

# The Free Market Mirage of Reimportation

By Doug Bandow



# **EXECUTIVE SUMMARY**

The reimportation of prescription drugs is being pushed not only by big government regulators but also by misguided free market advocates. The result: the effective imposition of foreign price controls on U.S. drug markets and the further erosion of genuine competition. But the cost could be worse than money. Governments that control drug prices routinely sacrifice their people's health in order to save money.

With the approval of Medicare drug benefit legislation last fall, public attention has shifted to reimportation of pharmaceuticals from foreign nations. Although some reimportation advocates are attempting to sell the practice as a simple matter of free trade, most supporters have a different agenda: they are pushing reimportation because it would effectively impose foreign price controls on the U.S.market.

Foreign governments have created artificial markets to take advantage of U.S. patients by free-riding on American R&D. Despite this, U.S. support for reimportation is now reaching from individuals to governments.

Genuine competition presumes the freedom to set and adjust prices. But the "competition" advanced by reimportation is competition against oneself. Thus, attempts at price arbitrage based on lower prices abroad effectively means applying foreign price controls at home.

But what of the free market argument that reimportation will force American companies to negotiate hard for prices increases abroad? The argument goes, "Liberalize your markets, or we will leave." The problem is that governments with nationalized systems routinely sacrifice their people's health in order to save money. For instance, pharmaceutical regulations have sharply reduced Canadian access to needed drugs. In the province of British Columbia more than a quarter of doctors report that they have had to treat or even hospitalize patients because of government substitutions of medicine. Incredibly, the more useful the medicine and the more people it would help, the smaller the likelihood that European governments will quickly approve it. Explains Europe Economics: countries "facing tight budget constraints will be more resistant to a given price demanded by a company the higher they expect the demand for the product to be."

If Congress approves reimportation, it will do so in the expectation that the practice will lower prices. Only a few members advocate the policy as a means to make the market work, to whatever end. Everyone else sees this as a politically popular way to deliver benefits to their constituents. The number one purpose of S. 1781, introduced by Sen. Conrad Dorgan, who has incongruously been joined by free market advocates to push reimportation, is "to give all Americans immediate relief from the outrageously high cost of pharmaceuticals." For most non-free market backers, reimportation is merely the first step of more regulation, and if it happens, neither foreign nor American governments are likely to fight fair.

Well-intended friends of freedom mistakenly view reimportation as a question of free trade. But friends of regulation have more accurately diagnosed the impact of reimportation: government control of drug prices at home. When forced to choose between innovative medical research and arbitrary cost controls, foreign governments routinely pick the latter. So, unfortunately, would many American politicians. If they succeed in doing so by legalizing reimportation, all Americans will be the losers.

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# Introduction

Pharmaceuticals have emerged as an increasingly important political issue. Until recently public attention focused on congressional efforts to craft a Medicare drug benefit. But with approval of such legislation last fall public attention has shifted to reimportation of pharmaceuticals from foreign nations, most of which sacrifice their citizens' health through use of price controls and formularies to save money. "It's between the people and the pharmaceutical companies," argues Rep. Ted Strickland (D-Ohio). More accurately, it's between the people and the demagogues.

Although some reimportation advocates are attempting to sell the practice as a simple matter of free trade, most supporters have a different agenda: they are pushing reimportation because it would effectively impose foreign price controls on the U.S. market. "This does provide some answer to the problems people are having," argued Rep. Richard Gephardt (D-Mo.), who said he preferred to legalize reimportation than to pass a limited Medicare drug benefit. Indeed, reimportation would be a first step towards turning the pharmaceutical market into a de facto public utility. Observes health care analyst Uwe Reinhardt: "On some occasions, lawmakers and the general public seem to expect pharmaceutical firms to behave as if they were community-owned, nonprofit entities." <sup>2</sup>

Reimportation

People always want something for nothing. Nowhere has that been more true than in health care. Americans have come to view medicine as an entitlement: they expect exceptional quality services for minimal cost. As third party payment has expanded, with roughly 80 percent of medical costs cov-

Reimportation would effectively impose foreign price controls on the U.S. market.

ered in the first instance by someone else, Americans are not used to heavy out-of-pocket outlays. Yet patients, especially those on Medicare, must pay a larger share of the cost of drugs than of other medical services, causing them to notice spending on pharmaceuticals more than on other medical goods and services. Ironically, hospital care accounts for a greater share of rising health care expenses, and the bulk of the rise in pharmaceutical spending reflects increased use and newer products.<sup>3</sup> In fact, drugs account for only about ten percent of health care costs, and total pharmaceutical expenditures includes the expense of generics and money paid to pharmacies.

Medicine in America is a messy mix of private and public, with nearly half of spending provided by the U.S. government, and federal tax preferences encouraging policies that turn insurance into prepayment of ongoing medical expenses rather than protection against unlikely catastrophic costs. Most foreign systems, in contrast, are government-controlled, with state control over the provision of and payment for care. That almost invariably means restrictions on pharmaceuticals.

Moreover, economic and legal environments vary among countries. Most residents of Third World states cannot afford the prices commonly charged in industrialized nations. A predisposition towards litigation raises costs in America compared to other industrialized states, like Canada. Exchange rates change over time. Generic drugs play a smaller role in many countries. Patients and even consumption levels differ. In an analysis based on data a decade ago, economists Patricia Danzon and Jeong D. Kim found that drugs cost less in America than in Canada, Germany, Sweden, and Switzerland, but more than in France, Italy, Japan, and the United Kingdom.

A more recent study by Danzon and Michael Furukawa, both with the Wharton School, concluded that "U.S.-foreign price differentials are roughly in line with income and smaller for drugs than for medical services." (Where this relationship did not hold, in Chile and Mexico, for instance, local usage is far lower than in America since people cannot afford to buy the products.) So adjusted, the U.S. ranked number two in drug prices, behind Japan, but ahead of European states and Canada. A report from Canada's Fraser Institute also found that income variations explained much of the difference between drug prices among America, Canada, and Europe.<sup>8</sup>

Interestingly, use of purchasing power parities, which attempt to measure a nation's buying power, instead of exchange rates, reduces the gap. "By contrast, when we use health PPPs," write Danzon and Furukawa, "all countries appear to have higher drug prices than the United States, except France, which is at par (0.99). This striking result implies that other countries' prices for medical services other than drugs are even lower, relative to U.S. prices, than their prices for drugs." Similarly, writes analyst John R. Graham of the Fraser Institute, "Canadian prices for health-related goods and services in general are even lower relative to those in

invariably ignore the benefits provided.

In two studies focused on Canada, Fraser Institute analysts found little consistency in pricing: branded medicines tended to cost more in the U.S., but generics were more costly in Canada. Moreover, for many drugs careful price-shopping in the U.S. could yield savings comparable to buying in Canada.

In short, making transnational cost comparisons yields a lot of data with complex meaning. What such comparisons most decidedly do not show is that drug companies are cheating consumers.

## IGNORING BENEFITS

the United States than prices for patented drugs." 10

Moreover, complaints over pharmaceutical prices invariably ignore the benefits provided. Wisconsin Gov. Jim Doyle (D) called a press conference to complain: "Wisconsin's seniors are forced to pay staggering prices for prescription drugs." <sup>12</sup> Staggering prices compared to what?

How much is it worth to live instead of die from AIDS? How much is it worth to have an effective treatment for kidney cancer? How much is it worth to be able to ameliorate the effects of chemotherapy? How much is it worth to deal with any number of irritating and bothersome, even if not life-threatening, conditions?<sup>13</sup> Politicians looking for cheap applause and votes seem to have a particularly difficult time understanding that it costs money, a lot of money, to develop new medicines. (Typically only one of every 5000 to 10,000 substances investigated ends up as a marketable drug, and 70 percent of those lose money.<sup>14</sup>)

Yet the existence of lower prices in foreign lands has spurred trans-border traffic, mail-order pharmacies, and internet sales. The result has been an ever-growing gray or parallel market. European Union rules have long encouraged the phenomenon in Europe: prices are set by individual governments even though sales are continent-wide, leading many consumers, particularly governments, to take advantage of the policies of governments which most penalize their entrepreneurial companies. Observes Stephen Pollard, a Senior Fellow at the Brussels-based Centre for the New Europe: "the primary cause of the wild variations in prices that enables parallel traders to make a profit is the price regulating systems of the various member states, and that is essentially a legislative barrier against competition." <sup>15</sup>

By some estimates ten percent or more of European drugs are sold in the parallel market.<sup>16</sup> Unlike some forms of reimportation, which in medicines is not a result of pure market forces. Explains a new study for the London School of Economics: "Unlike pure arbitrage, pharmaceutical parallel trade is a consequence of price differences arising from heterogeneous regulation across countries." <sup>17</sup>

There is money to be made, but the researchers found that most of the financial benefits from reimportation accrued to traders and pharmacists, not patients. Indeed, patient access to drugs reportedly suffered in some states due to resulting shortages. Nor were prices forced down. Researchers rejected the hypothesis of price competition and a downward price spiral within importing countries as a result of intensifying parallel imports from EU Member States where price levels are lower. The combination of the financial benefits from reimportation accrued to traders and pharmacists, not patients. Indeed, patient access to drugs reportedly suffered in some states due to resulting shortages. The were prices forced down.

However, the combination of government rate regulation and reimportation has degraded European pharmaceutical R&D, accelerating the dramatic decline of the industry over the past two decades. U.S. companies spend more to create new drugs and now create far more new medicines. <sup>21</sup> There is wide recognition that price controls and the resulting parallel pharmaceutical trade has had deleterious consequences. Declared Carsten Knop in the

The combination of government rate regulation and reimportation has degraded European pharmaceutical R&D.

Frankfurter Allgemeine Zeitung, "a glance at the list of the world's leading pharmaceutical companies shows that past savings attempts of German health policy makers have had an adverse economic side-effect: They are partly to blame for the German pharmaceutical industry's relegation to the second league." <sup>22</sup> Some analysts have suggested limiting government price controls to products directly purchased by governments, but reform seems politically unlikely in the nearterm, at least. <sup>23</sup> If European states do not act, however, the problem is likely to worsen once ten new states, most of them relatively poor, join the EU in May 2004. <sup>24</sup>

## PARALLEL TRADING IN AMERICA

The practice of parallel trading has been far rarer in the U.S. (America accounted for 37 percent of the global pharmaceutical market in 2002; Europe represented 15 percent and Canada two percent.<sup>25</sup>) Just four years ago reimportation from Canada was thought to run about \$14 million annually. Last year it was \$700 million and is expected to hit \$800 million in 2003.<sup>26</sup> That remains small compared to overall drug sales, but the increase is dramatic and sales are likely to continue growing.

The reimportation business also is booming in Mexico. Pharmacies in border towns cater to Americans seeking a better deal for drugs. Reports the *Washington Post*: "At peak season at Andrade, when snowbirds flock to the desert crossing west of Yuma, Ariz., 13,000 a day return from Mexico, 'and nearly everyone has medications,' [U.S. port of entry director William] Brooks said. 'The pharmaceuticals are absolutely the draw." <sup>27</sup> Indeed, Brooks himself admits to buying ointment for a skin ailment in Mexico.

Support for reimportation is now reaching from individuals to governments. Michael Albano, Mayor of Springfield, Massachusetts, has begun a drug import program from Canada: "We are mad as hell, and we can't afford it anymore," he declared. Boston has announced its intention to do so starting this summer. The Massachusetts cities of Cambridge, Somerville, and Wooster as well as Burlington, Vermont, and New York City are studying the issue as well. East Providence, Rhode Island, Montgomery, Alabama, and Suffolk County, New York are moving in the same direction. On the same direction.

Illinois Gov. Rod Blagojevich (D) has proposed importing drugs from Canada for state employees and retirees; in December 2003 he formally requested FDA approval to establish a pilot reimportation program.<sup>31</sup> Iowa, Michigan, Minnesota, Ohio, Vermont, West Virginia, Wisconsin are considering taking similar steps. Minnesota Gov. Tim Pawlenty (R) has created a website to allow private citizens to buy drugs from Canada and Wisconsin intends to follow suit.<sup>32</sup> Massachusetts legislators are pushing a plan to publicize Canadian sources of drugs; the Rhode Island legislature is considering a measure to license Canadian pharmacies to sell to Rhode Island residents. New Hampshire's Gov. Craig Benson said his state would start buying pharmaceuticals in Canada; several other states, as far south as Alabama and Louisiana, are considering the same approach.<sup>33</sup>

"We can't wait for Congress," contends Gov. Bob Wise (D-W.Va.).<sup>34</sup> But the campaign has spread to Congress. A large majority of the House voted to allow drug imports from abroad, despite the safety concerns expressed by the Bush administration and Food and Drug Administration. Joining socialist Rep. Bernie Sanders (I-VT) and populist Sen. Byron Dorgan (D-ND) were free market congressmen Jeff Flake (R-AZ) and Ron Paul (R-TX).

Although the Medicare bill did not lift the ban on reimportation (the legislation left intact the requirement for HHS approval), pressure for action has not ended. Within hours of passage of the drug measure, Senate

Internet pharmacies are increasingly obtaining their products from countries such as Bulgaria, Singapore, Argentina, South Africa, Pakistan and other sources.

Minority Leader Tom Daschle (D-SD) introduced legislation to eliminate the certification requirement: "This debate is not over. It's just beginning." <sup>35</sup> Congressmen Gutknecht and Sanders also have promised a major push in 2004. Moreover, Senators used the nomination of FDA Commissioner Mark McClellan to head the Centers for Medicare and Medicaid Services as an opportunity to press for reimportation; McClellan won approval only after promising to work with Congress in developing legislation to allow the safe reimportation of medicine. <sup>36</sup>

Some Republicans were more adept than Democrats at anti-corporate demagoguery. Ranted Rep. Dan Burton (R-IN), the FDA was working "in lockstep with the pharmaceutical industry" to protect its profits: "They are allowing the theft, this robbery, to go on." <sup>37</sup> It apparently has become part of Republican dogma that to invest in, produce, and sell a beneficial good is "theft." Better that people should do without drugs than they should pay the necessary costs of developing them, apparently.

## HEALTH AND SAFETY

Most of the ongoing debate over reimportation has focused on concerns over public health and safety. In a detailed series of investigative reports, *Washington Post* reporters Gilbert M. Gaul and Mary Pat Flaherty found a growing problem of adulterated and counterfeit drugs. Explained Gaul and Flaherty: "For half a century Americans could boast of the world's safest, most tightly regulated system for distributing prescription drugs. But now that system is undercut by a growing illegal trade in pharmaceuticals, fed by criminal profiteers, unscrupulous wholesalers, rogue Internet sites and foreign pharmacies." Congressional investigations also have highlighted a variety of problems. As a result, the Food and Drug Administration and individual states have been attempting to tighten controls over the distribution of pharmaceuticals.

Obviously, many medicines purchased abroad are perfectly safe and effective. <sup>41</sup> Moreover, these problems afflicting internet pharmacies exist without reimportation. <sup>42</sup> However, the challenge facing patients, physicians, and hospitals to ensure the quality of medications prescribed and

consumed would grow with reimportation. The problem is not just more sources of supply, but the destruction of industry distribution networks. Companies would lose control over the sale of their own products, making it harder for consumers to know whose drugs in fact were being sold. Notes Diane Duston, an analyst with Prudential Finance, "it appears that Internet pharmacies are increasingly obtaining their product for shipment into the United States from countries such as Bulgaria, Singapore, Argentina, South Africa, Pakistan and other sources."

The problem of dubious suppliers bedevils Canadian internet pharmacies. PharmacyChecker.com, an independent evaluation company, reports that one-third of Canadian online operations have no apparent affiliation with a licensed pharmacy, for instance. "There's a wide spectrum of pharmacies out there, including some that are very fine and others that aren't so good," said PharmacyChecker.com president Dr. Tod Cooperman.<sup>44</sup> At the behest of the FDA a federal district court judge shut down Rx Depot, an American firm, which imported drugs from Canada.

But FDA Administrator Mark McClellan allows that advanced technologies and expanded regulatory authority might cause his agency to rethink its opposition to reimportation. The more fundamental objection to the practice is an economic one. Complains Rep.

Gil Gutknecht (R-MN), one of the leading GOP proponents of reimportation: "American consumers are held captive in a market that forces them to pay four, five, six ... even ten times as much for the same prescriptoperations have no

Actually, the fault lies abroad, not at home.

tion drugs as our friends in Canada and Europe." 46

Foreign governments have created artificial markets to take advantage of U.S. patients by free-riding on American R&D. As Stephen Pollard writes of Europe, "parallel traders contribute nothing to innovation or the wider economy; they make their profits entirely on the back of government price controls." <sup>47</sup>

Of course, gray markets are not unusual—many autos may be more cheaply purchased in Europe and shipped to America, for instance. A parallel trade has even developed in textbooks, some of which are cheaper in Europe. 48 But, as the LSE study reported, the pharmaceutical market is dominated by government controls. This is what sets the gray market in drugs apart from others. Explains Pollard:

"Pharmaceutical companies are uniquely affected by parallel trade because of the nature of their business, and the legislative frameworks in which they operate. They have major sunk investment costs that can be recovered only through profits gained by current sales but they are subject to monopsonistic national purchasers and thus unable to charge market prices. The pharmaceuticals market is framed by governments as key players themselves in the provision of healthcare." <sup>49</sup>

This phenomenon is no less true among the U.S. and Canada and Europe as within Europe. And the deleterious impact on medical innovation is the same.

Perhaps the worst myth to arise involving reimportation is that it is just another free trade practice. The curious result is that what in Congress has long been a left-wing campaign to forcibly lower prices irrespective of market supply and demand is now being advanced as a means to let the market naturally adjust. Defenders of market economics are aiding industry critics as the latter demand that Washington force down drug prices. "Why aren't we for price controls?", asked Sen. Debbie Stabenow (D-MI), an advocate of reimportation who has organized drug-buying bus trips to Canada: "That's what everybody wants." <sup>50</sup>

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#### REIMPORTATION IS NOT COMPETITION

Rep. Paul, one of the most reliable defenders of liberty in Congress, declared: "Reimportation allows American consumers, particularly seniors, to benefit from worldwide price competition. ... The pharmaceutical companies should not be allowed to profit by this government-enforced price fixing." <sup>51</sup> Sen. Mark Dayton (D-MN) similarly argued: "This is exactly what free trade is intended to do—allow people to import things more cheaply." <sup>52</sup> Former Clinton administration staffer, Rep. Rahm Emanuel (D-IL) made the same contention: "The legislation we are debating today is about inserting competition and the free market into the pricing of medication." <sup>53</sup> If only this were true.

Although price differentials reflect economic as well as legal factors, the irreducible difference is foreign government policy. Companies cannot charge the same amount even if they desire to ignore differences in local conditions. Genuine competition presumes the freedom to set and adjust prices.

Moreover, the "competition" advanced by reimportation is competition against oneself. Llewellyn H. Rockwell of the Ludwig von Mises Institute contends that "the arguments used in favor of

cracking down on drug re-importation are identical to all the arguments used for all forms of protectionism." <sup>54</sup> Writer Jude Blanchette asks whether reimportation opponents "believe that the United States should cease trading with countries that have lower trade barriers than ours, as this would constitute an unlevel playing field?" <sup>55</sup>

This is an almost willful misunderstanding of the issue, however. Federal law does not ban foreign drug makers from selling their products in America. It does not prohibit American firms from offering alternative medicines. Nor does it bar foreign goods because, broadly speaking,

Foreign governments have created artificial markets to take advantage of U.S. patients by free-riding on American R&D.

another market is unfair. Rather, the ban on reimportation prevents third parties from reselling in the U.S. American company's medicines, or what they claim to be American company's medicines, originally sold overseas at an artificially low price fixed by foreign governments. The "government-enforced price fixing" is occurring on the other side of the border.

#### Foreign Price Controls Control Prices

The *New York Times* editorialized that reimportation "could provide a useful nudge to the industry to revise its global pricing policies to spread the burden more fairly." <sup>56</sup> That might be the case if the drug makers controlled their prices. They do not. For the most part, governments decide what companies can charge.

No, contended Rep. Gutknecht: "Other countries do not have price controls. They set reimbursement rates." <sup>57</sup> Actually, everything depends on what the meaning of "is" is.

Where the state does not control the health care market and there are multiple payers, reimbursement rates are just one of many sets of reimbursement rates. Health care in the U.S. remains a hodgepodge of private and public programs and individual decision-making.

However, government "reimbursement rates" mean something very different in countries where the state has nationalized health care. And most foreign nations to some degree concentrate decisions concerning medical services in government hands. Thus, public policies regarding formularies (what will be covered) and price schedules (how much will be paid) essentially set prices. Even where drug makers theoretically may charge more than official levels (such as state-set reference prices), "evidence suggests that most companies are unable to price above the reference price. Patients will not pay the premium." <sup>58</sup>

The Republican Policy Committee forthrightly reports that "Many of today's industrialized countries impose strict price controls on pharmaceuticals despite their developed economies." <sup>59</sup> The European Commission refers to continental drug prices as "administered prices." <sup>60</sup> The Fraser Institute's John Graham writes of "explicit price controls." <sup>61</sup> When asked about recent price increases on U.S. pharmaceuticals, Sylvie Dupont, secretary of Canada's Patented Medicines Prices Review Board, noted that while its approval was not required, it could roll back any excessive increases, which means roughly exceeding the rate of inflation—which it has done some 20 times over the last decade. <sup>62</sup> Of the latter, explains Sally Pipes, a Canadian who is president of the Pacific Research Institute in San Francisco:

"Canada's drug regulatory system is labyrinth of hurdles. The prices at which drugs can be sold to wholesalers and pharmacies are strictly monitored by the Patented Medicines Prices Review Board. In addition, each of Canada's 10 provinces maintains a government-approved formulary, which determines which drugs are available for Canadians who rely on public drug plans." <sup>63</sup>

These nationalized systems differ in their details but not their outcomes. In general, governments tax their citizens, decide on the medical products and services to be provided, and set prices to be paid. There is neither arms length bargaining between buyers and sellers, nor meaningful private markets (servicing people of moderate means) outside of government systems. Whether termed "reimbursement rates" or something else, government prices are in effect price controls. Thus, attempts at price arbitrage based on lower prices abroad effectively means applying foreign price controls at home.

#### AMERICAN COMPANIES POSSESS LITTLE NEGOTIATING CLOUT

One of the arguments for reimportation advanced by free market advocates—in contrast to the Byron Dorgans and Bernie Sanders and Gil Gutknechts who want to impose foreign price controls in the U.S.—is that doing so will force American companies to negotiate hard for price increases abroad. Allow reimportation and domestic manufacturers, threatened with the loss of revenue will bring foreign governments into line. Indeed, some advocate that the loss of revenue will bring foreign governments into line.

Governments with nationalized systems routinely sacrifice their peoples' health in order to save money.

loss of revenue, will bring foreign governments into line. Indeed, some advocates argue that legalized reimportation really is just a threat, and would never occur since the market would adjust. <sup>65</sup> In this view, foreign controls are not set in stone: U.S. drug makers "have options, but under current law they have no incentives, because American consumers pick up the tab." <sup>66</sup>

Actually, drug makers have an obvious incentive, that of making more money, to push for higher prices today. This argument presupposes that firms are lazy, choosing to leave easy money in the hands of foreign politicians. If a bit more negotiating would yield substantial profits, it seems strange that companies aren't doing that now, irrespective of prices in the U.S.

Still, this argument is advanced by reimportation advocates such as Rep. Pat Toomey (R-PA), a serious free market conservative running for Senate. He contended in a "Dear Colleague" letter: Reimportation would force drug makers "to present the price-setting countries with an ultimatum: Either liberalize your market or we will leave. It's hard to imagine that countries in this situation will deny their citizens access to life-saving drugs." <sup>67</sup>

His naiveté is so shocking as to be almost charming. At least it would be were lives not at stake. Governments with nationalized systems *routinely* sacrifice their people's health in order to save money. What is really hard to imagine is that their behavior would change in response to company attempts to withhold their products. In fact, despite growing patient awareness of their governments' shameful policies—in part because of expanded knowledge via the internet—and

occasional discussions about increasing health care choices available to patients, foreign nations have yet to meaningfully relax their controls.

For instance, pharmaceutical regulations have sharply reduced Canadian access to needed drugs. Of 400 drugs considered for reimbursement by the Canadian province of Ontario between 1994 and 1998, only 24 were added. Provinces waited months or years before adding medicines to their formularies. Sally Pipes reports that only 43 new drugs launched in America between 1977 and 1999 made it onto the Canadian market. Amazingly, notes Durhane Waong-Rieger, a Canadian patient advocate, "It takes twice as long to get AIDS drugs approved in Canada."

In the province of British Columbia more than a quarter of doctors report that they have had to treat or even hospitalize patients because of government substitutions of medicine; six of ten have seen their patients' condition deteriorate.<sup>71</sup> Complains

Wong-Rieger: "Patients who are waiting are getting sicker. It's a Catch-22. They can take the drug on the market and it won't do the job, or they can wait and get sicker." <sup>72</sup> People drive south to get drugs that aren't available at any price in Canada. <sup>73</sup>

Similar is Europe's experience. Europeans also have far less access to prescription drugs, particularly newer, more effective products. <sup>74</sup> Use of cancer drugs, as well as medications for a variety of less serious conditions, has been artificially limited. <sup>75</sup> Explained *Wall Street Journal* reporter Stephen D. Moore:

The European industry is shrinking, America has taken the lead in R&D and companies are moving their R&D operations to America.

"Innovative cancer drugs have gotten bogged down even earlier in the system. Herceptin, a new breast-cancer medication from San Francisco-based Genetech Inc., was approved two years ago by regulators in the U.S., where it benefited from an accelerated review offered to novel cancer therapies. It is still awaiting regulatory approval in most of Europe, where the drug will be marketed by Genetech's parent, Roche Holding Ltd."

Many European countries also attempt to restrict demand after new medicines reach pharmacy shelves. Drugs can be saddled with tight prescribing rules to limit consumption. Patients across Europe are fighting for improved access to older drugs such as Taxol, the world's top-selling anticancer drug, from Bristol-Myers Squibb Co.<sup>76</sup>

Drug makers sometimes delay launching medicines until they can achieve a continent-wide price. Moreover, reports Moore: "In some places, drug availability depends on whether the local health authorities are willing to pay their share. In other places, the introduction of a new medicine can be held up as drug makers spend months haggling with individual European governments over reimbursement prices. Elsewhere, the state bans altogether drugs it deems too costly." <sup>78</sup>

Recent research by Prof. Oliver Schoffski of Nuremberg University demonstrates that "despite the existence of effective drugs, available in principle to all European patients, not everyone receives sufficient therapies" due to government reimbursement policies. <sup>79</sup> Indeed, the research group Europe Economics has found that patients often wait years for access to even life-saving new medicines. <sup>80</sup> No surprise, Europeans (as well as Canadians and Japanese) consume far less new, as opposed to off-patent, drugs than do Americans:

"for compounds launched in the most recent two years (age twenty-four months or less), all countries except Germany have 50 percent lower consumption than the United States has; for molecules launched within the prior five years, all countries

except France, Canada, and Germany have at least 50 percent lower consumption per capita than the United States has." 81

Incredibly, the more useful the medicine and the more people it would help, the smaller the likelihood that European governments will quickly approve it. Explains Europe Economics: countries "facing tight budget constraints will be more resistant to a given price demanded by a company the higher they expect the demand for the product to be." <sup>82</sup> Consequently, the European industry is shrinking, America has taken the lead in R&D and new drug discoveries, and companies are moving their R&D operations to America. <sup>83</sup>

Of course, in the abstract, it is not a matter of concern to Americans which drugs foreign health care systems supply. For instance, one unnamed pharmaceutical executive told the *New York Times* "From now on, if the Canadians don't give us a price close to our United States price, I'm not selling it there. I would rather not have people in Congress see us launch a new produce in the United States with a price a lot higher than our Canadian price." <sup>84</sup> If the Canadian government is too cheap to protect its citizens, that is not America's problem.

But the continuing willingness of other governments to ignore their patients' needs means that they may take a hard-line stance towards U.S. firms with little political risk: accept a low reimbursement rate or nothing at all. Moreover, countries could easily play American companies against each other, introducing just one or another medicine within particular therapeutic groups. And even one concession to one country would make the drug vulnerable to reimportation. If the parties reached an impasse, leaving U.S. medications unsold, American companies will earn even less revenue. And U.S. consumers will bear an even larger share of the R&D burden.

In practice, countries have been willing to break patents to cut prices, and sometimes for nonessential drugs. In 2002 Egypt lifted the patent for Viagra.

#### FOREIGN GOVERNMENTS CAN (AND WILL) STEAL U.S. MEDICINES

Over the long-term, a united boycott by American companies would have a dramatic impact on health care in other nations. At some point, that might spur a patient—and political—revolt. Unfortunately, however, U.S. manufacturers would find it difficult to maintain a hard line negotiating position when other nations desire access to important new medicines. By law, most governments have the legal power to procure drugs at basement prices.

True, this is not fair, argue some free market reimportation advocates: "We enter treaties protecting intellectual property precisely to guard against that kind of theft." Yes, but compulsory licensure remains the international norm. That is, countries may seize patents from unwilling companies and allow in-country generic production. For instance, Canada has provided for compulsory licensing since 1923. Ottawa lifted Bayer's Cipro patent (though the government later rescinded that action) in the midst of America's anthrax scare. And there would be little to prevent a medicine produced under compulsory license from being exported to America.

Most nations are subject to some limitations on the exercise of this power under the TRIPS agreement as part of the WTO. A degree of necessity is required, but countries are largely their own judges. Notes economist Jacques J. Gorlin, "it was the United States which was the principal negotiating party that pushed for strong limitations on non-voluntary licensing," but Washington was forced to accept the less protective approach supported by other developed and developing states

alike. <sup>86</sup> The result, writes Kevin Hassett of the American Enterprise Institute, is to handcuff American firms. TRIPS:

"allows a country to violate a drug patent—steal the new drug—if the country is unable to negotiate a contract at "reasonable commercial terms." This condition may also be waived if a country declares a national emergency. In essence, the TRIPS agreement allows foreign governments to extort price concessions from drug companies." <sup>87</sup>

Moreover, recent WTO negotiations have attempted to expand compulsory licensure to include generic imports while limiting the option to poorer states. Although developing nations have focused on the issue of AIDS while attempting to weaken patent protection through the World Trade Organization, they have not limited their efforts in that regard.

Despite the presumption that compulsory licensure should be used only in public health emergencies, in practice countries have been willing to break patents to cut prices, and sometimes for nonessential drugs. In 2001 Brazil began the process of issuing a compulsory license for Viracept (nelfinavir), an AIDS drug, unless Hoffman-La Roche lowered the price; the company accepted a 40 percent cut on its already discounted price, agreeing to sell the medicine for less than one-third the price in America. In October 2002 Egypt lifted the patent for Viagra to allow generic production. In late 2003 legislation allowing compulsory licensing for AIDS and cancer drugs was debated by Mexico's legislature. Among the strongest supporters were domestic pharmacies,

In late 2003 Brazil was back, threatening to confiscate drug patents from Roche, again, as well as Bristol-Myers Squibb and Merck. (Brasilia planned either to produce the medicines locally or import cheap generics from India.) In response, the companies agreed to deeply cut the price of their anti-AIDS drugs. The issue was cost, not access, since

which specialize in selling knock-offs of branded products.89

some political activists freely admit that they want to break patents in developed nations for routine conditions.

Brasilia wanted to limit the costs of its free distribution program. Alexandre Grangeiro, coordinator of the Ministry of Health's AIDS program, put it simply: "We need a price reduction now, because of our budget limitations." Dr. Paulo Roberto Teixeira, Director of the Brazilian National STD/AIDS Programme, explained: "In previous negotiations, we managed to get the prices of these drugs reduced, but now we want to lower the costs even further because our consumption has risen and the drug firms have been selling these brands for long enough to recover their investments." The final price for Merck's Stocrin in Brazil—which possesses the world's ninth largest economy—ended up little above the cost in Sub-Saharan Africa.

Moreover, the formal decree issued in Brasilia would enable the government "to import any generic medication in case of a national emergency or in the interest of public health." <sup>93</sup> Even more ominously, Health Minister Humberto Costa indicated that Brazil intended, had it begun to make generic versions of the patented products, to provide discounted AIDS medications to several poor Latin American states. The international flood gates would have been open.

Some political activists freely admit that they want to break patents in developed states for routine conditions. Explains James Love, director of the misnamed Consumer Project on Technology: "This goes beyond AIDS, malaria and tuberculosis. Any health care item could be included. We want to use this in the United States, in Germany and in Switzerland." <sup>94</sup>

Nor does America have clean hands. When anthrax became a matter of serious concern in late 2001, Washington threatened to break the Cipro patent simply because the government desired to

acquire the drug more cheaply.<sup>95</sup> American officials considered Cipro, a common antibiotic, to be vital in the context of the threat of bioterrorism; foreign governments could make an equally compelling case for any number of medicines used to treat any number of conditions.

In fact, foreign governments with politicized health care systems are likely to have even less compunction about violating property rights, especially those of American companies. For Canada, writes Sally Pipes: "among the biggest sticks is the national government's threat to strip a drug company of its patent and allow generic companies, which bear no cost of research and development, the right to produce a drug if the patent-holding company fails to bring its products to market." <sup>96</sup> What if U.S. companies cut off drugs for Canadian consumers? Ottawa's actions, such as pushing for antitrust action, "give no confidence in this regard," observes John Graham. <sup>97</sup>

#### GOVERNMENTS HAVE WAYS OF MAKING AMERICAN COMPANIES COOPERATE

The ban on reimportation has become a proxy for pharmaceutical companies enforcing through local means the condition that their products are to be sold only in export markets. By ignoring individual consumption while targeting commercial enterprises engaged in parallel trade, the FDA has essentially left Americans free to buy in a gray market while punishing business entities which are intentionally interfering with contracts, a traditional civil tort. As University of Chicago law professor Richard Epstein writes: "All too often, these contractual restrictions are worthless because it is hard to trade drugs that pass through several vendors. Thus, statutory restrictions on reimportation of patented products act as an effec-

Even so, one normally would not assume enforcement was the responsibility of the U.S. government. And the policy has drawn heated objection from serious free market advocates: "rather than insist that those governments police their own vendors, American companies turn to the *American* government, asking it to enforce contractual terms

tive substitute for a valid, if ineffective, private contractual restraint." 98

Were the international pharmaceutical market truly free there would be no problem. But it is not.

binding foreign governments by restricting the freedom of Americans who are not parties to the contract." <sup>99</sup> Yet as Epstein responds, "the law is filled with all sorts of cases where actions are allowed against third parties because the direct remedy is blocked for some reason." <sup>100</sup>

Moreover, enlisting Washington seems more reasonable if that becomes the only remedy available. That will almost certainly be the case if reimportation becomes widespread. Then both the U.S. and Canadian governments are likely to bar companies from imposing restrictions rather than enforcing them.

There are now about 140 on-line pharmacies in Canada. All exist for the purpose of violating both legal and contractual restrictions on parallel exports. Monitoring sales by such pharmacies to ensure that they are not servicing American customers is no mean feat: on-line pharmacies have aggressively attempted to circumvent sales restrictions imposed by drugmakers.<sup>101</sup> The problem is exacerbated by Canadian government promotion of such sales.

Provinces like Manitoba, which hosts about 62 of the on-line services, are actively encouraging the industry: "It's a very dynamic new niche ... and I am proud to back it," explained Maryann Mihychuk, Manitoba Minister of Industry, Trade and Mines. <sup>102</sup> The government "has been supportive of this as a developing industry," explained Marcia Thomson, Assistant Deputy Minister for Health. Even cities are involved; the small town of Minnedosa built a distribution center to lease to Mediplan, an internet pharmacy. <sup>103</sup> Cross-border traffic—represented by famous bus rides by senior citizens into Canada—also yields substantial profits.

In response, in January 2003 GlaxoSmithKline, the second largest global drug maker, cut sales to Canadian wholesalers supplying on-line pharmacies. AstraZeneca, Eli Lilly, Pfizer, and Wyeth followed suit. In January 2004 Pfizer announced further restrictions. 104 Should Congress legalize parallel trade, drug makers would likely further curtail supplies: they would lose less money from ending all sales in Canada than charging Canadian prices in America. 105

In response to the limited cutbacks so far, the gray marketers have turned to smaller pharmacies across Canada. Nevertheless, says Andy Troszok, vice president of the Canadian International Pharmacy Association, "They're having a substantial impact, squeezing supply lines." 106 There have been a number of reports of shortages affecting local Canadian customers. 107 Canada's National Association of Pharmacy Regulatory Authorities has requested that the Canadian government ban parallel exports "until such time as the government can implement systems that will ensure the effective regulation of these practices to protect public safety." <sup>108</sup>

Obviously, such an industry tactic becomes more difficult the more broadly parallel imports are allowed. More important, though, are the political repercussions from limiting sales. Were the international pharmaceutical market truly free there would be no problem. But it is not, which is why reimportation has become a controversial issue. And the politicization of the drug industry makes it more difficult for drug makers even to control their own sales.

If Congress approves reimportation, it will do so in the expectation that the practice will lower prices. Only a few members—such as Congressmen Flake and Paul—advocate the policy as a means to make the market work, to whatever end. Everyone else sees this as a politically popular way to deliver benefits to their constituents. (Market-friendly advocates allow that "many supporters" might advocate this result, but "overwhelming majority" would be a more accurate characterization.<sup>109</sup>) The number one purpose of S. 1781, introduced by Sen. Conrad Dorgan, who has incongruously been joined by free market advocates to push reimportation, is "to give all Americans immediate relief from the outrageously high cost of pharmaceuticals." Drug maker restrictions on supplies to Canada are "a real risk factor to our plans,"

complains Minnesota Gov. Tim Pawlenty. 110 Thus, if companies attempt

For the Dorgans, Gutknechts and Sanders, reimportation is merely the first step of more regulations.

to thwart the politicians' goal of imposing foreign price controls, the Dorgans, Gutknechts, and Sanders will likely return to the political warpath in search of more votes. For them, reimportation is merely the first step of more regulation.

Indeed, the Medicare legislation which passed the individual chambers included not only approval of Canadian reimportation but restrictions on companies which "discriminate," that is, attempted to restrict supplies that would be reimported. 111 Expressly prohibited were supply limits. Writes John Calfee of the American Enterprise Institute: "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." 112

Such restrictions, not included in the final Medicare measure, are integral to the push for reimportation. "There was not, in either the House or Senate bill [of 2000], any provision that prohibited contractual arrangements that would allow opponents of reimportation to undermine the statute," complained John Rector, general counsel of the National Community Pharmacists Association. But, he added, "We're glad the conference committee added something to prevent that kind

of conduct." <sup>113</sup> The provision failed to take effect only because the Clinton Health and Human Services Department refused to certify the safety of reimportation.

Even if Congress approved a "clean" bill simply dropping any restriction on parallel trading and no more, that would not end the political battle. After Glaxo began reducing sales in Canada, senior activists staged predictable public protests in the U.S. Maine and Vermont legislators, who have been among the most active in the nation attempting to impose price controls for political gain, passed resolutions urging pharmaceutical firms to resume sales. In congressional testimony Gov. Pawlenty called such industry actions "reprehensible." 114

Retaliation also would be likely from state attorneys general, who have long been viewed as governor-wannabees, ever-willing to sacrifice the public interest in an attempt to gain public attention and votes. For instance, the Connecticut Attorney General has threatened to begin an investigation of the drug makers for restricting sales in Canada.

Once Glaxo began reducing sales in Canada, the Minnesota attorney general opened an investigation against the company for allegedly improperly organizing a boycott. (Instead of combating real corporate crime, that office published a report complaining that the pharmaceutical firms, among other things, did not release proprietary R&D data to their critics. 115) Gov. Pawlenty opined to Congress: company threats to cut supplies "may be a violation of federal and state anti-trust laws" which should be investigated by the committee. 116

Congressmen have begun making the same threats. "Americans should not have to wait for states' attorney general to enforce anti-trust laws," complained 22 congressmen of industry efforts to limit sales: "It is obvious that these actions are an attempt to prevent American consumers from accessing affordable prescription drugs." 117 Rep. Gutknecht organized the bipartisan letter asking Attorney General John Ashcroft to initiate an antitrust investigation of drug makers. "We must not allow pharmaceutical companies to abuse American consumers, and place lives at risk, by illegally manipulating supply," contended the lawmakers.118 It turns out that choosing how much to sell to whom at what price is abusive and illegal!

Congress wants to place domestic markets under the influence of foreign price controls.

Pressure also would increase in other countries to respond to supply restrictions. One tactic would be to legislate against reimportation, to essentially replace the forgone U.S. restriction. But equally likely would be to punish U.S. firms that restrict sales.

For instance, the European Commission (EC), backed by nearly 30 judgments by the European Court of Justice, has for years impeded company attempts to thwart parallel imports. 119 Most recently, the EC used "competition" rules against Bayer for limiting sales in France and Spain in response to parallel trading and against Glaxo for setting a higher wholesale price on exported drugs in Spain. Bayer lost at trial and won on appeal; the EC ruled against Glaxo, which has appealed. <sup>120</sup> In the former case, the EC claimed the result merely reflected lack of sufficient evidence. Explained spokeswoman Amelia Torres, the EC would continue to monitor the industry: "The decision today in no way prejudices future commission decisions." 121

Indeed, the European Association of Euro-Pharmaceutical Companies called on the EC "to take decisive action against other supply quota systems." 122 As of January 2004, more than 40 complaints against similar supply quota systems were pending before the EC. Moreover, legislation was pending before the European Parliament to prohibit supply quotas.

In 2002 South Africa's Competition Commission initiated an investigation of AIDS drug producers for allegedly overcharging for their medicines and refusing to license their products to their competitors in order to suppress competition. To avoid a trial which would expose internal firm pricing and marketing data, Glaxo agreed to lower its royalty rates and allow generic imports of its products. The German firm Boehringer Ingelheim was expected to similarly surrender.<sup>123</sup>

Health Canada (the nationalized system) Assistant Deputy Minister Diane Gorman said that her agency "regards [supply cuts] as a very serious matter." When Glaxo became the first American company to restrict sales in Canada, Manitoba Minister Mihychuck, unashamedly dedicated to building a Canadian reimportation industry, enlisted national Industry Minister Allan Rock to request an investigation of Glaxo by the Competition Bureau. The Bureau said no. But if the restrictions become deeper, more widespread, and thus more painful, that could change. Ottawa could either admit that its entire pharmaceutical regulatory set-up was wrong or it could attack the drugmakers. Which way would Canada go? In response to a FDA request to help stem reimportation, Health Ministry spokeswoman Jirina Vik noted that "We've got this system" of regulation, shared with most of the world, "and the United States is the outlier."

In the end, such regulatory and antitrust assaults might be rebuffed or even fail to materialize. But companies still might hesitate putting their profits on the line when facing an imposing phalanx of legislators, regulators, lawyers, and judges. It would take only one state antitrust victory, for instance, to set off a feeding frenzy by the trial bar.

#### REGULATORS ARE REALISTIC AND DEREGULATORS ARE NAIVE

The alliance between price controllers and free marketers in favor of drug reimportation reflects different assumptions about the effect of the policy. The former believe that reimportation would impose foreign price controls in America, sharply lowering prices. The latter believe that reimportation would force international prices up to market levels. One of the groups must be wrong.

\*\*Reimportation\*\*

\*\*Reimportation\*\*

\*\*means surrend\*\*

Given the realities of both the economic and political marketplaces, price controllers have more accurately judged the likely impact of reimportation. But then, political activists dedicated to pervasive government intervention in the economy to restrict freedom are much more likely than market advocates dedicated to deregulation to effectively manipulate government

Reimportation means surrender in the name of principle unless the market is first freed.

to their own ends. Whatever the merits of reimportation in theory, neither foreign nor American governments are likely to fight fair: when it comes to saving money, they will, routinely and inevitably, violate property rights, ignore contractual responsibilities, politicize health care decisions, sacrifice the health of their citizens, choose short-term political gains over long-term medical benefits, and enshrine good politics over good policy.

Price control advocates know what they are doing. Why does Sen. Dorgan support reimportation? "It is not my intention to have the American people go to another country for their drugs. It is my intention to force the pharmaceutical industry to re-price their drugs here in the United States." <sup>128</sup> He wants to put "downward pressure on drug prices" in order "to make drugs more affordable." <sup>129</sup> Rep. Sanders is even more explicit: "it is likely that the day after reimportation passes, the pharmaceutical industry will lower their prices in the United States to the same level that they sell their products worldwide." <sup>130</sup> Presumably not just in Canada or Europe, but in Mexico or, even better, in Afghanistan or Congo.

The response of some market advocates is that reimportation remains the right approach; its supporters simply must fight against other unfair pricing, patent, and trade policies as well.

Yet the defenders of freedom will find themselves alone in this regard—their erstwhile reimportation allies will be on the other side of the barricades. And groups unable to prevent a hodge-podge of price controls, formularies, and restrictions in America, let alone full-blown socialized medicine abroad, are unlikely to be able to stop foreign governments from stealing U.S. patents and penalizing U.S. manufacturers. Especially, as noted earlier, when these governments for years have denied necessary medical care to their citizens.<sup>131</sup> Reimportation means surrender in the name of principle unless the market is first freed.

#### THE COST OF IMPOSING FOREIGN PRICE CONTROLS WOULD BE HIGH

Demagogic legislators work hard to demonize drug makers. Says Rep. Dan Burton: Reimportation "is about money, the money that the pharmaceutical companies are making on the backs of the

American people." <sup>132</sup> Come again? Drug makers make money only by developing and producing medicines that Americans value and are willing to pay for. Companies make money only by benefiting people. For a politician, who rarely produces anything of value, to complain about an industry that saves and enriches lives demonstrates the sad character of political debate in Washington today.

Application of Canadian prices would cut industry R&D by between 30 and 50 percent.

Following Rep. Burton's example, Kentucky Gov. Ben Chandler (D), defeated in his reelection race in November 2003, desperately tried to salvage his campaign by attacking his opponent, Rep. Ernie Fletcher (R-KY), who voted against reimportation: Chandler promised to save money on Medicaid by "taking it out of the hide of drug companies." That was undoubtedly a favorite applause line for some audiences. And that approach might work in the short-term. But consumers would be the long term losers. Just as they would be from reimportation. The drug makers obviously would lose because they would face below-market prices. Patients would enjoy buying existing drugs at less, but they could not look forward to continued production of drugs for less.

John Vernon of the University of Pennsylvania's Wharton School found that the larger the proportion of a firm's pharmaceutical sales are subject to price regulation, the smaller its R&D expenditures will be as a proportion of its sales. Price controls and other restrictions reduce the expected return on investment. Vernon figures that if U.S. policy mandated price regulation identical to the "average" degree of overseas price regulation—roughly what reimportation would do—it would lead to a 46.5 percent reduction in industry R&D. 134 Application of

Canadian prices would, depending on several specific assumptions, cut industry R&D by between 30 percent and 50 percent.<sup>135</sup> In short, the cost of foregone medical innovation would be horrendous.

Exactly what that would mean in practice is hard to say, of course. It is generally accepted that the emphasis of European governments in cutting pharmaceutical costs has hindered R&D. 136 European companies have gone

No profits, no products. No products, and we die earlier and suffer more painfully.

from spending 75 percent more on R&D than U.S. firms to American drug makers spending a third more. U.S. enterprises account for most of the big new drugs and, because of the complex, expensive regulatory process, new medicines reach patients far more quickly in America. AIDS patients have gone from a world in which no drugs were available to one in 1987 to 74 today, with another 83 in development. Cutting prices and thus returns would inevitably reduce new drug development. One attempt to measure the benefits of patent protection estimated that there would be three times as much harm to future innovation as benefits from lower prices by eliminating patent protection. The researchers argued that present protection levels are inadequate because

existing consumers—voters with loud political advocates—have greater influence than "unidentified potential consumers of prescription drugs not yet on the market." <sup>138</sup>

Indeed, Smith's work suggests that R&D would start to flatten after five years and decline after ten years; the negative impact on the introduction of new products would not become noticeable until after 20 years. No wonder demagogic politicians like to attack the pharmaceutical industry. They will almost certainly be out of office before their constituents would begin paying the price of their political attempts to hamstring the pharmaceutical industry.

# Intolerable Status Quo

"The status quo on prescription drugs is intolerable and unacceptable," argues Illinois Gov. Blagojevich. It is. Americans ought not to have "to pay the highest prices in the world," argues Sen. Dorgan. They ought not. "It is neither right nor good that Americans bear so great a portion of the health-care costs of the world," argue leading reimportation advocates. It is not. But the pharmaceutical industry is not to blame.

Politicians have come to believe that there is an electoral advantage in beating up on the drug makers. Yet by most measures profits cannot be considered excessive. <sup>143</sup> In any case, writes Uwe Reinhardt, "they are not

Foreigners paying cut-rate prices are not bearing their fair share of the cost of developing new medicines.

large enough to offer much relief for any cost containment effort, as they constitute only a minute fraction of total national health care spending." <sup>144</sup> More important, those profits are the incentive for drug makers to develop and market medicines that improve and save lives. No profits, no products. No products, and we die earlier and suffer more painfully.

That doesn't change the fact that the international market is unfair to Americans, of course. But reimportation is no answer. Americans are not paying more because others are paying less. Even some free market advocates mistakenly believe that U.S. consumers are subsidizing foreign buyers, and thus raising foreign prices would lower American ones. However, firms attempting to profit maximize are charging what they can in America, irrespective of the price available in foreign markets. So long as the ultimate price exceeds the marginal production cost, they will sell in lower-price foreign markets too.

However, foreigners paying cut-rate prices are not bearing their fair share of the cost of developing new medicines. Alas, reimportation would not equalize the burden: foreign price controls prevent U.S. companies from raising their prices to American levels. As an alternative, domestic companies could simply abandon foreign markets. As noted earlier, however, that would result in a new round of political attacks at home and abroad. And if U.S. companies stopped selling overseas, they would lose sales and revenue. As a result, Americans would bear an even greater relative burden of global R&D expenditures.

Americans would enjoy lower prices today but fewer medicines tomorrow.

The worst option would be to allow reimportation to do what its proponents intend: lower U.S. prices by imposing foreign price controls in America. As John R. Graham writes, "parallel trade simply transfers one country's regulated prices to its neighbors." <sup>146</sup> Americans would enjoy lower prices today but fewer medicines tomorrow.

If Canada wants to design a health care system in which its citizens stand in line for medical services, that is of no concern to America. <sup>147</sup> But if Canada wants to leech off of U.S. medical R&D,

that is something very different. The same goes for the European nations. As political analyst Morton Kondracke notes, "Patients and politicians here are outraged. But their rage should be directed at the free riders in foreign lands, not the drug companies." <sup>148</sup>

Rage alone is not enough. To believe that nationalized systems will change voluntarily is to believe that the Easter Bunny is prepared to cooperate with the Tooth Fairy to eliminate cavities. Washington should directly challenge foreign price-setting, prodding its friends in the industrialized world to stop free-riding on America.

Former FDA head Mark McClellan made this point before moving to head the Medicare and Medicaid programs. The Republican Policy Committee, a group of conservative House members, has urged the U.S. Trade Representative "to begin a dialogue with our trading partners in order to obtain more open, equitable, and reciprocal market access for pharmaceuticals," including "pricing disputes." The issue has come up in trade negotiations with Australia, though U.S. Trade Representative Robert Zoellick reportedly opposes mixing the issues. <sup>151</sup> Canadian John R. Graham has suggested that there may be grounds under the North American Free Trade Agreement for challenging Canadian government support for pharmacies concentrating on reimportation. <sup>152</sup>

But this course requires more than a little courage for the administration, since most advocates of reimportation really don't care about sharing the burden for funding R&D and simply want to score points by lowering pharmaceutical prices in America. Sen. Dorgan, Rep. Sanders, and others in the reimportation mob would become only more enraged if the administration succeeded in such efforts. They want lower prices, not market prices, unlike their laissez-faire allies.

Moreover, the U.S. needs to reduce regulations over the development and approval of pharmaceuticals, reducing the cost and time necessary to produce drugs. Washington also should abandon its policy of requiring that drug makers provide pharmaceuticals for Medicaid and the Department of Veterans Affairs at the lowest price given to any private purchasers, since doing so discourages companies from accommodating needy private buyers with special discounts. More broadly, the U.S. needs to address the many perverse incentives, most as a result of government budget and tax policy, that have created a cost-plus medical system, inflating costs throughout the system.

Playing a game of chicken, threatening to wreck the domestic pharmaceutical industry in hopes of raising foreign prices, is not a good strategy. Worries Epstein: "this is a treacherous game: there are many foreign nations and no particular nation will raise its local prices if others do not. So we could find ourselves in the situation where no foreign country responds to the threat, which cuts off the innovation on which so many lives turn." <sup>156</sup>

## Conclusion

"It's going to take some courage and guts for the folks in D.C. to stand up to this industry," said Iowa Gov. Tom Vilsack (D) in launching a predictable attack on the drug makers. But given the plethora of demagogues like Vilsack willing to sacrifice medical R&D for the promise of lower drug prices, real courage is required to stand against the many costly panaceas being advanced in Washington, such as reimportation.

Well-intended friends of freedom mistakenly view reimportation as a question of free trade. But friends of regulation have more accurately diagnosed the impact of reimportation: government control of drug prices at home. When forced to choose between innovative medical research and arbitrary cost controls, foreign governments routinely pick the latter. So,

unfortunately, would many American politicians. If they succeed in doing so by legalizing reimportation, all Americans will be the losers.

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