhelming incentives to protect their own reputations for quality, as do the original manufacturers, who can and do choose distributors carefully when it is necessary to do so. But as we just saw, S. 1 threatens to dismantle these incentives.

Proposals such as Section 804 (i)(2) of S. 1 cannot even achieve their primary purpose, which is to forestall limitations on supplies to wholesalers. Supply limitations

are inevitable for the simple reason that the total amount demanded by those wholesalers at controlled prices will greatly exceed the total supply available from manufacturers. After all, each one of those wholesalers will want to service the entire U.S. market in addition to the much smaller market it traditionally serves.

Intractable problems would also occur within the markets of the nations that currently produce or import pharmaceuticals for sale at price-controlled levels. Those nations would be expected to serve as depots for mass exportation to the mammoth U.S. market at locally controlled prices. Products shipped to Portugal or Greece at bargain prices would be in great demand from wholesalers willing to pay well above those prices. Internal shortages would occur almost immediately. Whether pharmaceuticals were on the landing docks, in wholesalers' warehouses, in transit to hospitals, pharmacies, and clinics, or residing in storage facilities at their final destination, buyers representing the American market would offer quick profits to anyone holding those supplies.

If importation legislation is to achieve its goals in the United States, the shortages in low-price nations could easily become very serious. The Canadian Department of Health recently warned pharmacies and the medical community about the possibility of shortages as importation to the U.S. ramps up. News reports indicate that spot shortages have already occurred even though the volume of imports from Canada to the U.S. remains well under 1 percent of the U.S. market.[16]

Regulatory authorities in low-price nations would attempt to prevent leakage into the American market—a leakage that must occur if importation is to meet its goals in the United States—and the resulting web of rules, restrictions, quotas, and monitoring would resemble a very large and lucrative black market. The situation would strongly resemble current arbitrage from low-price to high-price markets in the U.S., as described in the October 22, 2003, *Washington Post*, with at least one important difference—one that directly involves safety. Once drugs in Canada or Germany, not to mention Spain, Greece, and Hungary, are diverted from normal routes into channels to the U.S., domestic regulatory authorities would no longer have responsibility for the integrity of the supply line.[17] Of course, degraded products could then leach back into the domestic supply chain as parties sought to make up for shortages.

These nations would fully understand that the source of their problems is the disparity between their prices and ours. They would face the choice of relaxing their price controls, thus increasing the costs of their socialized health care systems, or putting up with serious supply disruptions.

The Emerging Politics of Price Controls

The dynamics outlined here are likely to feed the rapidly escalating political pressure for pharmaceutical price controls. Low-price nations whose drugs are diverted to the United States will see importation legislation as a mechanism to let American drug prices dictate their own prices and increase their own healthcare costs. Drug prices will become an article of international diplomacy. In fact, they already have. Press reports indicate that the Australian government is alarmed by talk about how free-trade agreements might require the dismantling of Australia's "reference price" system for prescription drugs.[18] That is only a sample of what would happen if virtually all developed nations were put on notice that their drug prices will be linked to American prices. If drug importation from price-controlled nations becomes law, pharmaceutical prices will become an essential component in the mix of trade issues on which sovereign nations constantly seek compromise and accommodation while inching forward toward freer markets.

Just as the United States and its rich trading partners have compromised on such basic issues as intellectual property for pharmaceuticals, there will be tremendous pressure to reach some kind of compromise on worldwide drug prices. Such a compromise would involve the fateful step of establishing explicit price controls in the United States to relieve pressures on Canadian, European, Japanese, and Australasian healthcare costs. The destructive effects of such a move are the topic for another article.

Notes

1. Two exceptional sources on issues in drug importation, especially from Canada, are John R. Graham, "Prescription Drug Prices in Canada and the United States—Part 4: Canadian Prescriptions for American Patients Are Not the Solution," (Fraser Institute, *Public Policy Sources* 70 [September 2003, http://www.fraserinstitute.ca/pharmaceuticalpolicy/index.asp?snav=pa]) and Blanchard Randall IV, Susan Thaul, and Donna U. Vogt, "Importing Prescription Drugs: Comparison of the Drug Import Provisions in the Medicare

Reform Bills, H.R. 2427, and Current Law," (Congressional Research Service, October 8, 2003).

2. Jeffrey Krasner, "FDA Eases Stance on Importing Medicines," *Boston Globe* (October 24, 2003).

3. As Rother said, "I think there are five areas of public attitudes that we at AARP are hearing very strongly from every part of the country on this. The first is that, although we define the issue in Washington as an issue of drug coverage, the issue at the grass roots outside the Beltway is almost universally defined as drug prices. People think drugs cost too much. They think that the price increases are unreasonable. They think that we are shmucks for paying so much more in this country than any other country today and there's real anger behind it."

4. On events in Canada, see Graham, "Prescription Drug Prices." The FDA case is *U.S. v Rx Depot, et al.*, brought in the Northern District of Oklahoma.

5. My account is based on viewing the NBC evening news and reading the transcript. The drug was Femara, recently approved for advanced breast cancer. The trial results were rushed into online publication by the *New England Journal of Medicine*: Paul E. Goss et al., " A Randomized Trail of Letrozole in Postmenopausal Women after Five Years of Tamoxifen Therapy for Early-Stage Breast Cancer," (October 9, 2003).

6. This is most notably articulated in an October 19–23, 2003, series in the *Washington Post*.

7. Graham, "Prescription Drug Prices."

8. Mark McClellan, "Remarks before the First International Colloquium on Generic Medicine," Cancún, Mexico (September 25, 2003).

9. Patricia M. Danzon and Michael F. Furukawa, "Prices And Availability Of Pharmaceuticals: Evidence From Nine Countries," *Health Affairs* web exclusive (October 29, 2003), pp. 521–536.

10. Paul Waldie, "Ottawa Fears Medicine Shortage," *Toronto Globe and Mail* (October 29, 2003).

11. "Editorial: The Safety of Imported Drugs," *New York Times* (September 20, 2003).

12. A recent report by Reuters indicated that CBO staff estimate that H.R. 2427 would reduce total drug costs by less than 1 percent during the next ten years. Reuters, "Opening U.S. Prescription Drug Market Could Save Consumers $40 Billion," (October 21, 2003); Congressional Budget Office, "Cost Estimate of H.R. 1 and S.1," (July 22, 2003).

13. Verband Forschender Arzneimittelhersteller e.V. (VFA), "The Pharmaceutical Industry in Germany: Statistics 2003."

14. McClellan, "Remarks on Generic Medicine."

15. Mary Pat Flaherty and Gilbert M. Gaul, "Higher Prices, More Compromises," and "Medicaid Is Start of Drug Resale Trail," *Washington Post* (October 19 and 22, 2003, respectively).

16. Waldie, "Ottawa Fears Medicine Shortage."

17. Flaherty and Gaul, "Medicaid Is Start of Drug Resale Trial."

18. David Wroe and Tim Colebatch, "Deal May Push Up Drug Prices," *The Age* (October 23, 2003), Australia.