

Drug Reimportation The Free Market Solution

by Roger Pilon

Executive Summary

As modern “miracle drugs” play a growing role in medical practice, drug prices in America soar far beyond prices in the rest of the world. Yet our law prohibits Americans from buying American-made drugs abroad at those prices and “reimporting” them to the United States. That has led many Americans, and even some state and local officials, to ignore the law and go to Canada and Mexico for their drugs; to the passage in the House last year of a bill lifting the ban on reimportation; and to similar bills now in the Senate—legislation that Health and Human Services Secretary Tommy Thompson recently called “inevitable.”

The ban’s defenders raise several concerns. The safety of reimported drugs cannot be guaranteed, they say. Moreover, lifting the ban will amount to reimporting the foreign price controls that largely explain the price differences—and that will dry up the funds needed for the research and development that produces modern drugs. Food and Drug Administration regulations impose extraordinary costs on drug companies, they add, but when companies go to recoup those costs, they find that only in America, with its relatively free market, can they do so. The rest of the world, with socialized med-

ical systems, will simply not pay market prices, they claim, or if threatened with product withdrawal will steal the patents and produce the drugs themselves. But ban defenders also argue that price discrimination enables companies to exploit different levels of demand and hence to maximize profits, to the benefit of all; yet the only way to enforce that market segmentation, they contend, is through an American ban on reimportation.

As a practical matter, however, Americans end up paying for most of the costs of drug R&D while the rest of the world rides free—and that is politically unsustainable, as events are demonstrating. The current ban should be lifted, therefore, not to encourage reimportation, but to allow the incentives to surface that will “force” wider use of market practices and the international trade regimes that reflect such practices. The last thing we want, however, is to move away from today’s regulated market to the kind of forced trade that one prominent bill now in the Senate, backed by the AARP, would impose. That would indeed import foreign price controls, ending the pharmaceutical revolution the world’s capital markets underwrite here at home and the miracle drugs it produces.

Roger Pilon is vice president for legal affairs at the Cato Institute where he holds the B. Kenneth Simon Chair in Constitutional Studies and is the director of Cato’s Center for Constitutional Studies.

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Introduction

Doctors today rely on pharmaceutical “miracles” only dreamed of half a century ago, prescribing “wonder drugs” where surgery was once the only option. But drugs cost too much—at least that’s what many Americans, especially senior citizens living on fixed incomes, have been telling their Congress members.¹ And they are especially upset to learn that drugs made in America cost far less abroad,² yet American law forbids them from buying those drugs abroad and “reimporting” them to America.³

In growing numbers, therefore, Americans have been ignoring the law and buying their drugs abroad, mostly in Canada and Mexico, or from Internet firms buying abroad.⁴ Food and Drug Administration officials charged with enforcing the law have generally looked the other way when individuals have violated the law, but lately they’ve cracked down on American firms engaged in drug reimportation on a larger scale.⁵ In addition to citizen action, however, a number of state and local officials have revolted against the ban, some threatening to import drugs for their own public programs, others actually importing them.⁶ And, increasingly, members of Congress are speaking out as well.⁷

Political momentum is thus building to revisit the reimportation ban. Last year, to the surprise of many, the House did take action to lift the ban.⁸ Similar bills are now in the Senate.⁹ And although the administration has opposed such bills, Health and Human Services Secretary Tommy Thompson said in May that legislation is “inevitable,” thus signaling a possible change in the administration’s position.¹⁰ When Americans see the drugs they use, most made in America, selling next door at a fraction of what they’re selling for here at home, and see their own government telling them they can’t buy those drugs, they know intuitively that something is wrong. It is becoming increasingly clear to most observers, therefore, that this arrangement is politically unsustainable.¹¹

Yet the issue is not as easy as critics of the ban too often suppose. Even if safety con-

cerns proved negligible, it is not simply a matter of allowing cheap drugs to be imported from price-controlled countries and thereafter all will be well, as too many in Congress seem to believe.¹² Nor of course is it a matter of vilifying drug companies, as many in Congress have done—ignoring the fact that it was Congress that enacted the ban in the first place.¹³

There are reasons the ban was enacted. To get to the bottom of things, therefore, we will have to examine those reasons. After doing so, it will be clear that reimportation is not the main answer to the problem of high drug prices, although lifting the ban on reimportation is a step toward addressing that problem. At bottom, as with so many other political issues today, the ultimate solution to the host of problems surrounding drug reimportation is a free market. But the argument for that contention has to be set forth in slow, deliberate steps, beginning with the principles of a free market as they apply in the case of pharmaceuticals. I will do that largely in the abstract, relegating such evidence as may be useful to endnotes, the better to keep the focus on the main line of argument.

Why Drugs Cost So Much

FDA Regulation

In a truly free society, pharmaceuticals would be manufactured and sold like any other product, on the basis of elementary principles of property and contract, together with common law rules concerning the distribution of risk. Long ago, however, we abandoned that free market regime for a more paternalistic statutory scheme and the ensuing regulations the FDA writes and administers. Today, before the first pill can be offered for sale to the public, a drug company must go through years of costly research and development to satisfy FDA requirements that a drug be not only safe but efficacious for its intended use.¹⁴

The implications of assuming that the public is so risk averse or so unable to judge

and assume risk are many, but two stand out. First, given that today it takes 12 to 15 years on average from discovery of a new compound to FDA approval,¹⁵ the process heavily discounts the risk of not having a drug available for those it may help during that period: in the name of safety and efficacy, that is, many who would be willing to shoulder the risk of an unsafe or inefficacious drug are left to suffer because the FDA has not yet authorized the drug for sale.¹⁶ Here, basic market principles—freedom of contract and assumption of risk—cry out for greater recognition. This objection to the current regime follows a well-traveled path, of course.¹⁷ Suffice it to say that a more flexible FDA approach to safety and, even more, efficacy, would better balance the competing risks.

Second, and more to the point here, an FDA process that allowed greater scope for individual consent could reduce substantially the extraordinary up-front costs drug companies begin incurring long before they are able to bring a drug to market. Reducing those costs would reduce consumer prices, one would imagine. An April Congressional Budget Office brief addressed the up-front costs of drugs by citing a recent study: “when all relevant economic costs are taken into account, including costs from unsuccessful compounds, an average of about \$800 million in R&D spending is incurred for each internally produced new compound reaching the market.”¹⁸ In few industries is the ratio of R&D costs to those of manufacturing and marketing greater. The first pill is enormously expensive. The second costs almost nothing to produce.

Patents

That brings us to the crucial role that patents play in the pharmaceutical industry. Given the industry’s enormous R&D costs, companies can attract capital to underwrite those up-front costs over long periods only if those offering it are assured of seeing a good return on successful investments. And they will be so assured only if the drug that eventually emerges receives a patent—a property

right that excludes others for a time from making a generic copy of the drug. Since the issue of compulsory licensing and patent theft will arise below, it is crucial to secure here an elementary but too often discounted point: without patents, and the property rights they secure, there would be few miracle drugs beyond those underwritten by public funds. To be sure, one can debate whether the private or the public sector more efficiently funds pharmaceutical research, but we have relied on the former for the most part because the evidence suggests that it is better than the public sector at discovering and exploiting entrepreneurial opportunities.¹⁹

Thus, far from being an impediment in a free market, as some argue, a patent simply signifies the product of past investment; it recognizes a “monopoly,” for a time, on use of that product. Like other property rights, patents ensure the production of goods that are then traded in the market. As with the simplest of property rights—ensuring that those who grow crops over time will be able to reap them in time, absent which we would all still be hunters and gatherers—so too with pharmaceutical patents: those who risk their assets over time to bring new drugs into being must receive the rewards available for successful ventures, absent which we would have no new drugs. To later deny those rewards in either case, crops or drugs, takes property belonging to the owner.

But unlike ordinary property rights, patents recognize the underlying claim only for a period of time—currently, 20 years—after which the invention can be copied by anyone. That 20-year patent clock starts ticking, however, from the time the company first applies for FDA approval. As one observer notes, “given the glacial pace of the FDA’s testing and approval process, the effective life for drug patents is about nine years, as compared to around 18 years for other patentable products.”²⁰ Here too, then, is another explanation for the high cost of drugs. The shorter the time the company has to recoup its extraordinary R&D costs, the more it will need to charge per unit sold,

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other things being equal, before the patent expires and the drug is available for others to copy. Thus, if a company's up-front R&D costs are not reduced by shortening the time required for FDA approval, and even if they are, lengthening the effective life of the patent to equal that available for other products, whether through ancillary patents or otherwise, would enable the company to recoup those costs over a longer period of time and, presumably, charge less per unit sold during that period.²¹

Pricing

That brings us to the complex issue of pricing. Companies don't seek simply to recoup their up-front costs, of course, but to maximize their return on investment. Thus, even if those costs play a crucial part in drug-pricing decisions (pricing below cost will not keep a company in business for long), a company's main goal—the reason it's in business to begin with—is to maximize profits, which is perfectly proper, and why congressional complaints about “price-gouging” and the like are so misplaced. Drug companies are not welfare agencies, after all. They serve mankind by creating and selling new drugs. And the incentive to do so is the profit they hope to make. The greater the profits, the greater the incentive. That is why price controls on drugs or on anything else are so shortsighted, as history from antiquity to today amply demonstrates.²²

But pricing is hardly an exact science, as a walk through any supermarket will reveal. In a dynamic free market, prices for goods and services are constantly adjusting, reflecting any number of constantly changing factors. Drug prices are no exception. Even when a company has a “monopoly”—the sole drug for a particular condition—its ability to price is limited by the ability and willingness of buyers to pay. More precisely, such a company will maximize profits for that drug only by finding the optimal price for doing so, not some mythical “maximum” price. Far more often, however, a drug is competing against other drugs, including generics. And in the end it is primarily

competition—that is, the ability of buyers to turn elsewhere—that keeps prices in check.

The world of drug pricing is further complicated, however, by the presence of large buyers, public and private, who are able to negotiate prices that are generally unavailable to individual buyers. And that greatly complicates efforts to make meaningful price comparisons in both the domestic and the international contexts. As one close student of the subject put it, “there is no ‘right’ answer to the question of how high drug prices are in the United States relative to drug prices in other countries.”²³ Still, the evidence at home does seem to suggest that drug prices are increasing faster than other prices. Thus, an AARP study released in late May found that “prices for those brand-name prescription drugs most frequently used by older Americans and available in January 2000 increased, on average, a cumulative 27.6 percent over the four-year period 2000 to 2003 as compared to a general inflation rate of 10.4 percent.”²⁴

Reports such as that, of which there is no shortage, may or may not be accurate. At the end of the day, however, that is likely beside the point, for as a practical matter, Americans themselves are increasingly making international price comparisons for the drugs *they* regularly use, and that is what is driving the current debate—and driving ordinary citizens to buy abroad, where they generally find their drugs selling far more cheaply.²⁵ This is a case of perception becoming reality, which no new price-comparison study is likely to change. Indeed, proponents of the reimportation ban cannot on one hand minimize international price differences, which they sometimes do,²⁶ while on the other hand complaining about letting cheap foreign drugs back into the country. Americans see the differences with their own eyes.

The Ban on Reimportation

Rationales for the Ban

What then is the rationale for the reimportation ban? Given that people generally want

to buy where prices are low, relatively speaking, why are Americans being told by their government that they cannot look abroad to buy those lower-priced drugs? For some time, drug companies have pointed to safety concerns by way of an answer, but regarding imports from developed countries, the evidence does not seem to support those concerns.²⁷ Nor has safety been a serious issue in the European Community, where “parallel trade” in pharmaceuticals has been taking place for some time.²⁸ After all, ordinary business reasons and the ability of developed legal systems to impose liability give drug companies and vendors an incentive to ensure drug integrity. Moreover, if the reimportation ban is lifted, yet reimportation emerges as merely a threat aimed at encouraging international price adjustments, as will be urged below, then the safety issue will be moot because there will be little or no reimportation.

We come then to the main argument supporting the ban: If the ban were lifted, it is said, that would be tantamount to importing foreign price controls; and soon enough that would afford drug companies insufficient funds for the R&D that is necessary to continue producing the miracles of modern medicine.²⁹ That is a serious argument. It cuts against proposals for domestic price controls as well, of course. But it implies, first, that the rest of the world, paying far lower prices than Americans are paying for the same drugs, is “free riding” on Americans’ contributions to drug R&D, and, second, that there is nothing we can do about it, that this situation is somehow set in stone. The first implication is true: as with the cost of international defense, Americans are paying the lion’s share of the cost of drug R&D, while the rest of the world rides free or at well below true cost.³⁰ The second implication, however, is probably not true, yet we will never know whether foreigners are unable or unwilling to pay their “fair share” of drug R&D as long as drug companies, shielded by the reimportation ban, have little incentive to test it. As long as the American market affords them sufficient revenue to cover R&D costs and more, companies

will have little incentive to press the issue, to “force” market pricing on socialized medical systems abroad, not least because anything they earn there now, in those essentially “closed” systems, is so much additional revenue.

The basic underlying question, then, is this: Why are there, in essence, two sets of prices for the same drugs—market prices in America, and far lower prices abroad? There are two main explanations for this state of affairs. The first, just sketched, is more a way of looking at the matter: it portrays drug companies, not without reason, as something like hapless victims of socialized medical systems abroad, taking what they are fortunate enough to be offered by “monopsony” buyers—foreign bureaucrats, the sole buyers for their systems, whose interest in controlling spending trumps any interest in providing citizens with better medicine.³¹ Regrettably, that pretty much characterizes how socialized medical systems work. On this view, then, after an American company completes the arduous FDA approval process and is finally authorized to market its new drug, it looks out at basically one free market, America, where it prices its drug at an optimal, profit-maximizing level. In the rest of the world the company has to accept what each national system is willing to pay because any higher demand, backed by a threat to withhold product, would be met by a counterthreat from the country at issue to steal the patent and produce the drug itself.³² We will return to this argument presently.

The second explanation for there being two sets of prices looks more to economic theory than to political reality. Although it dovetails with the first explanation, it portrays the company not as a victim but as the driving force, segmenting markets and pricing drugs differently in each market. The company accepts the world as it is, assumes that some buyers are willing or able to pay more than others, and then seeks to maximize its profits in light of those differences in demand. Thus, the company charges high prices where it can and lower prices in other markets. In each market seg-

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ment the company tries to find the optimal price for its product—the price that will maximize its profits—but that varies from market to market according to the demand in each market. The net result, however, is a win for all: one price set high would exclude too many potential buyers and hence generate too little profit; one price set lower than many buyers would be willing to pay will also generate too little profit. Segmenting the market and pricing differentially will maximize aggregate welfare.³³

Keeping Markets Segmented

Whether the assumptions underlying this second explanation for price discrimination are correct in the case of drugs—and whether, in particular, companies have correctly calculated the demand in each market, especially in an essentially nonmarket context—is an open question, of course: we will turn to it shortly. But one thing is clear: price discrimination can be sustained only if sellers in lower-price markets do not resell to higher-price markets, or buyers in higher-price markets do not gravitate to lower-price markets to make purchases—precisely what is happening today with pharmaceuticals. In some price discrimination cases that problem does not arise since sellers can unilaterally establish and enforce rules to preserve market segmentation: date-of-purchase rules for airline seats, for example, or time-of-viewing rules for theater seats. In those cases not only can the seller keep the markets segmented by enforcing the rules that do so, but the buyer can take advantage of lower prices simply by following the rules—seeing an afternoon rather than an evening show, for example. In the international drug context, however, manufacturer-sellers have less control, especially with the advent of the Internet. And as parallel trade expands, undercutting the price discrimination schemes sellers rely on to maximize profits, the system for generating capital to underwrite drug R&D is undercut as well.

We come, then, to the nub of the matter. If market segmentation is indeed the most efficient arrangement for producing and mar-

keting drugs, how can it be preserved consistent with the principles of a free society—consistent with exchanges being grounded on consent and force being used only to secure rights? Plainly, if those standards are to be met, there is only one legitimate way that segmentation in this context can be preserved: drug companies must sell drugs in low-price markets on the explicit understanding that they not be resold to buyers in high-price markets. As a condition of receiving a lower price, that is, buyers must agree not to resell to certain others. Companies can bring this result about through either no-resale contracts or label licenses that specify the conditions of purchase. Such no-resale devices are perfectly consistent with a free market: they violate no one's rights because prospective buyers in low-price markets have no right to buy from otherwise unwilling manufacturer-sellers, and prospective buyers in high-price markets have no right to buy from would-be sellers in low-price markets unwilling to risk losing the benefit of their bargain by breaching the no-resale contract or label license.³⁴

It appears, however, that American drug companies have mainly avoided that consensual route to preserving segmented markets (but, see below). Instead, in 1987 they went to *Congress*, asking Congress to treat what should be a contract matter as a trade matter. By statute, Congress prohibited foreign drugs, whether made in America and shipped abroad or made abroad in the first instance by American companies, from being imported into the United States by anyone except the original American manufacturer.³⁵ Faced essentially with a private law problem, even though the buyer on the other end may have been a government or a quasi-governmental entity, companies sought a public law solution—a statutory reimportation ban. And therein lie difficulties.

The main difficulty is this: absent a no-resale contract or label license, government force is being used not to secure rights but to violate rights by blocking trade. The statute is keeping willing sellers and willing buyers apart—indeed, Canadian provincial officials

are actually *encouraging* reimportation,³⁶ and American buyers of course are more than happy to accept those offers. In a case in which perception is reality, the perception of the average American is that his own government is preventing him from buying drugs where they're selling cheaply—and worse still, doing so at the behest of greedy drug companies out to maximize profits. And he's right!

Yet even if American drug companies have put consensual mechanisms in place to try to staunch parallel trade, enforcement through an American statutory ban on reimportation is problematic. It is sometimes said that resorting to a ban is necessary because drugs, once shipped abroad, can pass through several vendors, making contract enforcement difficult.³⁷ That may be so, but notice what this approach to enforcement comes to. Foreign governments or their agents buy at prices insufficient to sustain drug R&D—on threat, some say, of stealing the patent; in doing so they agree not to resell the drugs in higher-price markets; then they breach those no-resale agreements—and the *American* government steps in, not to insist that *foreign* governments abide by the terms that bind them, but to restrict the freedom of *American* citizens *who are no parties to the agreement*. Is it any wonder that Americans are upset over this arrangement? They see foreigners buying American drugs at a fraction of what they have to pay. Then when foreign agencies offer to resell those drugs to them cheaply, their own government tells them they can't accept the offers. And to add insult to injury, Americans bear the enforcement costs as well. However rationally compelling market segmentation, price discrimination, and second-best statutory enforcement schemes may be, this arrangement, as unfolding events are demonstrating, is politically unsustainable.³⁸

Removing the Reimportation Ban

Free Market Options

What, then, is to be done? Clearly, the reimportation ban seeks to protect market

segmentation the easy but wrong way. Although it can be made to appear otherwise, it comes across to most as restricting the wrong parties, American citizens. It should be removed. That will leave American drug companies with two options: continue to practice price discrimination using contractual mechanisms to do so, but enforce those agreements through litigation or self-help (withholding product), not through legislation; or, if enforcement should prove too difficult, too costly, or illegal, adjust international prices sufficiently to discourage reimportation.

No-resale contracts. Taking those options in order, it seems that companies face a mixed situation with no-resale contracts, which are illegal in much of the world—and in the European Community in particular—as restraints on trade.³⁹ In Europe that has led to a thriving “gray market” in drugs: to parallel exports that are undercutting drug company profits there.⁴⁰ To be sure, no-resale contracts do restrain trade, but that's what contracts do generally: if *A* agrees to buy goods from *B*, those are goods that won't be bought from *C* or *D* or by *E* or *F*. No-resale contracts are little different. Because they are voluntary on both sides, benefit both sides, and violate no third-party rights, they should be perfectly legitimate. To maximize its profits, the company is offering country *A* a lower price than the optimal price toward that end offered to country *B*; it can offer that lower price, however, only if country *A* agrees not to resell the drugs to buyers in country *B*. Absent that no-resale agreement, the company will have to charge country *A* a price high enough to discourage exports to country *B*—or sell it no drugs at all.

Where such contracts are legal, however, a company has two standard ways to enforce them. It can litigate, seeking to hold the country to its bargain through injunctive and/or compensatory remedies. Or it can withhold supplies; and if sued as a result, it can offer the country's breach as a defense.

But as drugs pass through the hands of more vendors, as is common, enforcement becomes increasingly difficult. In that case

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the self-help remedy of limiting supplies is a company's only real option.⁴¹ And that will be its remedy as well where no-resale contracts are illegal and drugs are sold on an informal, tacit understanding that they are intended for that country's market only. In either case, however, the company should deal straightforwardly with the country—telling it, in effect, “You police your vendors to prevent reselling abroad or you will get no more drugs at this low price.” Nothing in that proposition offends free trade principles. Moreover, it gets the incentives right, placing the burden of enforcement on the right party. The country benefiting from the low price has the incentive to restrict *exports* of the drug. It should not fall to the American government, whose citizens are paying the highest prices, to restrict *imports*.

But if the country in question won't or can't police its vendors—indeed, if it encourages reselling, as noted above—the company then will have no choice but to withhold supply or raise prices; for if it continued to sell at prices insufficient to cover its actual costs, including R&D, the below-cost exports to profit-making markets would eventually drive it to insolvency. More generally, however, in a large and complex world, it may turn out, with the reimportation ban removed, that companies will be unable to stanch the movement of drugs from lower- to higher-price markets; or the cost of doing so may prove too much. In either case, companies then will need to rethink their pricing strategies.

Repricing drugs. Yet even if market segmentation could be maintained without the ban, other considerations could move companies to rethink their pricing strategies. For we would still be left with price discrimination—and with the perception among Americans that drug companies are gouging them while giving the rest of the world a low-price ride. No one likes paying more than others—being treated unequally and hence, many believe, “unfairly.” It is that perception, of course, that has mainly brought us to this political pass, not the average American's misunderstanding of economic theory. The

virtues of market segmentation and price discrimination may be compelling on the chalkboard, but if their practice leads to serious calls for domestic price controls, profit maximization may have to take a back seat to profit optimization—calculating for political reaction—even if the former would be of greater net social value.

On balance, however, it might not be all that bad if removing the ban “forced” companies to rethink their pricing strategies. After all, the whole theory of market segmentation and price discrimination turns on the idea that there is an optimal price for each drug in each market; yet absent a real market—which doesn't exist abroad, defenders of the ban say—we have no way of knowing what that price is. Governments abroad simply dictate what they are willing to pay.⁴² Drug companies garner market prices only in America. In the rest of the world they sell at prices insufficient to recover costs, including R&D, were that the only market. Shielded by the ban, they never have to test markets abroad to see what the true demand is. With the ban removed, however, if companies cannot limit reimportation sufficiently by contract or clampdowns on supply, they would have to raise prices abroad and/or reduce them here sufficiently to discourage the reimportation that would otherwise undercut their American profit-making market. They would be “forced,” in a word, to shift some of the true costs of modern medicines to those who have avoided paying them for years, thanks to the reimportation ban, and off the shoulders of Americans.

Removing the reimportation ban should not be seen, therefore, as tantamount to reimporting foreign price controls, as many defenders of the ban have argued.⁴³ For with the ban removed, other measures aimed at enforcing price discrimination unavailing, and companies thus “forced” to demand market prices abroad, prices should adjust sufficiently to discourage reimportation and the added costs reimportation would involve. Indeed, once permitted, reimportation should be seen simply as a threat—a measure at hand,

if needed, to keep prices in check. There may have been a time when the poor Swiss, Germans, and French could not afford the latest pharmaceutical miracles. We are long past that time—and long past time for the free ride to end.

Does that mean that truly poor countries would have to pay market prices for drugs as well? No, not if drug companies wished to supply those countries with drugs at discounted prices or even free—provided they were able to police any exports, of course. A better way to handle this matter, however, would be to stop viewing drug companies as charitable organizations. Just as we ought not to compel doctors, lawyers, or anyone else to do charitable work (with lawyers, as a condition of licensure), so too we ought not to expect private, profit-making entities to be public servants. If people around the world wish to engage in such charitable work, there are international organizations dedicated to that end, able to draw on private voluntary and, if necessary, public nonvoluntary resources to underwrite the costs of such programs and to buy drugs at prices companies are willing to accept. It is important to keep commercial and charitable undertakings separate—for the integrity of both.

Compulsory Licensing

Today, however, we undertake such international charity very differently, as part of a larger, problematic process called “compulsory licensing.” I will touch upon the charitable use of that process in a moment, but first we need to address the objection raised by those who defend the reimportation ban, that if foreign countries were “forced” to pay market prices for drugs, they would force compulsory licensing on drug companies: faced with rising prices, that is, foreign countries would license a domestic company, which does not hold the patent, to manufacture the drug as a “generic,” thereby stealing the patent from its rightful owner. Given that threat, ban defenders continue, drug companies are forced to accept the price the country offers for a drug rather than a market price. In effect, the foreign

country is telling the company, “Take what we offer or we’ll steal your product.” The company accepts the offer, on this view, only because it is able to make up the difference in the American market, thanks to the reimportation ban. Hence the fear, with the ban lifted, about “reimporting foreign price controls,” which would make the drug business a losing proposition.⁴⁴

That view appears to be something of an overstatement, although the facts and history here are not entirely clear. Without question, compulsory licensing occurs, and horror stories can be found.⁴⁵ In fact, the process is sanctioned by the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement),⁴⁶ which all developed and most developing nations have signed. In its agreements over the years, the WTO has been trying “to strike a balance between promoting access to existing drugs and promoting research and development into new drugs.”⁴⁷ As that formula suggests, the “access” the WTO seeks to promote is not meant to be achieved through markets, for which a “balance” could be struck using the price mechanism, but through inroads on patents—yet not to such an extent, apparently, as would compromise drug R&D. We have here, of course, the familiar struggle between more- and less-developed countries, with the less developed seeking to impose legal obligations of assistance on both developed countries and the businesses that thrive in them. Notwithstanding that agenda, recent events seem to be moving in a direction that should mitigate somewhat the fears of reimportation opponents.

In brief, under the 2001 Doha Declaration and the agreement pursuant to it that was reached last August,⁴⁸ member nations may impose compulsory licensing of a drug if efforts to obtain the drug “on reasonable commercial terms and conditions” have been unsuccessful or “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”⁴⁹ On their face, those terms allow great latitude, of course. Quite apart from the mean-

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The problem, at bottom, is with the TRIPS Agreement itself, which tries to solve a poverty problem by turning private drug companies into public charities.

ing of “national emergency” and “extreme urgency,” the language would appear, more broadly, to allow for compulsory licensing even when the country is unable to negotiate a price “on reasonable commercial terms”—or if its intent is “public non-commercial use,” which might mean for its socialized medical program. To be sure, the patent owner must be paid “adequate remuneration.”⁵⁰ And the drug must be produced “predominantly for the supply of the domestic market,” a limit on export that gave rise to the August agreement.⁵¹ As a protection for patents, however, the “balance” is precarious. And “least-developed” countries may practice compulsory licensing until the year 2016.⁵²

To put all of this in perspective, one more issue needs attention. After the 2001 Doha Declaration, there remained an “access” problem, for although the compulsory licensing provisions helped less-developed countries, they were of no value to even poorer countries that had little or no capacity themselves to manufacture drugs; and the “no-export” provision just noted prohibited the former countries from exporting generics produced under compulsory licensing to the latter. Last August’s agreement eased the no-export restriction, therefore, allowing generics to be exported, but only to such very poor countries.⁵³ Taken as a whole, however, the focus and tenor of the agreement suggest that the “balance” these documents mean to strike is mainly, if not entirely, for the benefit of the world’s poorer countries. As a September WTO “Fact Sheet” puts it, these provisions “aim to ensure the beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets.”⁵⁴

The no-export provision is thus key to understanding the TRIPS Agreement as it now stands. In fact, to allay fears that compulsory licensing might lead to widespread exports of drugs manufactured under such conditions,

23 developed countries are listed in the

decision as announcing voluntarily that they will not use the system to import. . . . Another 10 countries about to join the EU said they would only use the system to import in national emergencies or other circumstances of extreme urgency, and would not import once they had joined the EU. . . . And 11 more said they would only do so in national emergencies or other circumstances of extreme urgency.⁵⁵

That still leaves countries free to impose compulsory licensing, of course, provided the conditions for doing so are met. But it suggests that national emergencies or helping the poorest countries are the main purposes for compulsory licensing; the practice is not meant to be a bargaining chip in price negotiations, even though cases in which developing countries so used it can be found.

Still, this issue in all of its reaches needs to be monitored closely, especially if the U.S. ban on reimportation is lifted. If developed countries that negotiate low prices do not or cannot restrict exports, and drug companies are thus “forced” to renegotiate those prices, the compulsory licensing provisions of the TRIPS Agreement could be abused even by such countries.⁵⁶ At that point, the U.S. government would need to think about reimposing the reimportation ban, for we would be reimporting what are, essentially, stolen goods. We would no longer have a regime of free trade—trade unencumbered by anything but rules about property and contract, reflecting the preconditions of trade. Instead, we would have a regime that strikes at those very preconditions.

The problem at bottom, however, is with the TRIPS Agreement itself, which tries to solve a poverty problem by turning private drug companies into public charities. As noted above, rather than stealing the patent, which is what compulsory licensing amounts to, it would be far cleaner if private and public charitable institutions in the developed world left private enterprise alone and simply pooled their resources to buy drugs on the

market for the world's poorest nations. Under such an arrangement, free from the threat of patent seizures, companies would doubtless offer deep discounts, if only for the good-will value. By contrast, the present arrangement, with its compulsory licensing, not only distorts the drug market, shifting the costs of international charity back to American drug consumers, but provides ample opportunity for developing countries, neither rich nor poor, to game the system. And compulsory licensing raises safety concerns as well. It is far better for charitable organizations to buy discounted drugs from an original, reputable manufacturer than to try to save a few dollars by buying them from a manufacturer who stole the patent through compulsory licensing. Those are precisely the drugs that give rise primarily to safety concerns.

Summary

In summary, then, the American reimportation ban should be lifted as part of a larger effort to better discipline drug prices by expanding the scope for market principles to operate. Americans pay the bulk of the huge drug R&D costs because the ban shields drug companies from having to charge market prices abroad; to that extent, therefore, Americans subsidize those socialized medical systems as well. With the ban removed, drug companies will still be free to segment markets and price differentially; but they will have to police those arrangements through no-resale contracts, withholding supplies, or export controls enforced by the countries that benefit from discounted drugs. Failing that, companies will have to adjust prices, raising them abroad and/or lowering them here sufficiently to discourage the reimportation that would otherwise undercut the profits that support future drug R&D. And in the international treaty arena, the U.S. government should continue to press for the expansion of free trade principles and further restrictions on compulsory licensing, moving ideally to the complete separation of commercial and charitable undertakings.

Reimportation Bills Currently in Congress

In General

Current law respecting drug reimportation is a maze of regulations too complex to summarize here. Lifting the ban should be a relatively simple matter, but the bills now in Congress aimed at doing so are anything but simple, largely because they build on and preserve most of that law, often in ways that are unclear or inconsistent with free market principles. Thus, they seek to establish a regime that at once allows American firms and citizens to import deeply discounted drugs while at the same time assuring the American public that the drugs are safe, ends that often conflict. Labeling and dosage regulations could limit supply, for example, as could regulations requiring imported drugs to be made only in FDA-approved facilities. And supply limits like those lead often to higher prices. Thus, just as safety regulations raise the cost of domestic drugs, so too could regulations aimed at ensuring the safety of reimported drugs.

More generally, however, we need to ask what the aim of these bills is. Is it to encourage reimportation—or simply the presumed effects of reimportation? If the former, does that make sense—manufacturing a drug in America, only to send it abroad and then bring it back? Isn't that a roundabout way to reduce drug prices—using foreign price controls, in effect, as price-reducing filters? If that's what reimportation amounts to, why not just impose price controls ourselves and be done with the export/import business? The reason we don't is because enough members of Congress realize the folly in that, thankfully. The reason *drug companies* don't reduce prices from the start, however, is because they don't *have to*—thanks to the reimportation ban. If the aim, then, is not so much to encourage reimportation but to lower domestic prices, why not just lift the reimportation ban? Prices should then adjust naturally. Doubtless they will rise abroad—lifting the ban will “force”

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companies to demand market prices there—and/or fall at home—all from the mere *threat* of reimportation (and assuming the failure of other measures aimed at enforcing price discrimination, as discussed above). Companies will not sell drugs cheaply abroad and dearly at home as long as they know that people can easily get on the Internet or on a bus and buy them abroad. And with prices thus adjusted, that will resolve the safety issue, for there will be, in fact, little or no reimportation.

Still, the safety issue cannot be ignored because the threat to buy abroad must be credible; if consumers are concerned about the safety of reimported drugs, that is, their threat will be compromised, which is why drug companies repeatedly raise the issue. For that reason, therefore, legislation will have to choose between letting the consumer bear the risk, limiting protection to after-the-fact recovery through litigation, or providing before-the-fact safety regulations, with all their potential costs. If FDA safety regulation is the choice, as is likely, then given the larger aim of facilitating reimportation—at least in principle if not in fact—that regulation should be tied directly to safety. It should not serve as a vehicle to frustrate reimportation.

But at the same time, if market principles are to rule, neither should regulations restrict companies from trying to maximize profits by segmenting markets and pricing differentially. Thus, companies should be free to produce and package drugs variously, to employ no-resale devices, and to resort to such self-help measures as raising prices or limiting supplies to foreign purchasers who might otherwise breach no-resale contracts or ignore label licenses. Indeed, the last thing we want is to move from a regime in which trade is restricted to one in which it is forced through measures compelling trade. Safety regulations could restrict trade unnecessarily. Other regulations could force trade. It is the latter that will mainly concern us here.

In the House

Last July, by a surprising vote of 243 to 186, the U.S. House of Representatives

passed a bill aimed at lifting the drug reimportation ban. Spearheaded by Rep. Gil Gutknecht (R-MN), H.R. 2427, the Pharmaceutical Market Access Act of 2003, would amend Section 804 of the Federal Food, Drug, and Cosmetic Act to permit pharmacists, wholesalers, and “qualifying individuals,” meaning ordinary citizens, to import prescription drugs from 25 developed countries, mostly in Europe. Unlike previous measures, the bill does not require the secretary of Health and Human Services to certify that certain safety and cost-saving requirements have been met—the “poison pill” that currently blocks reimportation. Thus, it opens the door to reimportation. And it would add a new section 505B to the FFDCA to require drug companies to incorporate various tamper-resistant technologies in all prescription drug packaging.

H.R. 2427 has the virtue of being a relatively simple bill. Nevertheless, it retains a provision from current law that warrants concern. When Congress amended the FFDCA by enacting the Medical Equity and Drug Safety Act of 2000 (MEDS Act)—which allowed drugs to be reimported, but only after HHS certification—it added a subsection to section 804 that prohibited manufacturers from contracting to prevent the sale or distribution of imported products.⁵⁷ That provision, aimed at frustrating company efforts to in turn frustrate drug reimportation, is inconsistent with market principles, of course; companies should be free to sell their products on whatever terms they wish—in this case, terms that seek to preserve market segmentation and price discrimination. Shortly after H.R. 2427 passed in the House, however, Congress enacted and the president signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which repealed the MEDS Act’s prohibition on contractual restrictions on drug imports.⁵⁸ Thus, companies are now free to try to frustrate drug reimportation through contractual devices. That freedom should be preserved by any drug reimportation legislation Congress enacts in the future.

In the Senate

S. 2328. Two bills now in the Senate are given some chance of passing. On April 21, Sens. Byron Dorgan (D-SD) and Olympia Snowe (R-ME), along with eight others, introduced S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004. On June 15, the powerful AARP gave its support for the bill.⁵⁹ S. 2328 is anything but simple. In part, upon enactment it would allow individuals, for their own and their family's personal use, to import a 90-day supply of FDA-approved drugs from Canada. Individuals traveling outside the country would be allowed to bring back for their personal use a 90-day supply from Canada, Australia, current EU countries, Japan, New Zealand, or Switzerland, or a 14-day supply from another foreign country. Within 90 days of enactment, pharmacists and wholesalers would be allowed to import drugs from Canada and, beginning one year from enactment, from the aforementioned countries. Much in the bill concerns safety—licensing, chain-of-custody tracking, labeling and relabeling, and the like.

Although Sen. Dorgan's website claims that S. 2328 "is the Senate companion to H.R. 2427,"⁶⁰ two differences stand out, the second starkly.⁶¹ First, S. 2328 addresses a patent-law matter that might otherwise block reimportation. The bill protects pharmacies, wholesalers, and individuals from suits for patent infringement as follows:

It shall not be an infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.⁶²

That provision is noteworthy. Here, in brief, is why.

Upon issue, a U.S. patent protects the right of the owner to exclude others from making, using, selling, offering to sell, or importing into the United States the patented inven-

tion.⁶³ In general, however, once the product is sold, absent any agreement between seller and buyer to the contrary, the buyer may resell the product. This "first-sale rule" or "exhaustion doctrine" is said to exhaust any resell right the patentee might claim, for with the first sale, presumably, he has been fairly compensated for his product.

Patent law is country specific, however: thus, an inventor must apply for a patent in every country in which he wants his patent protected, and national patents must be enforced country by country. That has led to a degree of uncertainty in patent law, even in the United States, especially after a 2001 decision by the U.S. Court of Appeals for the Federal Circuit, *Jazz Photo Corp. v. United States International Trade Commission*.⁶⁴ There the court held that a sale exhausts a U.S. patentee's sale rights only if it takes place in the United States; if it takes place in a foreign jurisdiction, the patentee's right is not exhausted. Thus, the court applied the "territorial exhaustion" doctrine, not the "international exhaustion" doctrine whereby a sale *anywhere* exhausts the patentee's right. Even though the patentee had sold the product abroad, and had been paid for it, he retained his right to prevent the new owner from reselling it in the United States.

The *Jazz Photo* decision has been criticized,⁶⁵ and rightly so. Indeed, with any ordinary nonpatent sale, the act of selling, absent an agreement to the contrary, would alienate the seller's control over subsequent sales regardless of where the first sale took place. Yet here, under the territorial exhaustion rule, that same act does or does not alienate the seller's right based simply on where the sale is made, even though the same substantive law may be in place in both jurisdictions. A matter that should be addressed through *contract* law—controlling resale of a product—is addressed instead through *property* law, the law of patents. The issue here, after all, is not the theft of an invention—the proper business of patent law—but the reselling of a product for which the inventor/owner has already been paid. Properly, that payment

S. 2328 would keep companies from preventing reimportation through what is, in fact, an overextension of patent law principles.

In the patent area, the Dorgan-Snowe bill moves in the right direction. Unfortunately, that cannot be said of the part designed to prevent drug companies from “gaming the system.”

should sever his control over subsequent sales.

Nevertheless, *Jazz Photo* is the controlling American law today, and its implications for drug reimportation are clear. A company can sell a drug abroad, yet retain the right to prevent the buyer from reselling the drug here—not as a matter of contract but of patent law. It is to address that problem, therefore, that S. 2328 would enact, in effect, the international exhaustion doctrine for pharmaceuticals. Such a provision would keep companies from preventing reimportation through what is, in fact, an overextension of patent law principles.

This matter has been further clouded, however, by the United States–Australia Free Trade Agreement that Congress just ratified on July 15, which contains a provision that appears to establish the territorial exhaustion rule between the parties. Article 17.9.4 of the treaty reads:

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product . . . without the consent of the owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.⁶⁶

The main part of that provision seems to say that patentees can prevent reimportation of drugs sold abroad—that is, can block application of the international exhaustion rule. At the same time, the force of the “at least” proviso, recognizing a patentee’s restriction of reimportation through contract, is unclear since the territorial exhaustion rule alone would allow a patentee to prevent reimportation. Perhaps the “at least” proviso should be read as a *necessary* condition—that is, as *requiring* a patentee to contract for the right to prevent reimportation in order to preserve it. If that is the purport of “at least,” it corrects for the mistaken, court-imposed territorial exhaustion rule (although it doesn’t explain the language

preceding it). Alternatively, perhaps the proviso anticipates that a court might revisit and reverse the *Jazz Photo* decision and incorporate the international exhaustion rule in American law. If that were to happen, companies would need to resort to contractual mechanisms to try to forestall reimportation. That would be the right way to do it in any event, rather than through patent law.

In the patent area, then, the Dorgan-Snowe bill moves in the right direction. Unfortunately, that cannot be said of the second area of the bill that should concern us—the part designed to prevent drug companies from “gaming the system,” as Sen. Snowe’s press materials put it.⁶⁷ Companies would be prevented “from taking actions that would have the effect of thwarting drug importation,” those materials say; anyone who takes such actions would be in violation of the Clayton Act, risking treble economic damages.

Under its section 27, “Restraint of Trade,” S. 2328 would prohibit companies from directly or indirectly charging higher prices to foreign exporters or domestic importers than to those who do not export or import; denying or restricting supplies of drugs to foreign exporters or domestic importers; publicly, privately, or otherwise refusing to do business with registered exporters or importers; changing the color, dosage form, or place of manufacture of drugs so they are no longer FDA approved; or engaging in any other action that the Federal Trade Commission determines would unfairly restrict competition. In other words, companies would be prohibited from taking any of the actions they might otherwise legitimately take to try to maximize profits by segmenting markets and pricing differentially—entering no-resale contracts, incorporating label licenses, limiting supplies, or raising prices.

Thus, in addition to removing the reimportation ban—the illegitimate means of enforcing market segmentation—the Dorgan-Snowe bill would deprive companies of legitimate means of doing business. Its aim, clearly, is to force something close to equal international pricing. That may (or may not) be a

desirable result, but in a free society it has to come about by legitimate means, not by prohibiting companies from doing what they would otherwise have a perfect right to do.⁶⁸

Indeed, the sponsors of this bill have issued statements that indicate that they really do want to force prices toward equality—but equality at levels set by socialized medical systems abroad. Sen. Dorgan writes, for example, “The Pharmaceutical Market Access Act would create a competitive marketplace so that Americans can purchase FDA-approved drugs at the much lower prices available in other countries.”⁶⁹ Sen. Edward Kennedy, a bill sponsor, echoes that view: “Bipartisan legislation introduced by Senators Dorgan, Snowe, McCain, Daschle, myself, and others will, at long last, give American patients a fair deal. . . . It will enable U.S. consumers to buy FDA-approved drugs at the same fair prices as they are sold abroad.”⁷⁰ Taking a swipe at drug companies in the process, Sen. McCain defends securing that result with the measures just noted: “Putting profits before patients, [drug companies] have limited the supply of pharmaceuticals to Canadian pharmacies and wholesalers who export to the United States. . . . [O]ur bill seeks to close potential loopholes that would allow companies to game the system and unfairly discriminate against pharmacists or wholesalers.”⁷¹ And in a frequently-asked-questions sheet that Sen. Snowe’s office issued when S. 2328 was introduced, the sponsors’ misunderstanding of market principles is clearly indicated: “[This bill] merely extends the benefits of free trade to buyers of prescription drugs. . . . Drug manufacturers today are subverting the free market by charging higher prices to Americans for drugs than they charge to patients in other countries. . . .”⁷² If market practices don’t “force” uniform prices, these senators apparently will. But under current conditions, those will not be market prices. Instead, they will be prices set by foreign diktat.

S. 2493. On June 2, Sen. Judd Gregg (R-NH), chairman of the Health, Education, Labor, and Pensions Committee, introduced a different drug reimportation bill on behalf of himself, Sens. Gordon H. Smith (R-OR),

Susan Collins (R-ME), Norm Coleman (R-MN), Jeff Sessions (R-AL), Trent Lott (R-MS), and Michael B. Enzi (R-WY). Since the HELP Committee has jurisdiction over this issue, the Gregg bill may have the best chance of passing. It is also the bill the administration, were it to get behind any bill, would be most likely to support.⁷³

Dubbed the Safe Importation of Medical Products and Other Rx Therapies Act of 2004, S. 2493 is both more modest and more restrictive than S. 2328. In general, upon enactment, it would allow individuals, with certain restrictions,⁷⁴ to import a 90-day supply of drugs for personal use from Canada or the 15 countries that were members of the European Union as of December 31, 2003. The bill would give the FDA one year from enactment to create a regulatory system for the commercial importation of drugs from Canada and three years to expand the system to those 15 European countries the secretary of HHS had certified as eligible to export. Thus, under the Gregg bill, reimportation would take longer to open up and fewer countries would be included in the plan. Moreover, HHS retains substantial authority to block reimportation.

With regard to safety, both S. 2493 and S. 2328 read more like regulations than statutes; in fact, the provisions are so detailed, especially in the Gregg bill, that one is tempted to say their aim is more to discourage than to allow importation. The licensing, record-keeping, and Internet pharmacy regulations in the Gregg bill, for example, run detailed page after page. Yet S. 2493, unlike S. 2328, does nothing to block the illegitimate patent law rights of drug companies to prevent reimportation of already sold drugs, as discussed above. On the other hand, neither does it impose the illegitimate market restrictions of the Dorgan-Snowe bill. Thus, rather than try to force international prices toward equality, it would allow companies to try to segment markets and price differentially. On balance, therefore, the Gregg bill is probably a better bill from a free market perspective than its bipartisan counterpart, although the patent

The sponsors of S. 2328 have issued statements that indicate that they really do want to force prices toward equality—but equality at levels set by socialized medical systems abroad.

However varied or mistaken the different proposals may be, they all turn on the basic idea that free markets and the competition they encourage, not price controls, are the way to produce more and better drugs at lower prices.

law omission, the temporal and geographic limits, and the extraordinary regulatory overlay need to be addressed before the bill can be said to be consistent with free market principles.

Conclusion

“Drug reimportation” has become the focus for a host of drug problems that have become political problems primarily because drugs are so highly regulated, both here and abroad. The natural solution to such problems is to allow greater scope for market forces. That is the correct intuition, which animates, initially, all of the proposals for lifting the reimportation ban now in place in America. However varied or mistaken the different proposals may be, they all turn on the basic idea that free markets and the competition they encourage, not price controls, are the way to produce more and better drugs at lower prices. Indeed, what is the reimportation ban if not an impediment to free trade and a free market?

This study has brought to the surface several issues that need to be addressed if we are to move toward a free market in drugs. First, as long as risk-averse regulators assume that all Americans are equally risk averse, the long and costly FDA approval process will continue to impose huge up-front costs on drug companies, costs that will have to be recovered if new drugs are to be produced in the future. Rather than continuing with a one-size-fits-all approach to risk, therefore, measures should be developed to allow less risk-averse tastes to be satisfied, thereby potentially reducing those up-front costs.

Second, and closely related, the lifespan of the drug patent that follows upon that long process should equal the average life-span of all other patents. However complex the economics of drug patents, we know intuitively that a shorter patent life discourages investment and raises product prices. At the same time, the central purpose of patents—to encourage and protect intellectual property—

should guide patent law. Congress has the power to enact the international exhaustion rule, which would sever a company’s control of its product (not its invention) after the first sale. It should do so. But Congress and the administration both should also work to better secure patent rights through international treaties. In particular, commercial and charitable undertakings should be sharply separated, for the integrity of both, and drug companies should not be used as charitable institutions.

Third, drug companies should be free to market their products as they wish, with the aim of maximizing profits for the benefit of shareholders, retirees, and all who would benefit from greater investment in drug R&D. That means companies should be free to exploit different levels of demand, to segment markets and price differentially, and to try to secure those arrangements with contractual mechanisms, supply controls, and pricing decisions. At the same time, buyers should be free to accept offers from willing sellers. Thus, the American reimportation ban, which restricts buyers, should be lifted.

If the ban were lifted, no one knows exactly how things would evolve. Clearly, drug companies would continue to have an interest in seeing to the integrity of their products. As for marketing, companies would need to employ no-resale contractual devices if they wanted to secure market segmentation schemes. But if they were unable to enforce those widely enough, or if such devices were made illegal, as in the Dorgan-Snowe bill, we need only look to Europe to see the result. Because no-resale devices are illegal there, a “gray market” has emerged in which drugs are moving increasingly from low-price to higher-price markets, increasingly undercutting profit margins. The situation there can be sustained at present only because the lucrative American market enables drug companies to endure it.

Were the American market to be threatened by a similar “race to the bottom,” companies would be forced to rethink their pricing strategies. They would have no choice but

to abandon their market segmentation schemes and adjust prices internationally, moving them toward equality, even though the net profits that resulted would be sub-optimal and there would be less money for R&D. That result is what the Dorgan-Snowe bill would try to force. That is a mistake. No-resale devices, pressed by companies with an incentive to see them enforced, and enforced by countries with an incentive to enforce them, should be given a chance. If the EU will not allow them, or individual countries will not enforce them, then let prices rise to equality in Europe, with the threat by companies to withhold product if price demands are not met. Still, companies should be free to try to segment markets, even if the history of such efforts is not entirely promising. In an increasingly transparent world, free from political restraints, prices tend to move toward equality. If that is the natural course of things, we should not try to force that result but simply allow it to happen. The first step toward that end is to lift the American reimportation ban.

Notes

1. See, for example, Donald L. Barlett and James B. Steele, "Why We Pay So Much For Drugs: How the Clamor for Cheap Canadian Imports Is Heating Up the 2004 Campaign and Giving Washington a Headache," *Time*, February 2, 2004, p. 44.
2. It is difficult to generalize about cross-country price comparisons, but in 2002, according to Canada's Patented Medicine Prices Review Board, U.S. patented drug prices were 67 percent higher, on average, than those in Canada. PMPRB, *Annual Report* (Ottawa, Ontario: 2002), p. 23.
America constitutes by far the world's largest drug market. According to IMS Health, Inc., during the 12 months concluding with April 2004, drug purchases in North America, measured in dollars, constituted 49 percent of total world purchases, 94 percent of which were American purchases, which means American purchases constituted 46 percent of world purchases. See http://www.imshealth.com/vgn/images/portal/cit_4000_0873/40/42/49941481IMS_Retail_DM_APR04_.pdf.
3. The term "reimportation" is used here to refer to the importation into the U.S. of a drug that was first manufactured in the U.S. and then exported, or to the importation of a drug that was manufactured by a U.S. manufacturer outside of the U.S. for sale abroad. The Medicine Equity and Drug Safety Act of 2000, P.L. 106-387, 114 Stat. 1549, amends section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §381(d)(1), which was passed as part of The Prescription Drug Marketing Act of 1987, by adding a new section 804. As thus amended, current law permits reimportation from 25 named developed countries, but only by the manufacturer or by licensed pharmacists or wholesalers, and only after the secretary of Health and Human Services has certified that certain safety and cost-saving requirements have been satisfied—the "poison pill" that has blocked commercial reimportation. Individuals may not bring drugs into the U.S., but the FDA has had a lenient enforcement policy that allows individuals to bring in a 90-day supply for their personal use. "Coverage of Personal Importations," *Regulatory Procedures Manual*, Office of Regulatory Affairs, FDA, http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.
4. Barlett and Steele; Bernard Simon, "Big Sales of Cut-Rate Drugs From Canada," *New York Times*, October 30, 2003, p. W7.
5. "Firm That Imports Drugs from Canada Closed," *Washington Post*, Nov. 7, 2003, p. A32. Ceci Connolly, "FDA Steps Up Enforcement on Drug Imports," September 30, 2003, p. A2; "FDA Warns CanaRx Services about Its Illegal Internet Website and Mail Operation Obtaining Unapproved and Potentially Risky Drugs from Canada," *FDA News*, September 16, 2003, <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00946.html>.
6. Portland, Maine, is now following Springfield, Massachusetts, and Montgomery, Alabama, in instituting a program to import drugs from Canada for its municipal employee health plans. WSJ.Com/The Daily Scan: "Maine to Import Drugs from Canada," June 28, 2004. States that have begun to pursue the issue include Alabama, California, Illinois, Massachusetts, Minnesota, New Hampshire, Vermont, Washington, and Wisconsin. Steve Lawrence, "Calif. Oks Web Site to Buy Canada Drugs," Associated Press, May 27, 2004; "Highlights from the States," *Congress Daily/A.M.*, February 23, 2004; "Governor Hints He May Bend Drug Laws: Blagojevich May Follow Other States in Importing Cheaper Prescriptions," *Chicago Daily Herald*, April 21, 2004. Montgomery County, Maryland, a Washington, D.C., suburb, is also studying the issue. Matthew Mosk, "Montgomery to Study Buying Canadian Drugs," *Washington Post*, November 5, 2003, p. B1.
7. Geoff Earle, "It's Do or Die for Drug Bill: Senators

Claim 60 Votes for Legislation Allowing Reimportation from Canada,” *The Hill*, June 1, 2004, p. 1; “U.S. Congress Support Grows for Canadian Prescription Drugs,” Dow Jones Newswire, April 21, 2004.

8. H.R. 2427, the “Pharmaceutical Market Access Act of 2003,” passed on July 24, 2003. On May 21, 2004, 228 members of the House sent a letter to Senate Majority Leader Bill Frist, urging the Senate “to move quickly on pending Rx drug importation legislation.”

9. S. 2307, the “Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004,” sponsored by Sen. Charles Grassley (R-IA), introduced April 8, 2004; S. 2328, the “Pharmaceutical Access and Drug Safety Act of 2004,” sponsored by Sens. Byron Dorgan (D-ND), Olympia Snowe (R-ME), Edward M. Kennedy (D-MA), John McCain (R-AZ), Thomas Daschle (D-SD), Trent Lott (R-MS), Debbie Stabenow (D-MI), Tim Johnson (D-SD), Mark Pryor (D-AK), and Russ Feingold (D-WI), introduced April 21, 2004; S. 2493, the “Safe Importation of Medical Products and Other Rx Therapies Act of 2004,” sponsored by Sen. Judd Gregg (R-NH), Gordon H. Smith (R-OR), Susan Collins (R-ME), Norm Coleman (R-MN), Jeff Sessions (R-AL), Trent Lott (R-MS), and Michael B. Enzi (R-WY), introduced June 2, 2004.

10. Vicki Kemper, “Passage of Drug Import Bill Seen as Inevitable: The Health Secretary’s Observations Do Not Reflect a Policy Change, an Official Says,” *Los Angeles Times*, May 5, 2004, p. A1.

11. The private sector is speaking out also: “The nation’s two largest chain drug stores, CVS and Walgreens, launched a challenge to the nation’s drug manufacturers yesterday by calling on the Bush administration to develop a legal, safe channel for Americans to buy imported drugs.” Christopher Rowland, “2 Chains Urge OK for Drug Imports: CVS, Walgreens Add to Growing Support,” *Boston Globe*, May 6, 2004, p. E1.

12. The Senate bills, noted above, are clear examples of this: they are written in great detail, as though their passage would lead to a regime of regular reimportations rather than to international price adjustments by drug companies to ward off reimportation—the more likely scenario.

13. There is no shortage of congressional demagoguery against drug companies from both sides of the aisle: for example, Sen. Dan Burton (R-IN): “He accuses the FDA of acting ‘in lockstep with the pharmaceutical industry’ to protect prices and profits. ‘They are allowing the theft, this robbery, to go on,’ he charges.” William M. Welsh, “Once Just a

Trickle, Canada’s Rx Drugs Pouring Into USA: Seniors Seek Bargains; FDA Cracks Down,” *USA Today*, October 7, 2003, p. A1; Sen. Byron Dorgan (D-ND): “The American consumer is being cheated and the FDA is driving the getaway car.” PBS Newshour, March 12, 2004, http://www.pbs.org/newshour/bb/health/jan-june04/drug_03-12.html; Rep. Rosa DeLauro (D-CT): “It is time that this Congress stop acting as a wholly owned subsidiary of the pharmaceutical companies and step up to its responsibility to the consumers of this nation.” Sheryl Gay Stolberg, “House Passes Drug Bill: Battle Is Likely in Senate,” *New York Times*, July 26, 2003, p. A11.

14. Safety has been an FDA concern from the outset. Efficacy, a much more problematic and costly issue, became a concern in 1962 with the Kefauver-Harris Drug Amendments of the Food, Drug, and Cosmetic Act. See, for example, Sam Peltzman, “An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments,” *Journal of Political Economy*, vol. 81, no. 5 (1973), pp. 1049–1091. Peltzman’s study suggests that the new regulations imposed by the 1962 amendments resulted in a decreased number of new drug approvals in the years following the amendments. According to Peltzman’s data, an average of 41.5 new chemical entities and 297.9 other new drugs were introduced between 1951 and 1962, compared with an average of only 16.1 new chemical entities and 94.4 other new drugs introduced between 1963 and 1970.

15. That figure comes from the Pharmaceutical Research and Manufacturers of America, <http://www.phrma.org/issues/researchdev/lead.cfm>.

16. In 1987 the FDA introduced a “compassionate use” policy that allows individuals to seek approval, on a case-by-case basis, to use “experimental” drugs. The regulations for gaining approval, however, are complex and burdensome. See http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr312_03.html and <http://www.fda.gov/cdrh/devadvice/ide/print/early.html#emergencyuse>.

17. See, for example, Milton Friedman: “The FDA has done enormous harm to the health of the American public by greatly increasing the costs of pharmaceutical research, thereby reducing the supply of new and effective drugs, and by delaying the approval of such drugs as survive the tortuous FDA process.” Quoted in Durk Pearson and Sandy Shaw, *Freedom of Informed Choice: FDA Versus Nutrient Supplements* (Neptune, N.J.: Common Sense Press, 1993), p. 39. See also Peltzman.

18. “Would Prescription Drug Importation Reduce U.S. Drug Spending?” *CBO Economic and Budget Issue Brief*, April 29, 2004, citing Joseph A. DiMasi, Ronald W. Hansen, and Henry G.

Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003), pp. 151–85.

19. A recent NBER working paper suggests, for example, that because private investment in drug R&D is driven by the market, private investors are more likely to abandon a project if costs are too high or returns are too low. Abandonment is less likely with public funding because each taxpayer bears only a small part of the risk of an unsuccessful project, and there is no price mechanism to direct the decision to abandon. See Eduardo S. Schwartz, "Patents and R&D as Real Options," NBER Working Paper 10114, November 2003.

20. Gary Hull, "Pharmaceutical Patents Deserve the Same Protection as Other Property Rights," *Barron's*, June 2, 2003, p. 46.

21. It appears that the Medicare Prescription Drug and Modernization Act of 2003 provides for patent term extensions in some cases. Under the act, the term of a patent eligible for extension may be extended by the time equal to the regulatory review period for the approved product. 35 U.S.C. §156 (2004).

Economists are often heard to say that "sunk costs" are irrelevant to pricing decisions. But they are not irrelevant to investment decisions. The higher such costs, the further out the start of the period of recovery, and the shorter that period, the riskier the investment, other things being equal. That is part of what drug companies mean, after all, when they explain high drug prices by pointing to high up-front costs. And the main rationale for patent protection is to enable companies to price at a level that will enable them to recover those costs—costs that a generic competitor would not have incurred and hence would not need to recover. Increasing the effective length of the patent could reduce a drug's price per unit by forestalling cheaper generic competitors, even though new patented competitors will come on stream over time.

22. Robert Schuettinger and Eamonn Butler, *Forty Centuries of Wage and Price Controls: How Not to Fight Inflation* (Thornwood, New York: Caroline House Publishers, Inc., 1979) See also, James K. Glassman, "Price Controls and the Economics of Medical Innovation: Part One," *USA Next*, vol. 1, no. 2, p. 5: "Because of price controls on drugs and the inevitable rationing that accompanies such controls, Germans spend more time in the hospital than Americans and lose more working days through sickness." Citing Jim Gilbert and Paul Rosenberg, "The High Cost of Europe's 'Free Ride' in Pharmaceuticals," paper presented at the 2004 annual meeting of the Governors of the World Economic Forum for Healthcare, Davos,

Switzerland, January 22, 2004, <http://www.bain.com>.

23. Patricia M. Danzon, "Making Sense of Drug Prices," *Regulation* 23, no. 1 (Spring 2000): 57.

24. AARP press release for David J. Gross, Stephen W. Schondelmeyer, and Susan O. Raetzman, "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 Through 2003," May 25, 2004, <http://www.aarp.org/Articles/a2004-05-25-drugs.html>. On June 30, 2004, PhRMA issued a press release challenging the AARP report, <http://www.phrma.org/mediaroom/press/releases/30.06.2004.1037.cfm>.

25. Thus, an aide to Rep. Gil Gutknecht (R-MN), who has led the reimportation effort in the House, last year compared the costs of several common patented drugs if purchased in Germany or in Minnesota. The prices for Coumadin, for example, were \$28.44 in Germany, \$92.66 in Minnesota; for Glucophage, \$15.50 and \$45.21, respectively; for Tamoxifen, \$56.34 and \$102.19. Those are the types of comparisons ordinary citizens are likely to make. See <http://www.gil.house.gov/IssueItems/PDrugs/Comparison2004.pdf>. See also note 2 above.

26. Danzon.

27. "I have held four hearings in my capacity as Chairman of the House Government Reform Subcommittee on Human Rights and Wellness regarding the safety and efficacy of imported pharmaceuticals. Despite clinging to claims of the dangers of counterfeit and misbranded drugs, the pharmaceutical industry as well as the FDA have been unable to cite a single incident of adverse health reactions caused by Canadian imported FDA-approved prescription drugs." Rep. Dan Burton (R-IN), quoted in "October 28, 2003—Boston Forum Delivers Resounding Message: Affordable Rx Drugs for All Americans," Committee on Government Reform, <http://reform.house.gov/WHR/Hearings/EventSingle.aspx?EventID=587>.

28. "Parallel trade" arises when goods intended by a manufacturer for sale in one market, usually at a lower price, are resold by other than the manufacturer in another market, usually at a higher price.

29. See, for example, Doug Bandow, "The Free Market Mirage of Reimportation," Institute for Policy Innovation Policy Report 180, May 2004, <http://ipi.org>; Sally C. Pipes, "Cheap Drugs from Canada are a Harmful Illusion," *San Francisco Chronicle*, January 22, 2004, p. A19; James K. Glassman, "Importing Socialism," *Tech Central*

Station, July 23, 2003, http://www.techcentralstation.com/0723_03B.html; James K. Glassman and John R. Lott Jr., "The Drug World's Easy Riders," AEI News & Commentary, July 23, 2003, http://www.aei.org/news/newsID.18078,filter./news_detail.asp; John E. Calfee, "The High Price of Cheap Drugs," *The Weekly Standard* 08, no. 43 (July 21, 2003).

30. "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 of 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." Mark McClellan, then FDA commissioner, "Remarks before the First International Colloquium on Generic Medicine," Cancun, Mexico, Sept. 25, 2003, <http://www.fda.gov/oc/speeches/2003/genericdrug0925.html>. See also Bandow, p. 17; "Pharmaceutical Price Controls Abroad: An Unfair Trade Policy," Republican Policy Committee, Nov. 6, 2003.

31. "If Canada and Europe paid market prices for drugs, even more pharmaceuticals would be available to fight disease and save lives around the world. But that's a fantasy; they won't. The best the world can hope for is a continuation of the current process—which is another example of how Americans, often maligned by others for their selfishness, are, in fact, carrying heavy burdens for the rest of the world." Glassman and Lott.

32. Bandow, p. 10.

33. See, for example, Milton Friedman, "Milton Friedman and the Reimportation Debate," *Tech Central Station*, February 2, 2004, <http://www.techcentralstation.com/020204D.html>; Richard A. Epstein, "A Perversion of Free Trade," *Tech Central Station*, July 24, 2003, <http://www.techcentralstation.com/072403F.html>.

34. Epstein, "A Perversion of Free Trade."

35. See The Prescription Drug Marketing Act of 1987, section 804.

36. "It's a very dynamic new niche . . . and I am proud to back it," said Maryann Mihychuk, Manitoba Minister of Industry, Trade, and Mines. Quoted in Gilbert M. Gaul and Mary Pat Flaherty, "Canada Is a Discount Pharmacy for Americans," *Washington Post*, October 23, 2003, p. A17.

37. Epstein, "A Perversion of Free Trade." See also Richard A. Epstein, "Once More into the Breach," *Tech Central Station*, August 18, 2003, <http://www.techcentralstation.com/081803A.html>,

responding to Edward H. Crane and Roger Pilon, "Conservative Drug Split," *National Review Online*, July 29, 2003, <http://www.nationalreview.com/comment/comment-crane-pilon072903.asp>.

38. Responding to this argument, Epstein ("Once More into the Breach") notes that "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." He then gives a few *private* law examples of enforcement actions against third parties and the reasons that purport to justify them, all of which point to the consequences of not doing so. Here, however, we have a *public* law remedy for a *private* law problem—enforcement of a private contract, if there is one—and hence a kind of passive subsidy for the drug companies. Moreover, if consequences are our concern, the major consequence of this arrangement today is the political firestorm the free riding has generated and the view, increasingly, that it is politically unsustainable.

39. European Union law prohibits all agreements that may affect trade between member states and have as their object or effect the prevention, restriction, or distortion of competition within the common market. EC Treaty, article 81, http://europa.eu.int/comm/competition/legislation/treaties/ec/art81_en.html. Such agreements may be inferred from the parties' conduct. For example, the European Court of Justice found a prohibited agreement in *Sandoz Prodotti Farmaceutici v. Commission*, in which Sandoz, a pharmaceutical company, inserted into customers' invoices the express words "export prohibited," and the customers continued to purchase from Sandoz without complaint. Case C-277/87, *Sandoz Prodotti Farmaceutici v. Commission*, discussed in joined cases C-2/01 P and C-3/01 P, *Bayer v. Commission*, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=62001J0002. The ECJ held that the customers' conduct constituted tacit acquiescence to an export ban. However, in *Bayer v. Commission*, the ECJ did not find a prohibited agreement between Bayer UK and its wholesalers. Joined cases C-2/01 P and C-3/01 P, *Bayer v. Commission*, http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=62001J0002. In that case, Bayer UK refused to fill all of the increasingly large orders from its French and Spanish wholesalers because the wholesalers were exporting drugs to the United Kingdom, allowing consumers to purchase the drugs much more cheaply than if they purchased from Bayer UK, thereby severely undercutting Bayer UK's sales.

40. See the statement by the European Federation

of Pharmaceutical Industries and Associations, <http://www.efpia.org/2%5Findust/paralleltrade.pdf>. Compare that with the statement by the European Association of Euro-Pharmaceutical Companies, <http://www.eaepc.org>.

41. A number of the world's largest pharmaceutical companies have threatened to withhold or have withheld product from foreign wholesalers and retailers suspected of reselling to Americans. Among those are Eli Lilly, Pfizer, GlaxoSmithKline, Wyeth, and AstraZeneca. See HDMA News Media Factsheet, April 15, 2004, http://www.healthcaredistribution.org/resources/pdf_news/Drug%20Importation.pdf; Mark Jewell, "Lilly Ups Campaign to Curb Drug Imports," Associated Press, March 31, 2004; Christopher Rowland, "Pfizer Targets Canadian Pipeline: Cuts Supply of Drugs to Wholesalers It Links to US Mail-Order Deals," *Boston Globe*, February 28, 2004, p. D1.

42. Bandow; Pipes; Glassman, "Importing Socialism;" Glassman and Lott; Calfee; McClellan; and "Pharmaceutical Price Controls Abroad."

43. *Ibid.*

44. *Ibid.*

45. See, for example, Gardiner Harris, "Pfizer Reports China Has Lifted Its Viagra Patent," *New York Times*, July 8, 2004, p. C1.

46. For an overview of the TRIPS Agreement, July 11, 2000, see "Pharmaceutical patents and the TRIPS Agreement," http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm.

47. Fact Sheet: "TRIPS and Pharmaceutical Patents: Obligations and Exceptions," September 2003, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

48. *Ibid.*; WTO News: "Decision Removes Final Patent Obstacle to Cheap Drug Imports," August 30, 2003, http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

49. "TRIPS and Pharmaceutical Patents," article 31(b).

50. *Ibid.*, article 31(h).

51. *Ibid.*, article 31(f).

52. WTO Press Release, "Council approves LDC decision with additional waiver," June 28, 2002, http://www.wto.org/english/news_e/pres02_e/pr301_e.htm.

53. The August agreement waives countries' obligations under Article 31(f) to use the compulsory

licensing system predominantly for the domestic market. See "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," August 30, 2003, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

54. "TRIPS and Pharmaceutical Patents: Obligations and Exceptions."

55. *Ibid.*, listing the 44 countries that have so agreed.

56. In a December 11, 2003, meeting with U.S. Trade Representative Robert Zoellick, then FDA commissioner Mark McClellan, and officials from the leading pharmaceutical companies, Speaker of the House J. Dennis Hastert charged, "[i]t is wrong that our friends in Canada use threats to steal the patents of American drug companies in order to negotiate lower prices." "Hastert Meets With U.S. Trade Representative and FDA Commission on High Drug Prices; Pushes for Fairer Pricing for Canada and the United States," <http://www.speaker.gov/library/health/031211medicare.shtml>. Canadian ambassador to the U.S. Michael Kergin promptly responded with a December 16 letter to Speaker Hastert: "Contrary to the allegations made in the press release, Canada does not 'use threats to steal the patents of American drug companies in order to negotiate lower prices.' Canada eliminated compulsory licensing in 1987. Drug companies that do not want to sell their pharmaceuticals in Canada are certainly free not to." "Ambassador Kergin's Letter to House Speaker Dennis Hastert, 16 December 2003," <http://www.canadianembassy.org/ambassador/031216-en.asp?format=print>.

57. Pub. L. 106-387, § 1(a) (title VII, § 745(c)(2)), 114 Stat. 1549, 1549A-36 (October 28, 2000).

58. Pub. L. 108-173, § 1121(a), 117 Stat. 2464 (December 8, 2003).

59. See Geoff Earle, "AARP backed drug bill to appease Dems, says GOP," *The Hill*, June 17, 2004, p. 1.

60. Available at <http://dorgan.senate.gov/legislation/rxdrugs.cfm>.

61. A third important difference, not directly related to securing market principles and so not discussed above, concerns S. 2328's staggered implementation scheme. Since the Canadian drug market is so small, it would be at least a year after enactment before supply sufficient to satisfy the American market could be on stream.

62. S. 2328, 108th Cong., § 4(f) (2004), amending 35 U.S.C. § 271 by adding a new subsection (h), as stated in the text above.

63. 35 U.S.C § 271(a) (2000). See generally, John R. Thomas, "Patents and Drug Importation," CRS Report RL32400, May 25, 2004.
64. 264 F.3d 1094 (Fed. Cir. 2001).
65. See, for example, Daniel Erlikhman, "Jazz Photo and the Doctrine of Patent Exhaustion: Implications to TRIPS and International Harmonization of Patent Protection," *Hastings Communications and Entertainment Law Journal* 25 (2003): 307.
66. Available at <http://www.ustr.gov/new/fta/Australia/final/ausfta%20text%20june11%20rect.pdf>. Similar provisions were included in the United States–Singapore Free Trade Agreement, entered into force January 2, 2004, <http://www.ustr.gov/new/fta/Singapore/final.htm>, art. 16.7.2, and the United States–Morocco Free Trade Agreement, passed by the Senate on July 21, 2004, and by the House on July 22, 2004, <http://www.ustr.gov/new/fta/Morocco/final/index.htm>, art. 15.9.4.
67. Available in author's file.
68. As an indication that this bill is written to prohibit market segmentation and price discrimination, section 27(c) allows a company to plead as an affirmative defense that its doing any of the proscribed acts was not aimed at frustrating reimportation.
69. Byron Dorgan, "Pharmaceutical Market Access Act," undated, <http://dorgan.senate.gov/legislation/rxdrugs.cfm>.
70. Edward M. Kennedy, "Statement at the Hearing on Re-importation of Prescription Drugs," May 20, 2004, http://kenedy.senate.gov/index_high.html.
71. John McCain, "Pharmaceutical Market Access and Drug Safety Act of 2004," Apr. 21, 2004, http://mccain.senate.gov/index.cfm?fuseaction=Newscenter.ViewPressRelease&Content_id=1259.
72. Available in author's file.
73. See Kate Schuler, "Senate Committee Set to Revive Drug Import Debate," *CQ Today*, July 16, 2004; Kate Schuler, "Senate Bill on Drug Importation Heads to Markup, But Floor Action Uncertain," *CQ Today*, July 12, 2004.
74. Personal imports for family members do not seem to be allowed, for example, and section 812(b)(6)(A) requires the individual to have a prescription valid in a state, cosigned by a prescribing physician in Canada or the permitted country.

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