Statement of

Roger Pilon, Ph.D., J.D
Vice President for Legal Affairs
B. Kenneth Simon Chair in Constitutional Studies
Director, Center for Constitutional Studies
Cato Institute

"Legalizing Prescription Drug Importation"

before the

Special Committee on Aging
United States Senate

January 26, 2005

Mr. Chairman, distinguished members of the committee:

My name is Roger Pilon. I am vice president for legal affairs at the Cato Institute and director of Cato's Center for Constitutional Studies. I want to thank the committee for inviting me to appear today to discuss legalizing prescription drug importation. In this statement I will simply summarize points I made in greater detail in my August 4 *Cato Policy Analysis No. 521*, "Drug Reimportation: The Free Market Solution," a copy of which is attached (available at http://www.cato.org/pubs/pas/pa521.pdf). Attached also is a copy of my October 11 *Wall Street Journal* op-ed, "The Reimportation Blues" (available at http://www.cato.org/cgi-bin/scripts/printtech.cgi/research/articles/pilon-041011.html) and a biographical sketch.

Let me begin by stating clearly that *I am not here to urge Congress to pursue a policy of drug reimportation*, as that idea has come to be called. However attractive such a course might initially seem, reimportation is not the answer to the problem, if it is a problem, of high prescription drug prices in America. Rather, *I am here to argue mainly for lifting the current statutory ban on reimportation*. That will better enable market principles and practices to surface, which alone can sort out the competing claims that arise in the drug reimportation debate. I'll now develop those points a bit more fully and conclude with a few additional points that do need Congress's attention.

The reimportation debate is before us, of course, because in recent years, owing in part to the rise of the Internet, Americans in increasing numbers have discovered that the patented prescription drugs they're using cost considerably less abroad. But they've also learned that American law, except under limited circumstances, prohibits them from buying those lower priced drugs. Thus, they're pressing Congress to lift the ban in the hope of lowering their medical bills. But in the meantime, they and many state and local officials are simply ignoring the ban and purchasing drugs abroad.

Why then do drugs cost so much? And why is there such a disparity between domestic and foreign prices? The answer to the first question points to the regulatory regime we've established in this country to ensure drug safety and efficacy. Rather than rely on common law principles to allocate the risks of unsafe or inefficacious drugs, early in the last century we established the Food and Drug Administration (FDA) and asked it to regulate the invention, manufacture, and distribution of drugs by private profit-making companies. Today, to win FDA approval for a new drug, a company must invest on average between 12 and 15 years and $800 million in research and development (R&D) before the drug reaches the market. 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.

In a moment I'll show how that first-pill/second-pill cost disparity is tied to the international price disparity, but first I want to note that the costly FDA approval process reflects the extremely risk-averse posture that we've taken. That posture is not cost-free, however, for in guarding so heavily against the risk of an unsafe or inefficacious drug, we've discounted the risk incurred by a drug's being unavailable, because not yet approved, or too costly. Suffice it to say that a more flexible FDA approval process, one that allowed for greater individual assumption of risk, would better balance those competing risks.

Given those extraordinary up-front costs, however, companies must charge prices sufficient not only to recover their investment but also to ensure future investment in drug R&D, or they'll not be long in business. And they've got only a limited time to do that because the 20-year clock on patents starts ticking from the time the company first applies for FDA approval, which means that drug patents run about half as long as other patents. Once the patent ends, others can produce the drug as a generic.

We come then to the second question: Why such a disparity between domestic and foreign drug prices? Some question whether there is a disparity, so let me grant first that for a number of reasons—including, most recently, the falling value of the dollar—international price comparisons are not easy to make. Nevertheless, domestic prices tend generally to be well above those abroad. In 2002, for example, patented drug prices here were 67 percent higher on average than in Canada, according to that country's Patented Medicine Prices Review Board. For the average American, however, what matters is the disparity in the prices of the drugs *he* uses, and that's what's driving the debate. So what explains the disparity?

There are two main reasons. First, when drug companies look at the world they see essentially one free market—America. Here they can set prices at levels that aim at maximizing profits. In the rest of the world, companies tell us, socialized medical systems set prices: "monopsony" buyers make take-it-or-leave-it offers. Because a company's marginal cost for the second pill is so low, as noted earlier, it can accept those offers and still come out ahead. But it can do so only because it has America—half the world market—to fall back on. In effect, the rest of the world rides free—or at least at

well below cost—while American citizens pick up the tab for drug R&D. And that, too, is driving this debate.

Given that scenario, it's no surprise that companies oppose lifting the importation ban. For if we imported drugs at those controlled prices we'd undercut the profits they make in the large American market, thereby rendering them unable to attract the capital they need for future R&D. And that would be bad for everyone, Americans and foreigners alike. In effect, as the companies rightly say, we'd be importing foreign price controls. If that's the case, why not simply impose the price controls ourselves and forego the added costs of reimportation? We don't do that, of course, because in this country, at least, we understand the folly of price controls—even as the rest of the world enjoys them at our leave.

But the scenario the companies describe, which renders them and us hapless victims of foreign price controls, is not the whole story. And so we come to the second, equally important reason for international price disparities—an explanation that puts companies more in the driver's seat. Recognizing different levels of demand in different countries, companies try to maximize profits by segmenting markets and pricing differentially. Selling too high in low demand markets excludes too many potential buyers, while selling too low in high demand markets excludes too many buyers willing to pay more. Market segmentation is a perfectly legitimate marketing strategy, but it invites parallel trading—buyers in low price markets reselling to high price markets, outside the control of the companies. When that happens, the advantages of market segmentation are lost. In fact, that's what drug reimportation would amount to, which is another reason companies oppose it.

Consistent with market principles, companies that segment markets and price differentially have two ways to try to frustrate parallel trading—no-resale contracts and supply limits. A statutory reimportation ban of the kind now in place, however, is inconsistent with market principles because (a), absent no-resale contracts, such a ban interferes with free trade, and (b), with no-resale contracts in place, a ban restricts the wrong party—the American buyer, who is no party to the contract. There are proper and improper ways to enforce market segmentation. We've chosen the improper way.

Actions to enforce no-resale contracts should be brought by the companies against breaching parties. If enforcement actions should fail, however, the proper response is for companies to limit supplies, as they're doing now in the case of Canada. Companies should never have run to Congress, as they did in 1987, seeking a ban on importing drugs; and Congress should never have granted such a request, which amounts to a passive subsidy to the companies. If they want to sell drugs to foreign governments at below "true cost," they need to say to those governments, "We'll sell to you at below cost, but you'll have to police your exports. It's not up to the American government to police imports." That gets the incentives right, putting the enforcement burden where it belongs, on the party receiving the benefit of the bargain. Today, however, not only do Americans pay the bulk of drug R&D costs; they also pay the costs of enforcing the ban that enables the rest of the world to escape those costs.

Thus, if the reimportation ban were lifted, and market principles and practices were to take its place, it would not follow necessarily that domestic drug prices would drop or that the free-rider problem would abate. In a free market, sellers and buyers are free to strike whatever bargains they wish. Americans might thus continue to face high prices if foreigners were unwilling to resell their limited supplies to them. But as price differentials increase, incentives on both sides to breach the market barriers only grow, as we are seeing today, even with a statutory ban in place. Thus, in a world of large differentials, multiple vendors, and ready information, it's not likely that no-resale contracts and supply limits would long stanch the cross-border flow of drugs. Companies in that case would have no choice but to adjust prices, raising them abroad and/or lowering them here sufficiently to discourage parallel trading.

Yet insofar as the reimportation ban is effective in restricting cross-border trade, companies to that extent are disinclined to take such measures—and disinclined, in particular, to do the hard bargaining that would "force" foreign governments to take on a greater share of the true costs of drug R&D. Today, we have no way of knowing whether foreign governments would be able or willing to pay more for drugs because companies, able to fall back on the American free market, have limited incentive to press the issue. The reimportation ban, in short, skews the incentives against American citizens, forcing them in effect and in fact to subsidize socialized medical systems abroad. It is a wholly un-American arrangement that should be ended immediately.

Congress does not need to exercise itself, therefore, with drafting extraordinarily complex measures of the kind we've seen, all to try to ensure that reimported drugs will be safe. *Just lifting the ban will do.* Companies already have more than enough market and legal incentives to ensure that their drugs, domestic or reimported, are safe. More to the point, the mere lifting of the ban should suffice to address the safety issue, by default, because with the ban lifted, companies will resort to no-resale contracts or supply limits or both; and if those should fail they will resort to price adjustments, all of which means that there will be little or no reimportation—which makes no sense to begin with—and *that will render the safety issue moot*. Indeed, it is the mere *threat* of reimportation that will bring equilibrium about. And so, as with so much else in life, this issue turns out to be simpler than at first it seems—once we get the principles right.

Nevertheless, there are related issues that Congress should address, which I discuss more fully in my August 4 study. Let me simply outline a few here.

Most important, in whatever measures Congress enacts, "anti-gaming" provisions of the kind that are found in the Dorgan-Snowe bill (S. 2328) of the last session of Congress must be avoided. Designed generally to prohibit companies from raising prices or limiting supplies abroad, such measures are likely unconstitutional; and if not, they truly would amount to importing foreign price controls. If that's what we want, then apply controls directly, as noted earlier. But of course that would mark the end of the market incentives now in place that have given us the miracle drugs that have so changed modern medicine—and no one wants that.

The Judd Gregg bill (S. 2493) does not contain such provisions. Its problem, rather, is in trying to micromanage reimportation, as if it would happen, by implementing a program for Canada to start a year after enactment, and then waiting two more years before starting reimportation from Europe and a few other developed countries. Were that course to be followed, companies probably could "game" the tiny Canadian market (about five percent of the American market), which is too small in any event to satisfy American demand. With companies limiting supplies, Canadian wholesalers would have incentives to seek supplies from the rest of the world, which would open the door to substandard drugs produced under compulsory licensing in third-world countries (see below). For those and other reasons, the two-year "experiment" in limited reimportation would likely fail before the large European market kicked in, and we'd be back to reimposing the reimportation ban. No, the ban should be lifted all at once. Then let the market sort the issues out.

On another matter, the Dorgan-Snowe bill, to its credit, does seem to address the complex patent law issues that have arisen since the U.S. Court of Appeals for the Federal Circuit handed down its *Jazz Photo* decision in 2001 (*Jazz Photo Corp v. United States International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001)). This is a confused area of the law today, with experts on all sides unsure about what the law is. In a nutshell, when a patent owner sells a product, he is said to have exhausted control over subsequent sales (not over the invention). But patent law is country specific, so we have two rules: the international exhaustion rule says that a sale anywhere exhausts the owner's subsequent control of sales; the territorial exhaustion rule says that a sale abroad exhausts control only in that country, which means that the owner retains the right to control reselling to other countries. The effect of the *Jazz Photo* court's having upheld the territorial rule seems to be that drug companies can invoke *patent* law to block reimportation—*i.e.,* they can use arguably overextended property law to try to accomplish what should be accomplished through contract law. The Dorgan-Snowe bill addresses that issue by enacting, in effect, an international exhaustion rule.

But this issue is further complicated by recent treaties—in particular, the free-trade agreements that were signed and ratified last year with Australia, Singapore, and Morocco, all of which appear to have established the territorial exhaustion rule between the parties. Here too, however, the issue is unclear, the language dense; but it has all the marks of an effort to frustrate reimportation in anticipation of the direct ban's being lifted.

Finally, there is the larger patent issue that is said to arise when drug companies threaten to raise prices in a foreign country and are met with the counter-threat that, if they do, the country will invoke the compulsory licensing provisions of the WTO TRIPS Agreement and will license a local company to reverse engineer the drug, manufacturing it as a generic. Compulsory licensing amounts to stealing the patent, of course, and companies are rightly concerned about such threats, if they exist. Unfortunately, the language of the TRIPS Agreement allowing compulsory licensing is not as tight as it might be. But the 2001 Doha Declaration and the August 2003 follow-up agreement, together with surrounding documents, suggest that compulsory licensing is to be used

only by poor countries under limited conditions, not by developed countries in bargaining over prices. In fact, some 41 countries have agreed not to so use those provisions. Nevertheless, this is an area in which Congress and the executive branch need to be vigilant, because the integrity of the international patent system is essential to the continued health of the American pharmaceutical industry, which in turn is essential to the health of the nation.