



## Drug Importation: A Solution to the Cost of Prescription Drugs?

*An Examination of Free Market Principles in Health Care*

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Nearing the end of the 79<sup>th</sup> Texas Legislature's regular session, the Texas House voted overwhelmingly to give state sanctioned support for importing pharmaceuticals from Canada. As a result, state law now directs the Texas State Board of Pharmacy to inspect and designate no more than 10 Canadian pharmacies from which Texans may purchase low-cost prescription drugs. Other states have instituted a similar practice, despite warnings from the federal government that such a practice violates federal law.

It is not surprising that drug importation has become an issue in many states and cities, as the promise of cheaper drugs from Canada has become an option for many people searching for the lowest price available. But is importing pharmaceuticals from Canada really the best solution?

More directly, should Texas pursue drug importation as the state's answer to high prescription drug costs?

Of course, the debate over drug importation is typically dominated by concerns regarding the safety of imported drugs. While these safety concerns are not without merit, they have shifted the focus away from what should be a question of free market principles and the consequences of allowing Canadian price controls to take hold in American health care. Many Americans, indeed many American lawmakers, are aware that prescription drugs cost less in Canada and other countries, but fail to understand why prices are

lower and consider the consequences of importing Canadian price controls to the United States.

Examining the price differences between prescription drugs purchased in Canada and those purchased in the United States reveals a system of Canadian price controls that limit Canadians' access to prescription drugs and extort the lowest prices from pharmaceutical products by threatening intellectual property. Ultimately, allowing Americans to import lower cost prescription drugs will not prove to be a good solution in and of itself, nor should the state look to importation as a way to bring lower cost drugs to Texas.

### Importation Overview

Safety concerns have long driven the debate over drug importation. In the late 1980s, a string of high profile stories on counterfeit drugs led many to believe the United States' drug supply was unsafe. Perhaps the most notable of the stories was the discovery of 2 million counterfeit birth control pills containing no estrogen, which made their way through Europe and South America and into the United States.<sup>1</sup> In 1987, Congress responded to drug safety concerns with passage of the *Prescription Drug Marketing Act* (PDMA), banning reimportation by anyone other than a drug's original manufacturer, regulating drug samples, prohibiting hospitals and charitable institutions from reselling prescription drugs they purchased, and establishing strict rules requiring state licensure of pre-

scription drug wholesale distributors.<sup>2</sup> The PDMA was necessary, Congress argued, to “ensure the safety and efficacy of the prescription drug supply of the United States by restricting or prohibiting certain distribution practices that have resulted in adulterated, outdated and counterfeit medication reaching American consumers.”<sup>3</sup>

While safety concerns drove legislation to more tightly regulate the distribution of pharmaceuticals, not everyone was convinced that the safety problems were significant enough to merit such regulation. When President Reagan signed the PDMA on April 22, 1988, he signaled a reluctance to do so, noting in particular that:

“...although the lack of traceability of drug products in the diversion market is a valid concern that I share, the magnitude of the public health problem created by diverted drugs is still not clear. I am therefore also concerned by provisions of the bill requiring use of substantial amounts of scarce Federal public health resources to police the practices.”<sup>4</sup>

While it is unlikely President Reagan’s concern about the cost of policing the practice could have contemplated today’s scenario, where a ban on drug importation requires covering 355 points of entry to catch an estimated 4.8 million packages of prescriptions drugs coming from Canada alone,<sup>5</sup> the job of enforcement is indeed daunting and costly. Given the scope of enforcement, the Food and Drug Administration (FDA) has developed enforcement priorities that allow for personal importation of a 90-day supply of prescription drugs.<sup>6</sup> This exception to the ban allows for “circumstances [that] may exist where, for example, a person has begun treatment with an unapproved drug in a foreign country or suffers from a condition for which there exists no FDA approved treatment.”<sup>7</sup> Although the exception requires personal importation to meet certain standards that attest to the safety of the prescription and intended personal use only, the U.S. Department of Health and Human Services (HHS) has admitted the majority of drugs entering the United States under this exception do not “technically meet all of these factors,” but “given the high demand and limits on available resources it is difficult to effectively police this practice.”<sup>8</sup>

When personal importation was practically limited to an individual physically crossing the nation’s border and returning with prescription drugs in hand, personal importation may have been easier to enforce. However, the Internet has changed this practice dramatically. The HHS department reports that in 2003, cross border internet prescription drug sales amounted to about \$408 million, while \$287 million in cross border sales came through foot traffic, illustrating the ease of importation via the Internet.<sup>9</sup> As it has become easier to obtain cheaper prescription drugs and public safety concerns have been minimized, the ban on importation has become more difficult than ever to enforce.

In 2000, Congress passed the *Medicine, Equity and Drug Safety Act*, which loosened the ban on importation and allowed pharmacists and drug wholesalers to import prescription drugs from foreign suppliers. According to the legislation, however, loosening the restrictions for pharmacists and drug wholesalers requires the Secretary of Health and Human Services to ensure the safety and effectiveness of the imported drugs by finding they would pose no additional risk to the public’s health and safety; and would result in a significant reduction in cost. Since its passage, Secretary Shalala under President Clinton, and Secretaries Thompson and Leavitt under President Bush, have not certified that such a practice would both ensure safety and provide for an attending reduction in cost. Accordingly, the ban on importation continues.

In 2003, Congress again focused on drug importation in the *Medicare Modernization Act*, allowing importation from Canada if the Secretary of HHS could certify safety and savings, in addition to directing the Secretary to undertake a study on the importation of drugs. This study, completed in 2004, pointed to both safety questions and uncertainty in cost savings as reasons to keep the ban in place.

Even with the regulations of the PDMA and its subsequent amendments in place, counterfeit, adulterated, and misbranded drugs can—and do—enter the United States. Yet while these holes may pose a threat to the safety of the country’s pharmaceutical supply, many Americans seem content to gamble on the safety of their drugs in hopes of purchasing cheaper drugs from outside our borders.

## Canadian Command and Control

There is little doubt that the ban on drug importation today is largely ineffective due to the lower cost of imported drugs and ease with which Americans can purchase drugs from Canada. So why are prescription drugs less expensive in Canada? The answer lies in Canada's command and control government regulation and illustrates why drug importation is neither the best—nor the free market solution.

To monitor and control the price of pharmaceuticals, Canada created the Patented Medicine Prices Review Board (PMPRB) in 1987 to “[limit] the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.”<sup>10</sup> According to the Board, which does not have authority to regulate prices of generic, non-patented drugs, pharmaceutical prices are established through direct price controls following four basic guidelines:

- A new patented drug is priced in the same range as an existing drug that treats the same disease;
- The cost of “breakthrough drugs” are limited to the median price for the same drug in seven countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States;
- Price increases are limited to the Consumer Price Index; and
- Canadian prices cannot be the highest in the world.<sup>11</sup>

Violating the guidelines may result in a Voluntary Compliance Undertaking (VCU), which requires the patentee to “reduce the price and to pay excessive revenues” back to the Canadian government.<sup>12</sup> In March 2005, for example, GlaxoSmithKline signed a VCU with the PMPRB regarding the patented antidepressant Paxil. As a result, the VCU reset the price and directed the company to pay the Canadian government \$310,403.64 to offset the “excessive revenues received by GlaxoSmithKline.”<sup>13</sup> Since 1993, the PMPRB has taken more than 30 actions through the VCU process, ranging from \$14,000 to \$3.6 million in excess revenues to be paid by a company.<sup>14</sup>

On the surface, these guidelines may help the government balance its books, but the negative effect in the Canadian market is significant. In fact, while it is popular knowledge that prescription drugs in Canada

are cheaper than those sold in the United States, such information is rarely held up for thorough inspection. The full story paints a less than ideal picture.

The United States has significantly higher prices for patented drugs than the other countries on Canada's comparison list for price setting guidelines. This is not surprising, as data has rather consistently shown that, despite difficulties in making precise cost comparisons across countries, Americans pay higher prices for top-selling, brand-name prescription drugs.<sup>15</sup> Importantly, however, each of the comparison countries imposes some type of price control on their brand-name pharmaceuticals.

In the *generic* market each of the comparison countries again employs price controls, with the exception of the United States and Canada. Predictably, prices on generic drugs are lowest in those countries with price controls; however, in the generic market, drugs cost less in the United States than in Canada—often much less. In fact, according to the FDA, in six of the seven biggest selling drugs used to treat chronic conditions, the U.S. generic was cheaper than the Canadian name-brand version; five out of seven U.S. generics were cheaper than the Canadian generics.<sup>16</sup>

The Fraser Institute, a Canadian market-based research organization, reports that the higher prices in Canada's generic market are primarily attributable to two things: 1) lack of competition among generic companies for market share coupled with protectionist public policy, and 2) unintended consequences of price controls in the patented drug market.<sup>17</sup> Whereas name-brand drug manufacturers have been primarily foreign companies, Canadian-owned companies have dominated the generic market until only recently, encouraging policies that give generic Canadian-owned manufacturers an advantage and subsidizing the domestic drug industry. In addition, the Fraser Institute speculates that price controls imposed on name brand drugs have an anti-competitive impact on the generic industry. As patents expire, drug manufacturers do not want to lower the price for their now off-patent, existing product, for fear of also lowering the benchmark price for any new drug entering the market, as Canadian guidelines require.<sup>18</sup> Thus, the Fraser Institute finds that price controls in the name-brand market create an artificial barrier for price competition among generic drugs and set a new ceiling price for generics.

Of course, pharmaceutical prices in the United States differ from Canada's prices (and the prices of other comparison countries that employ price controls) for good reason. The first is that in order to achieve savings, the Canadian government often limits the prescription drugs approved in Canada. As reported by HHS Task Force on Drug Importation, 227 of the 360 new active substances launched worldwide since 1994 are available in the United States.<sup>19</sup> Coming in behind the United States is the United Kingdom with 207. Canada comes in seventh, with only 174. These numbers reflect the more limited availability of drugs in price controlled countries and the detrimental impact of government controls on consumer choice.

The second reason prices differ between countries is market segmentation. In segmenting the market, producers price goods and services according to factors including market size and demographic variables like income. Accordingly, prices are set differently for different people according to people's ability to pay. Market segmentation works well when there is no arbitrage (people paying low prices selling for less to people paying high prices), such as when the physical exchange or resale of products is more difficult, as in cases of regulated international trade. Perhaps this condition was better met for pharmaceuticals prior to the advent of the Internet. However, when those paying higher prices can purchase from those paying a lower price, the lines of parallel trade are opened, generally against the interests of price discriminating manufacturers.

The Canadian system wields power over pharmaceutical manufacturers by controlling price as well as exacting penalties on those deemed to be earning excessive revenues. Under this arrangement, manufacturers have limited ability to negotiate with Canada, choosing either to accept the price controls, or lose Canadian market share. As a result, a manufacturer who chooses not to go along with the price controls or takes action to mitigate parallel trade, also risks losing their intellectual property. Although experts view the threat to intellectual property to varying degrees, there is clear evidence for concern. One way that a producer may seek to preserve market segmentation and prevent parallel trade is to manage distribution channels for its products by either negotiating a higher price, or limiting supply. In the case of Canada's drug prices, the

manufacturer has little room to raise price, but could reasonably attempt to limit the availability of their products in Canada to prevent parallel trade. In this scenario, the manufacturer limits the supply to Canada and blocks its ability to turn around and sell lower cost products to the higher cost American market. Manufacturers have begun to restrict Canada's supply to varying degrees, but such action gives manufacturers and many experts serious concern. To prevent shortages, the Canadian government could invoke compulsory licensing, effectively stripping patent owners of exclusive rights to their intellectual property and allowing the government to issue a license for production of the same product.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) allows for compulsory licensing, although the circumstances under which the practice is acceptable are vague. In 2001, Harvard Professor F.M. Scherer wrote about the compulsory licensing questions under TRIPs in a paper for the World Health Organization, finding that:

“Article 40 permits WTO member nations to take appropriate measures, including authorizing the compulsory licensing of specific patented inventions, under conditions that constitute ‘an abuse of intellectual property rights having an adverse effect on competition in the relevant market’...the article offers a non-exhaustive list of cases under which compulsory licensing might be authorized... the article's language appears to track in a general way the ‘abuse’ doctrine of U.S. patent anti-trust law, although the article as a whole can be reconciled with European legal traditions holding that failure to supply or license a patented product at all, or supplying the product at unreasonably high prices, might be deemed abusive.”<sup>20</sup>

Furthermore, Article 8.1 of the TRIPs Agreement specifically empowers WTO members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest,” a threshold that elevates matters of public health and leaves member countries considerable room to tread on the intellectual property rights of patent owners.<sup>1</sup>

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<sup>1</sup> The Doha Declaration does not limit the applicability of the TRIPs Agreement to specific diseases, such as HIV/AIDS, over the objections of some developed countries. Many believe that the Declaration has set a floor, not a ceiling, and may signal willingness to interpret public health needs more liberally.

Whether the argument for compulsory licensing is made on the basis of “unreasonably high prices” or to protect “public health,” global discussion and trade treaties like the TRIPs Agreement show a strong bias toward punishing profit and a disregard for intellectual property rights when the ends justify the means. In fact, the push for compulsory licensing may well be growing within Canada as disgruntled Canadians and Canadian companies push for compulsory licensing in an effort to protect supply and maintain low prices. For example, in a recent letter from Green Shield, a Canadian health benefits administrator, to the Canadian Minister of Health, the company suggests that the cross border prescription drug trade could lead to shortages of drugs as Americans continue to purchase drugs from Canada. Green Shield recommends that in order to combat Canadian shortages, the government should expand the role of the PMPRB to monitor the drug supply to identify any compulsory licensing needs in the industry.<sup>21</sup>

## The Free Market Problem With Importation

Friends of the free market typically oppose drug importation because it would “import Canadian price controls” to the United States. Although this statement is certainly true, it is imperative to think more deeply about the implications of allowing de facto price controls to dominate the American prescription drug market. Americans enjoy unparalleled access to new and innovative health care treatments; precisely because the United States has a more free market system than other comparison countries, allowing pharmaceutical companies to earn profits and direct those profits to investments that bring tomorrow’s new treatments.

As outlined in the previous section, Canada’s approach to managing its prescription drug market is a lesson in anti-market, statist policies, and hardly a model that free marketers would want to emulate. Consider four points:

1. The free market is characterized as the voluntary exchange of goods or services, without the influence of coercion or theft, a standard the Canadian system fails to achieve when pharmaceutical manufacturers must comply with government controlled prices under threat of losing their intellectual property.
2. Unlike the free market—where price is set in balance with supply and demand—the Canadian system relies on government price controls to keep prices artificially low.
3. Private property rights are essential to the free market, which Canada violates with the threat of trampling intellectual property.
4. Whereas a free market system is characterized by minimal government interference, government interference is the hallmark of the Canadian system.

Although Canadian price controls are among the most obvious of the country’s anti-market health care policies, the violation of private property rights is arguably the most insidious. The Canadian system relies on price controls to keep costs artificially low, and forces Canada to institute additional state regulations to prevent market responses that would interrupt their system. For instance, price controls would invariably lead to shortages, except Canada dangles the threat of compulsory licensing to limit the manufacturers’ ability to negotiate or reduce supply. Canada’s highly regulated prescription drug system is not merely about importing price controls, but truly undermines free markets, private property rights, and every notion of limited government.

## Profits

Underlying much of Canada’s regulation, as well as the drive to institute price controls here in the United States, is the pervasive notion that profits are to blame for high prices. In fact, most importation proponents seem to believe that the health care industry should act as a charitable institution, rather than a for-profit business that keeps the engines of health care humming. Although demagoging pharmaceutical company profits may play well politically, the economic reality is that profits have fueled pharmaceutical innovation that Americans—and the world—benefit from today. Free marketers know that pharmaceutical companies must set prices that allow them to recoup the significant costs associated with developing a new product, as well as earn profits that will allow continued innovation and development of new treatments. Undoubtedly, American-made profits continue to drive innovation through research and development, and allow price-controlled countries to effectively ride for free. In the long run, reducing profits will reduce availability of new and innovative prescription drugs in all

countries, as well as competition among manufacturers to bring new products to market at competitive prices.

Today, Americans enjoy access to many new and innovative medicines and treatments. In fact, as a consequence of government regulation, Canada's reputation for cumbersome regulations hinders its ability to maintain a competitive pharmaceutical industry. Data from the Fraser Institute underscores this fact, showing that only 12 generic companies control between 90 to 100 percent of the generic market in Canada, with two companies accounting for 62 percent of the market alone. In the United States, 10 companies accounted for only 61 percent of the generics industry.<sup>22</sup> More companies competing for market share in the United States results in greater price competition and choice for American consumers. In addition, these comparisons should also serve as a warning that greater government regulation in the United States would depress not only competition, but also the economic impact of the industry as a whole. Those lawmakers with an interest in greater government involvement and regulation may believe that the short-term solution to high prescription drug prices lies in government action, but the long-term sustainability and strength of the pharmaceutical industry lies in free market policies.

## Prices

Despite a small number of free market importation proponents who believe that drug importation (or lifting the ban on importation) will actually right the market, most importation supporters are really regulators at heart, looking for a way to force the price down at all cost. In fact, most drug importation supporters argue for lifting the ban, not because they want a working free market, but because they see an opportunity for government intervention. Drug importation advocates consistently suggest that a policy allowing importation will result in lower prices for prescription drugs in the United States, although such an outcome is far from certain.

If the pharmaceutical market were truly allowed to work worldwide, it is possible that American prices would be lower, but more likely that higher prices would prevail in now price controlled countries. However, the stated goal of most importation supporters is to simply lower the prices of prescription drugs in the United States, not to create market based

prices across the board. As discussed previously, differential pricing is a perfectly rational market practice under which "profit-maximizing firms will charge the most to market segments that are least responsive to price... price will be highest to market segments with the lowest price elasticity of demand."<sup>23</sup> Clearly, there would be little incentive or need for a pharmaceutical company to lower its prices when the American market can—and does—bear the current prices.

## Private Property Rights

Fundamentally, private property rights allow for development of property, creation and ownership of wealth, and efficient allocation of resources, each of which applies to intellectual property, just as it does to physical property. In the world of intellectual property, particularly as it applies to pharmaceuticals, the expectation for profit is important. Studies find that it costs roughly \$800 million and years of work and clinical trials to bring a single drug to market—if it makes it to market—a costly proposition, particularly if someone can steal the intellectual property and reproduce the drug. While profits make research and development possible, private property rights preserve the incentive to develop new products with an expectation of profits. Clearly, no manufacturer would invest in the research and development of a new drug if another manufacturer could simply take the technology and sell it first, without concern about recouping the money put in to product development. In fact, whether it is physical property or intellectual property, the issue is the *control* of the property. The government should no more take physical property than it should intellectual property, nor should it allow others to do so. As the underpinning for the free market and a strong economy, it is imperative to preserve strong private property rights.

## Government's Role

In all likelihood the objections to "importing price controls from Canada" are largely predicated on a belief in limited government, and recognition that government ought not be setting prices. By contrast, trade agreements, like those through the WTO, have shown that many governments are willing to run roughshod over property rights when it is expedient, and without limitation on government. Free market principles, including the ability to set market prices and protect private property are at the heart of the question on importation. The United States must en-

sure that domestic policy does not create unnecessary hurdles for manufacturers or consumers, but must resist the temptation to use importation to lower cost in the short-term, while creating costly consequences in the long-term.

In terms of domestic policy, Congress must ensure that bureaucracy does not drive up the price or slow down the pharmaceutical products being brought to market. As the Cato Institute's Roger Pilon stated in testimony before the U.S. Senate's Special Committee on Aging, U.S. prescription drugs are expensive because of the "regulatory regime we've established in this country to ensure drug safety and efficacy."<sup>24</sup> Pilon added that "rather than rely on common law principles to allocate the risks of unsafe or ineffective 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." He pointed out that the expenses of research and development are greater than the cost of manufacturing and marketing, resulting in a situation where "the first pill is enormously expensive; the second costs almost nothing to produce."<sup>25</sup>

Some free market proponents support importation and argue that lifting the ban on importation would allow the market to set the price of drugs. They argue that the market allows for the use of differential pricing, but not by way of government regulation. From this perspective, the ban on importation is still government's intrusion into the marketplace and prevents consumers from purchasing the lowest cost prescription drugs available. Indeed, the U.S. government should not be responsible for erecting and policing a fence between Canada and the United States in an effort to prevent parallel trade. Instead, pharmaceutical companies should have recourse to protect differential pricing by negotiating and enforcing a no-resale contract with the Canadian, and other similar governments. Pharmaceutical companies should have recourse if those agreements are not met, including the ability to limit supply. In order to protect the ability of American consumers to enjoy an unparalleled level of access to prescription drugs and health care in comparison to the rest of the world, the United States should focus on strengthening agreements with foreign governments to protect the pharmaceutical industry's ability to engage in legitimate, free market measures to protect their interests. In order to meet

this objective, the U.S. government must unequivocally protect patent owners from the threat of compulsory licensing and resist efforts to allow price controls to infiltrate U.S. health care through its northern backdoor.

## Drug Importation: The Lone Star Debate

The question on state-sanctioned drug importation came before the Texas House as an amendment to Senate Bill 410, the State Board of Pharmacy's sunset bill. Over the objections of the bill's author and a motion to table the drug importation amendment, more than 100 members of the House voted in support of drug importation. The debate featured members, both Democrat and Republican, insisting that the amendment was "pro consumer," "pro safety," and "capitalistic," and sharing anecdotal stories about their constituents struggling with high prescription drug costs. The very language of the amendment, as well as the debate on the House floor, reflects the absence of important facts and clear free market principles to help navigate the issue and the consequences of importation.

### Legislative Intent

Expressing the intent of the legislature, the legislative findings at the beginning of the amendment are evidence of the incomplete information that drives popular perception of the problem. These findings fail to add to the substance of the debate in a meaningful way, shunning fact in favor of feeling and emotion. When considered in light of the facts, however, the legislative findings serve as a questionable foundation for such a policy.

- 1. Prescription drugs are expensive to the point that some residents of this state have been forced to choose between purchasing prescription drugs and paying for other essentials, such as groceries or rent.*

No doubt anecdotal stories abound to support such a claim, but such stories merely highlight the very anecdotal nature of the debate. Truly the claim that people are foregoing food and rent in order to pay for prescription drugs has taken on a life of its own, and is repeated with authority as evidence that prescription drugs are too expensive. This is not to minimize

the significant burden that prescription drug costs may place on American—Texas—consumers, but such statements should hardly be the basis for forming public policy.

*2. Prescription drugs can be purchased at much lower costs in Canada.*

To kick off the debate, the amendment’s author used a chart comparing drug prices in the United States and Canada to highlight the disparity in price between the two countries. As discussed previously, there are several explanations for the price differences, including legitimate market segmentation and the government imposed price controls on prescription drugs sold in Canada. In addition, research has shown that while brand-name drugs in Canada are cheaper than brand-name products in the United States, generic products in the United States are cheaper than both generic and brand-name products in Canada. For instance, a *Wall Street Journal* article in 2004 compared the anti-depressant Prozac with its generic version, fluoxetine, and found that the Prozac was 33 percent cheaper at a Canadian pharmacy than the lowest price U.S. pharmacy, but the generic version was 85 percent cheaper through Costco.com than on Canadian sites.<sup>26</sup> Considering the growth of the generic market and availability of generic drugs in the United States, it is important that the complete story is told, both to shine light on the distortions created by price controls, and to rebut the claim that Canadian prescription drugs are cheaper.

In addition, it is important to point out that the price of prescription drugs can vary widely by retailer. A story in *U.S. News & World Report* reported that two Texans managed to reduce their monthly bill for prescriptions by 35 percent simply by shopping for a better price in their city.<sup>27</sup> The story noted that a single prescription for Avandia, used to treat diabetes, dropped from almost \$90 to \$58 just by switching pharmacies. The same story told how states like Maryland and New York had tackled the cost of prescription drugs by giving consumers access to pricing information for different pharmacies and the ability to search for the best price online.

Similarly, during the debate on the floor of the House, Representative Bill Zedler questioned the need for a website directing Texans to a Canadian pharmacy,

asking “if we’re gonna have a website, why don’t we have a website that tells people how to get drugs directly from the drug companies at a discounted rate?” His question not only points out that there are solutions that do not require government intrusion into the market, but that the free market allows the private sector to respond to need, as it has done. In fact, almost all of the major pharmaceutical manufacturers have patient assistance programs that offer low-income and uninsured individuals deeply discounted, if not free, prescription drugs. Many of the individual company programs have been in existence for more than 20 years, with new individual programs and joint-company programs created to respond to specific and changing needs. While politicians and the press have repeated stories about the expense of prescription drugs for the uninsured and seniors, pharmaceutical companies have developed programs that provide assistance to many low-income people and seniors across the country. Just as Maryland and New York have aided consumers in comparing prices across pharmacies, Representative Zedler’s approach—pointing people to private sector solutions—better empowers consumers and allows the market to work, rather than relying on Canadian price controls to deliver cheaper medicine.

*3. Scams offering low-cost prescription drugs are prevalent on the internet and in spam e-mail, and these practices make it difficult for consumers in this state to determine how and where to purchase safe and effective prescription drugs at affordable prices.*

When the HHS Task Force on Drug Importation solicited comments on drug importation, they received several comments suggesting that legalizing the importation of foreign drugs could be achieved by including and excluding particular drugs from this arrangement; some comments suggested that a list of approved drugs for importation would be useful for commercial importations. The proposed list and legalized importation of only select prescription drugs may sound like a reasonable half step, but as the report points out, it would be difficult to distinguish the listed and non-listed drugs as they enter the United States. It would also be virtually impossible to enforce as patients and foreign pharmacies may not adhere to the limitations and lists.<sup>28</sup>



Similarly, it is hard to imagine a system under which Texans would compartmentalize or distinguish between state sanctioned drug importation, while following a ban on all other importation channels. If, this amendment is a matter of ensuring the safe importation of drugs, is it realistic to think that safety concerns are met by telling Texans that drug importation is safe, but only through state sanctioned pharmacies? Or is it more likely that Texans will hear the message that importation is safe and thus continue importing prescription drugs through any channel, despite federal laws to the contrary? What's more, the state's Southern border with Mexico offers greater opportunity for importation, and from a country with arguably fewer assurances on safety. The state's interest in allowing controlled importation seems increasingly unmanageable under closer inspection.

4. *The Regulatory Procedures Manual of the United States Food and Drug Administration authorizes agency personnel to allow the importation of products regulated by that agency when the quantity and purpose are clearly for personal use and the product does not present an unreasonable risk to the user.*

5. *Other states and municipalities provide Internet websites and other methods to allow residents of those states or municipalities to safely purchase prescription drugs from Canada.*

Neither of these statements presents a convincing argument or legislative finding on which to base legislative action. In fact, while statement (4) is misleading and interprets the FDA's position too loosely, statement (5) is a weak justification for undermining the very rule of law. In particular, an FDA letter to Governor Perry warns against state sanctioned drug importation and explains the administration's position on personal importation. The letter notes that while it has enforcement discretion, the FDA allows importation in circumstance where "small quantities of drugs [are] sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically."<sup>29</sup> Nothing in the FDA's position would suggest that drug importation would be an acceptable substitute for legal pharmaceutical purchases—instead the personal importation policy attempts to offer some flexibility in extraordinary cases of need.

Statement (5) points to the absence of enforcement action as justification for pursuing such a policy in Texas. Again, the FDA's letter to Governor Perry outlines the terms of federal preemption, in which the agency argues that the federal government has not intended to allow states the room to set policy allowing for importation. According to the letter, through the Supremacy Clause of the United States Constitution, federal law preempts state regulation when Congress has "intended to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law."

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the states to supplement it;" 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute."<sup>30</sup>

State laws that allow for even limited importation would almost assuredly violate these points. Additionally, statement (5) expresses a reckless disregard for federal law merely because of weak enforcement. It is unlikely that the Texas Legislature would tolerate Texans taking such a cavalier attitude toward the rule of law—were it *state* law in question.

## The Role Of The State?

As author of the sunset bill, State Representative Vicki Truitt opposed the Canadian drug importation amendment. In her opposition, Representative Truitt asked lawmakers if they were prepared to extend the state's responsibility and tell the Board of Pharmacy to regulate the activity of a business in a foreign country. In fact her opposition highlighted not only whether the state was prepared to take on such regulation, but also stated unequivocally that the state would be taking action to legalize an activity that is currently illegal and deserves national—not state—debate.

The amendment, now in state law, establishes a bureaucratic process under which agents of the Texas

State Board of Pharmacy take on the additional responsibility of conducting annual inspections of pharmacies—on Canadian soil—to ensure compliance, collect consumer complaints against Canadian pharmacies, set related fees, and manage a website directing Texans to Canadian pharmacies. This process stands in sharp contrast to the websites previously discussed that merely give consumers easy access to compare pricing information, or the method suggested in an effort to boost awareness of private sector patient assistance programs.

The language of the amendment shows just how unmanageable such activity will become, both in terms of managing questions of liability, and in prohibiting the sale of prescription drugs from Canadian pharmacies the state wants to exclude from the arrangement. For example, Section 554.016(c) of the Occupations Code (as added by SB 410) directs the board to “establish and maintain an Internet website to provide information necessary to conveniently order prescription drugs from Canadian pharmacies” and “include on the website a statement that the board is not liable for any act or omission of a Canadian pharmacy designated as having passed inspection to dispense prescription drugs to residents in this state.” As the state wanders into new territory, its liability is unclear, and the disclaimer should raise serious questions in the minds of Texans regarding the safety of such purchases. Just as the FDA has maintained a ban on importation because it cannot ensure that American consumers will be at “no additional risk” by purchasing foreign prescription drugs, the state is even more unprepared to make such assurances.

The HHS Task Force on Drug Importation received comments that courts have held a defendant liable, even when the defendant has not been engaged in the distribution of a product. As such, the task force reported a comment noting that “the creation by states of websites to facilitate importation raises an issue as to whether the facilitation puts the state in the same position as a seller or distributor.”<sup>31</sup> The report also found that many of the cities and states that establish these websites distinguish themselves as only a source of information and not a dispenser, believing that this will also shield them from liability. While the litigation exposure of all parties is mostly uncertain, the amendment’s author assumed a tone of certainty in responding to a question about whether the

legislation is in direct conflict with federal law, insisting that activities like inspecting a pharmacy and posting on a website are not illegal.

Finally, in an apparent attempt to placate those who would have safety concerns, the legislation again reveals how truly unmanageable state sanctioned importation will be. Section 556.001(c) of the Occupations Code, extends the state’s licensing requirements to Canadian pharmacies, adding that:

“A pharmacy located in Canada may not ship, mail, or deliver to this state a prescription drug dispensed under a prescription drug order to a resident of this state unless the pharmacy is designated by the board...”

This provision exposes two great ironies. The first, that the state legislature would pass legislation effectively violating federal law, yet in the same legislation express a belief that it can prohibit Canadian pharmacies from disregarding state law. The second, that the legislative findings suggest the legislation is necessary to protect Texans from Internet scams that make it difficult for consumers to know where they can legitimately purchase prescription drugs—as if those otherwise unscrupulous scam artists would be effectively deterred from selling prescription drugs to Texas residents. Whereas the federal ban allows for some exceptions to the personal importation policy, the law is generally understood to ban American consumers from purchasing prescriptions from Canadian pharmacies. The law allowing for state-sanctioned importation not only blurs the lines of safety and legality, it attempts to use state law to regulate the business practices of Canadian pharmacies. This toothless admonishment to unapproved Canadian pharmacies should serve as an indication of how ill-prepared the state is to take on the responsibilities of policing this system.


## Conclusion

There is no question that the rising cost of health care, and the cost of prescription drugs in particular, creates a hardship for many Texans. Too often, however, the immediate response is to increase government’s involvement in a vain effort to ameliorate the problem, often leading to a cascading effect where layers of bad policy merely pave the way for new bad policy billed as a solution. This is clearly a case where layers

of bad policy, all the way from the far-reaching role of the Food and Drug Administration, to the burden the drug importation ban places on the American consumer, create few easy policy options. This is to say nothing of the impact that price controls on prescription drugs in foreign countries have on the American pharmaceutical market, or the free trade questions these international relationships generate. In order to truly address these issues, the layers of policy must be peeled back to allow a free market approach to take hold.

At the federal level, the United States Congress should ensure that bureaucracy does not slow the pipeline for bringing new prescription drugs onto the market, nor should it establish hurdles that unnecessarily drive up the price of research and development. The United States government must take a clear stand against the practices of foreign countries that violate free trade agreements or extort a manufacturer's participation—on the government's terms—with the threat of stripping patent protections. Ultimately, limitations on parallel trade and the pharmaceutical manufacturer's ability to maintain segmented markets depends entirely on strong intellectual patent protections that boost the manufacturer's ability to negotiate with these price controlling governments. Although government purchased health care is anti-market on its face, it is essential that pharmaceutical manufacturers have the ability to apply free market business practices to balance these interests. Undoubtedly, these questions are the purview of the federal government and the state should not intervene in what is effectively a contractual relationship between the patient holder/producer and the purchaser.

Texas can play a role in this effort, but the method established through Senate Bill 410 of the 79<sup>th</sup> Texas Legislature, is simply the wrong approach for Texas. While this is an issue for the federal government, the state can effectively encourage government leaders to steadfastly protect the interests of the American people by ensuring a free market and thriving pharmaceutical industry exists to bring ever-increasing innovation and competition to the American health care system. If Texas truly wants to ensure Texans can get the best price possible, the solution isn't merely to sanction drug importation and introduce Canadian-style price controls into the market. Instead, the state should ensure that Texas consumers have the ability to

shop for prescription drugs and other health care services according to price, highlight the ability of Texas consumers to compare prices of different pharmacies in the area, and allow private sector patient assistance programs to serve eligible Texans. Texas lawmakers should stop distracting themselves with schemes to import foreign price controls and consider how free market principles apply to this and other public policy questions. 

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The Center for Health Care Policy was established by the Texas Public Policy Foundation to provide policymakers with reliable information and champion market-based reforms of state policy to improve the quality and affordability of health care for Texans.

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