Drug reimportation practices in the United States

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Background: Drug reimportation is perceived as a costs-cutting strategy by Americans. Nonetheless, issues such as drug safety and efficacy prevent legalization of the practice. With the contradictory views from supporters and opponents, debate on drug reimportation continues to snowball. The objective of this commentary is to discuss issues regarding drug reimportation practices in the United States (US). It also examines policy implications and potential solutions of the controversy.

Findings: Comparatively inexpensive drugs available across the border help Americans relieve the burden of medication costs. Consequently, the volume of reimported drugs entering the US has considerably increased. However, these practices are illegal and legalization of drug reimportation is a political debate. While safety is the most important barrier for legalization, this concern does not seem to affect growing number of Americans who are getting their prescriptions filled from across the border. Canadians oppose legalization of reimportation in the US as it could exacerbate the problem of medication shortage in Canada.

Summary: Currently, legalization of drug reimportation has wedged between the arguments by different groups. Until the US government finds a solution to reduce medication costs, it seems to be impossible to stop Americans from buying the comparatively inexpensive medications available across the border.

Keywords: drug reimportation, drug importation, prescription drug costs, drugs from Canada

Background

The increasing expenditure on prescription medications is a big concern for consumers in the United States (US). Due to the increasing burden of medication costs, Americans, especially elderly and the uninsured, avoid taking medications or skip doses. According to a study, 22% of seniors do not fill their prescriptions because they cannot afford the cost of their medications (Safran et al 2002). The percentages are higher (32%) for uninsured population, which account for approximately 10% to 15% of the US population (Safran et al 2002).

Consequently, a growing number of Americans choose to buy comparatively inexpensive medications available in other countries such as Canada and Mexico. Several internet pharmacies help consumers obtain medications from other countries without requiring them to travel across the borders. Even though these drugs are often manufactured in the US, the drug price control acts in countries like Canada keep the prices of prescription medications lower than the US market prices (Wagner and McCarthy 2004). The practice of importing back to the US prescription drugs that were originally manufactured in the US and exported for sale in another country is referred as ‘drug reimportation’. Estimates indicate that buying medicines from a certified Canadian pharmacy can save Americans 20%–80% on brand name drugs (Vivian 2003). However, economists argue that these estimates could be dubious and are overestimated considering the complications involved in comparing medication prices across different nations (Danzon and Kim 1998; Wagner and McCarthy 2004).
Many concerns restrict drug reimportation from being a legal practice in the US. These include safety, efficacy, and therapeutic equivalency of reimported drugs. While these drugs are manufactured in the US, the storage and packaging conditions in countries where drugs were exported cannot be monitored by the US Food and Drug Administration (FDA) (Meadows 2002). In addition, inappropriate storage conditions while reimporting medications back to the US may degrade the quality of drugs. The most important issue is distinguishing between drugs that are manufactured in the US from those which were manufactured elsewhere. Although technically ‘reimportation’ involves importing back drugs manufactured in the US, there are no means to check the originality of drugs. Similarly, it is difficult to determine whether the drugs purchased from other countries have the same dosage form, potency, and amount of active ingredient as the prescribed medication. The FDA contends that legalizing reimportation would increase the entry of counterfeit medications in the US drug supply chain (Meadows 2002). The pharmaceutical industry criticizes the reimportation practice due to the potential harm to the recovery of the research and development (R&D) costs required for new drugs (Danzon 1998; Danzon and Kim 1998). While these opponents prevent the legalization of drug reimportation, various consumer advocacy groups support the practice.

The legalization of drug reimportation remains a controversial issue in the US. While important, limited work has been done on briefing the legislative history and current status of drug reimportation. This commentary tries to explore the perspectives of different groups, emphasizing the role of healthcare professionals in drug reimportation practices. In addition, the paper also discusses policy implications of the drug reimportation practice.

Key findings

US prescription drug expenditure and drug reimportation

The cost of prescription drugs is the fastest growing sector of US healthcare costs. In 1980, US prescription drug expenditures were $12 billion, accounting for 4.9% of total healthcare spending. By 2003, it had escalated to $184.1 billion or 11.0% of total healthcare expenditures (CMS 2005). The increased volume of prescription medications have also driven the overall costs of pharmaceuticals. The increasing number of prescription utilization was responsible for 42% of the overall increase in prescription spending from 1997–2002 (KFF 2004) (Figure 1).

On the other hand, measures such as drug price control acts in other countries such as Canada significantly reduce the prices of prescription as compared with the US. Thus in most cases, Americans can buy the same medication at significantly lower prices from countries like Canada and Mexico. For instance, the antiretroviral drug ritonavir (Norvir®, Abbott Laboratories), which is a part of many HIV/AIDS treatments costs as low as $700/per year in Canada as opposed to $7800/per year in the US (Nelson 2004). According to the Patented Medicine Review Prices Board of Canada (PMPRB), factory drug prices in the US exceeded seven nations including Canada and European countries in the year 2000. Consequently, the volume of reimported drug entering the US has significantly increased over the past decade (Dalzell 2000)

Legislative history

Various bills allowing reimportation of drugs have been proposed, but none of them have been implemented as legislation yet. The practice of reimportation is illegal in
the US (the legal exceptions are those drugs which are manufactured in the US, and may be reimported by the original manufacturer or if the prescription drug is required for ‘emergency medical care’) (Creech 2001). The FDA also allows 90-day supply of reimported drugs for personal use (Reichert and Friend 2000). In 2000, the Medicine Equity and Drug Safety Act of 2000 (MEDS act) was passed to allow pharmacists and wholesalers to reimport US manufactured, FDA approved drugs, previously exported to foreign countries, back into the US to sell them to Americans at cheaper prices. However due to lack of the congressionally required certification by the Department of Health and Human Services (HHS), the MEDS act was terminated at the end of December 2000 (Vogel and Joish, 2000). Before the proposal of this act, the Prescription Drug Marketing Act of 1988 (PDMA) allowed manufacturers to reimport drugs under FDA regulation (Creech 2001). Several times since 2000, both the US House of Representatives and the Senate have continuously discussed this issue in an effort to legalize reimportation practices. On July 25, 2003, the Pharmaceutical Market Access Act of 2003 (H.R. 2427) passed in the House had provisions to allow drug reimportation from 25 countries, including Canada, Australia, Japan, South Africa, and the European Union. A different version of this bill was passed in the Senate in June 2003 that allowed reimportation of FDA-approved drugs only from Canada (Moskowitz 2000). As a safety measure, this legislation required that the packaging of prescription drugs incorporate counterfeit-resistant technology. It also entailed a certification from the Secretary of Department of Health and Human Services that the prescription drugs do not expose consumers to any additional risks.

Currently the debate on drug reimportation practice continues to snowball although its status is still illegal. The legal status of reimportation may be misinterpreted by the consumers due to the ambiguous nature of different amendments and bills. A survey by IMS Health Inc in 2003 revealed that 45% of the respondents perceived reimportation practices to be legal, and 33% were unsure (Saatsoglou 2004). These results indicate consumers’ unawareness regarding legality of drug reimportation practices.

**Perspective of the US FDA**

The arguments about safety and legitimacy of reimported drugs restrict the legalization of the practice. The FDA has consistently denied guaranteeing the safety, efficacy and legitimacy of reimported prescription drugs. The FDA claims that there are no means to detect the origin of the drugs despite the fact they are manufactured in the US (Meadows 2002). The FDA argues that they do not have sufficient financial as well as technological resources to assure the safety and authenticity of drugs coming from across the border (Thompson 2000). Following are some of the key findings (FDA 2003, 2004; FDA Consumer 2003; Rudolf and Bernstein 2004) that support FDA’s positions on drug reimportation practices:

- The FDA and the Customs and Border Protection carried out a series of “blitz” examinations of 1982 drug packages mailed or shipped to individual recipients from abroad. Approximately 90% of these products were found to be unapproved and to present potentially severe health risks. The examined imports included drugs that had been withdrawn from the US market as unsafe; drugs with restricted distribution programs; drugs requiring initial screening and periodic monitoring of patients to ensure safe use; controlled substances such as codeine; animal drugs sold for human use; and drugs that might cause dangerous drug–drug interactions.

- The majority of the drugs had unknown quality and originated from Third World countries.

- The labeling and packaging of the reimported drugs may not be according to the FDA standards. Some medications with labels and inserts in different languages were found during the FDA inspection.

- In another case, FDA officials examined drugs ordered from a supposed Canadian pharmacy. These drugs, (including insulin) arrived in the regular mail and at room temperature (Insulin loses effectiveness at higher temperatures and is supposed to be shipped overnight to ensure it remains chilled) (Vogel 2002).

- The World Health Organization anticipated that in 2000 about 8% of bulk drugs imported to the US were counterfeit, unapproved, or substandard.

- The FDA claims that the number of counterfeit drugs investigated per year have increased to 20 since 2000 after averaging 5 per year in late 90s.

Drug reimportation is considered as a threat to recover the costs required for the new drug discovery. The pharmaceutical industry depends on patents to fund the R&D costs for new drug products. Pharmaceutical price controls reduces the amount of profit available for further R&D, which in turn affects the innovation (Vogel 2002). The average cost of bringing a new drug to market is estimated at almost $800 million (DiMasi et al 2003). These costs
could be recovered through branded medications since the prices of generic and over-the-counter medications need to be set according to the market competition. To recover the costs of innovation and to gain profit, companies set prices according to the different levels of demand and price sensitivity across the different markets (Danzon 1998; Danzon and Kim 1998).

**Perspective of US consumers on drug reimportation**

While reimportation remains a controversial issue, these concerns do not seem to affect growing number of Americans who chose to buy their prescription medications from across the border. Currently the estimates available indicate that 1 to 10 million of Americans purchase drugs from Canada alone, and spend more than $1.1 billion on these prescription drugs in 2003 (Finkelstein 2003). Survey results from various organizations reveal some interesting results. A national survey by researchers at Stony Brook University revealed that around 58% of the consumers perceive Canadian drugs to be safe or somewhat safe and 68% think that the practice should be legalized (SBU 2003). According to a survey by Kaiser Family Foundation (KFF), 63% consumers support drug reimportation and believe that the federal government should make it easier for Americans to get access to Canadian drugs (KFF 2003).

**Canadian perspective on US drug reimportation**

It is important to consider the drug reimportation issue from the Canadian perspective as well. A few US drug companies have already cut off drug supplies to the Canadian pharmacies that sell prescription drugs to US consumers (Elliott 2003). This has led to serious drug shortages at these pharmacies. Also, Canada’s drug supply is very limited and cannot service the need of the whole American population (Graham 2003). Considering the lucrative nature of the drug reimportation business, there is a high possibility that in fulfilling the increased demand of US consumers, Canadian pharmacists might order drugs from other countries such as India, Thailand, and Africa where the rate of drug counterfeiting could be higher. Nonetheless, various Canadian pharmacies available on the internet could be bogus and ordering medications from such online pharmacies could be dangerous (Mulligan 2003).

**Is reimportation really a cost beneficial strategy?**

While international price comparisons of medications show the comparatively higher prices in US, economists argue that international comparisons must be viewed with skepticism (Danzon 1998). Medication prices in other countries generally reflect the lower incomes in some states and the highly politicized nature of most foreign healthcare systems. Exchange rate variations also play a role in setting medication prices. The US has a relatively strong dollar in comparison with other countries, which could have made medications in some other countries seem particularly inexpensive. Research by Danzon and Kim (1998) studied the issues of patent protection, price controls, and continuing availability of prescription drugs without prescriptions. After adjusting for such factors as well as the role of generic equivalents, volume discounts, and frequency of use, they found that the average US consumer would have paid 3% more in Canada, 27% more in Germany, 30% less in France, 9% less in Italy, 8% less in Japan, 44% more in Switzerland, 9% more in Sweden, and 24% less in the UK.

Practices such as reference pricing and parallel trade, which are allowed in European Union (EU), may erode above-normal profits of the pharmaceutical industry if allowed in the US. While the concept of parallel trade is attractive, economic analyses showed that differential pricing is in fact beneficial for recovering costs of R&D of new drugs (Vogel and Joish 2001).

The medication costs issues in the US are mainly associated with brand name drugs. According to a new study by the FDA, Americans who buy drugs in Canada in hopes of saving money could pay significantly more for certain prescription drugs than if they had purchased generic versions of these drugs in the US. This study found that out of seven top-selling prescription drugs for chronic disease, six generic US versions cost significantly less than their Canadian equivalents (FDA 2003). A Canadian study of 27 top-selling generic prescription drugs concluded that three-fourths of those drugs cost less in the US, and Canadians could save millions by access to the US versions (D’Angelo 2002). These findings are asserted by another study, which found that US, on average, had higher prices for new originator products, but had the lowest generic prices compared with countries including Canada, Chile, France, Germany, Italy, Japan, Mexico, and the UK. The US also had the lowest over-the-counter drug prices (Danzon and Kim 1998).
Costs involved in legalization of drug reimportation should not be neglected as well. The major emphasis for legalizing the practice of reimportation in the US has been the cost savings it offers. However, based on the estimates by Congressional Budget Office (CBO), enactment of the H.R. 2427 bill that allows reimporting drugs into the US would reduce total prescription drug spending by only about 1% or US$40 billion in the next decade (CBO 2003). Few economists and researchers have concurred that drug reimportation might not be a panacea for the soaring drug costs (Thompson 2004). To ensure the safety and authenticity of reimported/imported drugs, researchers have proposed using anti-counterfeiting technology for medication packages to avoid the entry of spurious prescription drugs in the US. According to the FDA estimates, this anti-counterfeiting technology would cost approximately $2 billion.

Policy implications and suggested potential solutions

Legalizing the reimportation practices might not solve the problem of growing prescription medication costs. Drug reimportation certainly involves potential threat of counterfeit drugs, which could result in additional costs to the healthcare system. The problem of high drug costs should be solved using the combination of most safe and appropriate treatment strategies wherever possible. One such strategy may be to promote use of FDA-approved generic drugs. Policymakers should promote policies allowing easy market entry of generic drugs and increasing awareness of Americans regarding costs-savings due to generic drug use.

The Medicare Part D, an enhancement of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, will be implemented in January 2006. This outpatient prescription drug benefit plan has a potential to transform American healthcare delivery by significantly reducing the costs of prescription drugs along with increasing access to medicines. A transitional drug discount card program that has been ongoing since mid-2004 may be useful for elderly consumers to manage their prescription drug expenditures.

The major challenge for the US policymakers is to provide an access to affordable and safe medications to consumers without diminishing revenues available for pharmaceutical R&D. Although few solutions are suggested in the literature, an in-depth analysis and effectiveness of these solutions is required to solve the prescription drug problem. Until then, drug reimportation will continue to be a conundrum for US policymakers.

Conclusions

From its inception, the two main objections against reimporting prescription drugs from across the border have been the safety and authenticity of these drugs that could jeopardize public health, and that the profits of drug companies which is used for R&D of new drugs would be seriously hurt. Views on reimportation are extremely polarized among supporters and opponents with each trying to justify their own interests. The legislative and administrative bodies do not take the responsibility of the reimported drugs. On the other hand, various consumer groups and organizations continue to support the drug reimportation. The motive for consumers is the direct cost-savings offered by purchasing drugs from across the border. Increasing support from consumers might push legislatives to closely ponder over the issue of legality of drug reimportation practices.

References


November 12, 2013

Hon. Paul R. LePage, Governor  
Office of the Governor 
1 State House Station 
Augusta, ME 04333-0001

Re: P.L. 2013, ch. 373

Dear Governor LePage:

The Maine Board of Pharmacy ("the Board") respectfully submits this Statement of Concern arising from the enactment of Public Law 2013, chapter 373, An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Pharmacies ("the Act"). The Board’s primary purpose is to protect the public health and welfare through the regulation of the practice of pharmacy and oversight of the dispensing, delivery, or distribution of prescription drugs to Maine citizens. The Act exempts from the Board’s regulatory oversight retail pharmacies located in and “licensed” by Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia, or New Zealand who export drugs to Maine citizens for personal use and those entities providing drugs from those pharmacies or facilitating their provision.

From our public protection perspective this exemption from regulatory oversight and compliance requirements causes great concern in an area of significant risk. We wish to bring to your attention and incorporate herein the attached National Association of Boards of Pharmacy District 2 Resolution highlighting concerns with permitting residents to obtain drugs from sources outside the United States. With no regulatory oversight of these entities and the drugs that they provide to Maine citizens, the Board will be unable to respond to complaints or to assure that standards for purity and quality of drugs have been met. Neither the Board nor Maine citizens will know...
where the drugs received from the exempt entities were manufactured. Nor will there be anyone in Maine that can confirm that they have received the correct drug and strength. Maine citizens have initiated 131 complaints this year against pharmacists and pharmacies that the Board does regulate. Some of those complaints involved receiving the wrong drug, including situations involving patient harm. The Board reasonably believes that there will be similar complaints regarding the exempt entities, but Maine citizens will be unable to obtain assistance from the Board or its investigatory and regulatory staff. Not until after something goes wrong will our citizens discover that the Board does not have authority to address their concerns, or that the importation of their drugs may violate federal law. The Board was established to make sure that pharmacists are competent and that the drugs Maine citizens receive are safe. Sadly, some Maine citizens will not have the Board’s protection. For these reasons, we respectfully issue this Statement of Concern.

Joseph Bruno, R.Ph., Board President  
Paul Chace, R.Ph., Member, Chain Representative  
Donald Watson, R.Ph., Member, Hospital Representative  
Shane Savage, R.Ph., Board Complaint Officer  
Kevin Holland, R.Ph., Member, Independent Representative  
Joseph Pietroski, Jr., Public Member  
Kirsten Martin, Public Member

Sincerely,

Geraldine L. Betts, Board Administrator

Cc:  Anne L. Head, Commissioner, Department of Professional and Financial Regulation  
     Michael Miller, Assistant Attorney General

Enc.  National Association of Boards of Pharmacy District 2 Resolution
**District 2 Resolution - Permitting Residents to Obtain Drugs from Sources Outside the US**

Whereas, Maine has enacted a law allowing state residents to obtain prescription drugs from sources outside the United States, and

Whereas, these drugs are not FDA-approved drugs and therefore, may not be safe and efficacious, and

Whereas, pharmacies located within the United States must be licensed by their resident Board of Pharmacy and may only dispense FDA-approved drugs, and

Whereas, NABP’s research indicates 97 percent of the internet sites do not conform with federal and state laws, often dispensing counterfeit drugs, and

Whereas, there is potential for imminent patient harm with no regulatory oversight from the United States and accountability,

Therefore, be it resolved that NABP continue its efforts in educating state policy makers and the public in the danger of obtaining prescription drugs from sources outside of the United States without federal and state oversight.

This resolution was passed at the NABP District I and II annual conference held October 17 – 19, 2013 in Bar Harbor, Maine and subject to ratification at the 110th National Association of Boards of Pharmacy annual conference in May 2014 in Phoenix, Arizona
British Virtual Drugstore Offers Maine Consumers Cheaper Prescriptions

By PATTY WIGHT

October 8, 2014

Maine consumers have a new option for buying prescription drugs online, at much cheaper prices. On Oct. 1, the so-called Great British Drug Store launched a website specifically for Maine residents that offers prescription medications at savings of up to 70 percent. But critics say Great British Drug Store's virtual move into Maine violates both U.S. and U.K. law.

Maine has 222 pharmacies, says Great British Drug Store Director Mary O'Brien. Her company wants to be number 223. "We're here to tell the people of Maine that buying from greatbritishdrugstore.com is essentially no different than buying from their local pharmacy, because we're supplying British drugs at British prices," O'Brien said.

Great British Drug Store is owned by Weldricks, a pharmacy chain with 61 locations in the U.K. Their entry into Maine is the result of a Maine law passed last year that allows consumers here to import prescription drugs from registered pharmacies in the United Kingdom, Canada, Australia, and New Zealand.

Any Mainer can simply go onto Great British Drug Store's website to order medication - so long as they provide a doctor's prescription and fill out a confidential health questionnaire. If the order is approved, the medication is shipped within 24 to 48 hours for $15.

"They're guaranteed that the medicine they're buying is coming from our U.K. dispensary, dispensed by a U.K. pharmacist," O'Brien said.

That state law that opened the door to these transactions is under legal challenge, and one of the plaintiffs in the suit is the Maine Pharmacy Association. Past president Kenneth McCall questions the safety of online pharmacies. He cites the case of another operation - Canadadrugcenter.com - that has also advertised cheap prescription drugs in Maine newspapers.

"And we found out, in fact, that the medicines they were shipping were not approved by Canada Health, and had nothing to do with Canadian pharmacists or pharmacies," McCall says. "In fact, they were from Mauritius, India, Turkey. So I caution people here in Maine to be alert, be skeptical. And to not just take what you read on an Internet website at face value."

McCall says Great British Drug Store itself violates U.K. law, which prohibits pharmacists there from filling prescriptions from doctors in the the U.S. But Great British Drug Store's Mary O'Brien says there's actually a legal work-around to that problem. "It's called shadow prescribing," she says.

Shadow prescribing works like this: A U.K. physician will review every order from Maine, and, if approved, will recreate the prescription and send it to be filled.

The sponsor of Maine's drug importation law, Democratic Sen. Troy Jackson points out that, for nearly a decade, hundreds of employees of the state of Maine and city of Portland ordered online medications before the program ended due to legal issues, which have been resolved in the new law.

"Not one problem ever arose in that time, because, again, they're "Tier 1' countries, same as this company is, and they have as good, if not better, safety standards than the U.S."

Too many Mainers, Jackson says, can't afford their medications - and now they have options.

A new report in the Journal of the American Medical Association examines how suspicious prescriptions for HIV medications indicate that HIV drugs are being diverted for resale on the black market.

The September 17th 2014 issue of the Journal of the American Medical Association (JAMA) reports that HIV medication is being purchased by devious means and then resold on the black market. Titled “HIV Drugs Targeted for Black Market,” the report theorizes, "expensive HIV medications are likely being targeted for resale on the black market.”

The report’s author, Bridget M. Kuehn, MSJ, cites a recent study by the Department of Health and Human Services (HHS) which found that of Medicare Part D claims for HIV medication in 2011-2012, “almost 1,600 Part D beneficiaries had questionable utilization patterns for HIV drugs.”

The HHS study found that questionable HIV medication beneficiaries “had no indication of HIV in their Medicare histories, received an excessive dose or supply of HIV drugs, received HIV drugs from a high number of pharmacies or prescribers, or received contraindicated HIV drugs (i.e., HIV drugs that should not be used in combination with one another). In total, Medicare paid $32 million for HIV drugs for these beneficiaries.”

The HHS study also found that beneficiaries that were questionable were most likely to live either in New York or Miami. The report describes a few examples of HIV drug prescription dispensations that were particularly egregious.

One example HHS cited was someone who had no medical record of ever having HIV: “In 2012, Medicare paid $33,536 for HIV drugs for a 77-year old Detroit woman who had no indication of HIV in her Medicare claims history. She had prescriptions for 10 different types of HIV drugs prescribed by 6 different doctors. There is no evidence that she visited any of these doctors.”

Another example cited a beneficiary with a high number of pharmacies and prescribers. A 48-year-old Miami resident received HIV drugs from 28 pharmacies using 16 unique prescribing physicians, which included 15 different types of drugs. The beneficiary received excessive doses and excessive supplies during the year. In total, Medicare paid $198,272 for the HIV drugs for this beneficiary.”

Ms. Kuehn spoke with Dr. Aaron S. Kesselheim of Harvard Medical School, who warned physicians to guard against identity theft by protecting access to Drug Enforcement Administration numbers, prescription pads, and other medical information. “Physicians should be aware of the potential for identity theft because substantial profits can be made from diversion of prescription drugs,” Kesselheim said.

In the last year there have been at least three different high profile HIV drug diversion cases in the United States. The Department of Justice (DOJ) describes a 2013 case from Texas, where two prescription drug wholesalers pleaded guilty to running a prescription harvesting scheme for HIV drugs.

In New York, indictments have been handed out to a Queens pharmacist who is alleged by the DOJ to have purchased HIV medications and other prescription drugs from poor patients for resale on the black market. Additionally, the DOJ reports that several arrests have been made at a Bronx grocery store that trafficked in expensive HIV medications purchased from local residents who had them prescribed for their HIV infections.

FDA Warns of New Fake Batch of Cancer Drug Avastin

By THE ASSOCIATED PRESS

October 6, 2014

WASHINGTON—The Food and Drug Administration is warning U.S. doctors about another counterfeit version of the cancer drug Avastin, the third case involving the best-selling Roche drug in the past year.

The FDA said in an online post Tuesday that at least one batch of the drug distributed by a New York company does not contain the active ingredient in real Avastin, which is used to treat cancers of the colon, lung, kidney and brain. The drug was distributed by Medical Device King, which also does business as Pharmalogical. The vials are packaged as Altuzan, the Turkish version of Avastin that is not approved for use in the U.S.

The agency warned doctors in April about a similar case of fake Turkish Avastin distributed by a U.K. distributor. Prior to that, the FDA announced in February an investigation into a different batch of fake Avastin distributed to doctors in several states. Both of those cases appeared to involve different networks of distributors than the latest incident.

The FDA said it's currently unclear whether any U.S. patients have received the drug. Specifically, Altuzan labeled with the lot numbers B6022B01 and B6024B01 may be counterfeit. Importing even authentic Altuzan into the U.S. is illegal, since the FDA has only reviewed Avastin as safe and effective.

The agency is asking doctors to stop using any products from Medical Device King, Pharmalogical or Taranis Medical, another affiliated business.

A telephone number listed on Medical Device King's website was not in service. Company representatives did not immediately respond to emails sent Wednesday.

Roche's Genentech unit sells Avastin in 120 countries and manufactures and packages the drug at eight sites worldwide. The drug had sales of $5.8 billion in 2012 and was Roche's second-best selling drug overall. The injectable drug usually sells for about $2,500 per vial.

The FDA warned doctors to be wary of drug prices that seem "too good to be true."

"Deep discounts may be offered because the product is stolen, counterfeit, substandard, or unapproved," the agency states.

Incidents of counterfeiting reported by drugmakers have increased steadily over the past decade, though only about 5 percent of cases are typically reported in the U.S. The rise in counterfeiting comes as pharmaceutical supply chains increasingly stretch across continents. More than 80 percent of the active ingredients used in U.S. pharmaceuticals are now manufactured overseas, according to a recent congressional report.

Three percent. If you’re ordering prescription medicines online, those are the chances that you are buying from a legitimate, accredited internet pharmacy. With odds that slim, is it really worth it to risk your safety for savings that are nearly always too good to be true?

Unfortunately, the answer for many American patients is still yes. Drug counterfeiting, aided by the explosion of Internet pharmacies and the ease of online purchasing, is a multibillion dollar industry. And although our government has taken steps to make patients aware of the risks of purchasing medicines from illegal online pharmacies, it’s clear that we still have a long way to go in our education efforts.

Two years ago, America was shocked by counterfeit versions of the cancer drug Avastin that had infiltrated our secure supply chain and found their way to patients. That’s because for the first time, it became clear to many U.S. policymakers, patients, and the media that counterfeit medicines weren’t just a problem restricted to what many considered to be “lifestyle” drugs, like diet pills or erectile dysfunction treatments. This was cancer, and the fact that someone actually went to the trouble to produce, advertise and sell fake cancer medicine should leave no doubt about the types of criminals we’re dealing with.

The Avastin incidents happened to a large extent because healthcare professionals like doctors and purchasing managers for oncology clinics bought and administered the counterfeit medicines to their patients. If people who should clearly know better can behave in this way, the average American doesn’t stand much of a chance against professional scammers who stand to get rich by preying on innocent patients over the internet.

The magnitude of the problem that we can actually quantify is staggering. Earlier this year, the United States was one of 111 countries participating in INTERPOL’s Pangea sting operation, which led to nearly 11,000 illegal online pharmacies being shut down, the removal 19,000 ads for fake drugs on social media sites, the seizure of 9.4 million doses of phony medicines. And last month, Google agreed to spend $50 million annually over the next five years to crack down on advertising for illegal online pharmacies. The sheer size of these numbers means that although incremental progress is certainly being made to protect patients, much more work remains before we can eradicate the threat of counterfeits.

Congress and our federal government must take a more serious look at the problem, and work toward solutions that can drastically reduce, if not eliminate, the menace of counterfeit drugs. First and foremost, patient awareness isn’t anywhere near the level it needs to be to ensure people can make informed decisions when purchasing medicines over the internet. Agencies like the FDA should be given the resources to better educate Americans about the health and safety dangers from purchasing from rogue online pharmacies.

And in order to get to the root of the problem, stopping those who are manufacturing and selling potentially lethal fake medicines, law enforcement agencies should have appropriate funding to more aggressively pursue counterfeiters and put them behind bars. This is especially true for the overtasked, underfunded and very small Office of Criminal Investigations (OCI) within the FDA. Lastly, legislation should be enacted to give FDA/OCI administrative authority to require production of documents to assist in their Internet and related investigations, and increase penalties for trafficking in counterfeit, substandard, unapproved, and misbranded drugs.

In this era of federal budget cuts, resources are understandably scarce. However, with new illegal and fake internet pharmacies popping up far faster than regulators and law enforcement can ever shut them down, more needs to be done. The FDA and other agencies are doing the best with what they have, but Congress and the Obama Administration must get more involved. The risks to patients are simply too great to merely hope that another Avastin incident doesn’t happen again.

Drug Supply Chain Integrity News and Events

- May 9, 2014: Illegal Drug Company Gallant Pharma and Co-Founder Sentenced
- April 30, 2014: Two Officers of Long Island Based Company Indicted for Sale of $17 Million Worth of Misbranded Prescription Drugs Including Counterfeit Cancer Drugs
- March 7, 2014: Co-Leader of Illegal Drug Company Gallant Pharma Sentenced to 3 Years
- January 30, 2014: New York Man Arrested on Charges He Conspired With Others Involving Sales of Illegally Diverted Prescription Drugs
- January 29, 2014: Seven Oncologists Ordered to Pay Nearly $2.6 Million for Importing Unapproved Drugs
- January 10, 2014: Guilty Plea in Counterfeit Viagra and Cialis Case
- December 20, 2013: Fox Chapel Woman Sentenced to Probation for Smuggling Anti-Cancer Drugs into U.S. for Sale at Stanton-Negley Pharmacy
- December 20, 2013: Local Doctor Pleads Guilty in Misbranding Drugs Case
- December 16, 2013: Federal Jury Convicts Greeneville Oncologist And Practice Manager Of Violating Food, Drug And Cosmetic Act - Cancer Clinic Purchased Unapproved Drugs For Three Years
- December 13, 2013: Owner of Bluegrass Women's Healthcare in Elizabethtown Ordered to Pay Victims $50,663.31 for Misbranding
- December 4, 2013: Alvarado Pharmacy and Owner Plead Guilty to Importing Unapproved Oncology Drugs and Fraudulently Billing Medicare
- November 25, 2013: Letters to Doctors about Risks of Purchasing Fraudulent Versions of Botox from “Online Botox Pharmacy” and “onlinebotox.com”
- September 19, 2013: Pittsburgh Oncology Practice Pleads Guilty to Buying Unapproved Foreign Drugs
- August 12, 2013: Attorney General Conway Announces Sentencing of Grayson County Doctor for Use of Non-FDA Approved Birth Control Device
- August 7, 2013: Eleven Charged in Alleged Illegal Pharmacological Import and Distribution Scheme
- August 6, 2013: Two Men Charged in Texas and Arrested for Smuggling Counterfeit Viagra
- July 23, 2013: Pensacola Man Indicted For Counterfeit “Viagra” Trafficking
- Brookings Institution Meeting Summary: Reducing the Threat of Counterfeit and Unapproved Drugs in the Clinical Setting
- July 12, 2013: Paul Daniel Bottomley Sentenced in U.S. District Court
- July 11, 2013: English Citizen Sentenced for Distributing Adulterated and Counterfeit Cancer Drugs
- June 27, 2013: FDA takes action to protect consumers from dangerous medicines sold by illegal online pharmacies
- June 27, 2013: Letters to Doctors about Suspect Prescription Drugs Distributed by Medical Device King
- June 11, 2013: Johnson City Physician Sentenced to Serve Two Years in Prison for Unapproved Foreign Drugs
- June 3, 2013: Illinois Man Sentenced to Serve 72 Months in Prison for Conspiring to Distribute Prescription Drugs Over the Internet
- April 26, 2013: Fraudulent Versions of Botox Found in the United States
- February 5, 2013: Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in United States
- January 23, 2013: La Jolla Oncologist and Medical Practice Plead Guilty to Dispensing Unapproved Drugs
- December 19, 2012: Letters to Doctors about Risks of Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers
- December 11, 2012: Johnson City Physician Pleads Guilty To Receiving Unapproved Drugs
- September 9, 2012: Manager of Johnson City Cancer Clinic Pleads Guilty to Receiving Unapproved Drugs
- August 23, 2012: California Man Sentenced for Importing Adulterated Cancer Drugs; Forfeits $1.4 Million & Land Rover Automobile

Know Your Source: Protecting Patients from Unsafe Drugs

Beware of Rogue Wholesale Drug Distributors

Wholesale drug distributors are a link between manufacturers and health care professionals. Their role is to ensure prescription medications are delivered safely and efficiently to thousands of health care practitioners and pharmacies nationwide every day.

While the U.S. health care supply chain is one of the most secure and sophisticated in the world, there is a growing network of rogue wholesale drug distributors selling potentially unsafe drugs in the U.S. market.

Reduce the Chance of a Potentially Unsafe Drug Reaching Your Patients

In order to protect your patients from unsafe or ineffectve drugs, FDA urges health care professionals to verify that their supplier is licensed by the state. Drugs from rogue wholesale drug distributors may harm your patients and expose them to unknown risks or side effects. FDA advises health care providers to know the source for prescription drugs.

Verify that Your Wholesale Drug Distributor is Licensed in Your State

- http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm

URL: http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm
Prescription Drug Imports: Maine Leads, the Nation Follows?

By THOMAS HEMPHILL

November 12, 2013

On October 9, 2013, Maine became the first state government to legally allow its residents direct access to the importation of prescription drugs, albeit limited to properly licensed mail-order pharmacies operating from Canada, the United Kingdom, New Zealand, and Australia. This legislation, the “Act to Facilitate the Personal Importation of Prescription Drugs from International Mail-Order Pharmacies,” was introduced after Maine businesses were banned in August 2012 by then State Attorney General William Schnieder from purchasing less expensive pharmaceuticals from brokers in Canada.

Prescription drug importation has been a controversial topic over the last decade or so, with many states exploring the possibilities of allowing consumers and businesses importing pharmaceuticals – earlier in the decade at the behest of their senior citizens (who received a prescription drug benefit (Part D) added to Medicare effective January 1, 2006). More recent state-level efforts at exploring pharmaceutical imports legislation are being supported by cash-strapped small businesses and local governments searching for opportunities to reduce employee health care expenses.

At the federal level, the Obama administration initially proposed allowing some importation of pharmaceuticals (above and beyond the present exemption by the U.S. Food and Drug Administration (FDA) for which an effective treatment may not be available domestically) in the Affordable Care Act, but dropped this proposal after fervent opposition from the pharmaceutical industry. In 2012, Senator’s John McCain and Al Franken co-introduced an amendment to the re-authorization of the Food and Drug Administration Safety and Innovation Act to allow pharmaceuticals to be imported into the U.S. through verified Canadian online pharmacies. This amendment failed due to aggressive opposition from pharmaceutical manufacturers.

Under their socialized healthcare systems, foreign governments utilize their bulk-purchasing power to negotiate significantly lower prices than what American consumers are presently paying. Pharmaceutical industry research & development (R&D) costs are significant, with market research firm Kalorama Information reporting global pharmaceutical R&D spending exceeding $95 billion in 2009. Moreover, columnist Matthew Herper has calculated that the average drug developed by a major pharmaceutical company costs at least $4 billion, and as much as $11 billion, based on data on total R&D spending in the pharmaceutical industry from 1997-2011. Many Americans believe that if we are subsidizing the pharmaceutical industry’s R&D, then it is only equitable that U.S. taxpayers should also be benefitting from substantially lower consumer prices, and not the inverse.

The primary opposition to Maine’s legislation, however, is focused on consumer pharmaceutical safety and validity concerns. While Maine residents are now allowed to order these lower cost pharmaceuticals, it is the responsibility of the state’s citizenry to find reputable foreign pharmacies. Consumers are recommended to use only online and mail-order pharmacies that have been properly accredited and licensed by appropriate third-party organizations. In a formal statement, the Pharmaceutical Research and Manufacturers Association (PhRMA), the industry’s preeminent association, argues the following:

Importing drugs from other countries, outside of FDA’s purview, risks patient safety. For example, pharmacies that claim to be Canadian, Irish, or British over the internet may have no ties at all to Canada, Ireland, or the United Kingdom. Many pharmacies based in these countries obtain their drugs from third-world sources such as India, Thailand, and the Philippines.

The FDA (or the State of Maine), because it does not have oversight authority over foreign countries’ pharmaceutical distribution systems, cannot provide protection to American citizens against the possibility of counterfeit drugs, untested medications, foreign copies of FDA-approved pharmaceuticals, expired drugs, contaminated drugs, and pharmaceuticals warehoused under inappropriate and unsafe conditions. According to the FDA, it is illegal for an individual citizen to import prescription drugs into the U.S., whether for personal use or otherwise. However, in certain discretionary exceptions, such as when the intended use of the drug is for a serious condition for which effective treatment may not be available domestically, the FDA allows an individual entering the U.S. to import a three-month supply of an “unapproved” drug. The general policy of the FDA, however, is not to enforce the law against individuals,
but to focus its enforcement efforts on businesses profiting from this illegal activity and providing public education on the potential safety and validity issues with importing drugs.

Maine’s new law on prescription imports has resulted in a complaint and motion by Maine industry associations for a preliminary injunction to block implementation of the law in U.S. District Court in Portland, and in turn, the State of Maine has opposed plaintiff’s motion for preliminary injunction and moved to dismiss the complaint. There is always the possibility that the FDA may yet enter the legal fray to block implementation of the law, and likely has the backing of substantive case law to obtain an injunction. The lack of a comprehensive – or consistent – enforcement policy on the part of the FDA has left the issue of prescription drug importation in regulatory “limbo.”

When it comes to the potential for personal injury or death due to tainted, substandard or counterfeit pharmaceuticals, the FDA’s “gold standard” for regulating pharmaceutical safety is one in which Americans remain confident. The fact that this is a question of international trade also requires the regulatory involvement of the Federal government. For Maine’s government or any state governments that follow Maine’s lead, to basically operate with a “buyer beware” edict, is simply bad public policy. With the potential for a significant increase in the volume of American prescription drug prescriptions from other states following Maine’s legislative lead, will these foreign pharmacies be able to maintain the safety and validity of their prescription supply chains? Is Maine’s legislation a prescription for future American consumer health care tragedies? Federal government edicts may yet intervene before these troubling public policy questions are answered.

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Complaint challenges legality of Canadian company’s medication sales to Mainers

By ERIC RUSSELL

April 8, 2014

The president of the Maine Pharmacy Association has filed a complaint with state regulators alleging that a Canadian company broke state law by selling him generic drugs from prescriptions that were filled in India, Turkey and Mauritius.

In a complaint to the Board of Pharmacy, Kenneth “Mac” McCall, who is also an associate professor at the University of New England School of Pharmacy, says that Maine law requires the company, Canada Drug Center, to sell Maine consumers only drugs that are made or processed in Canada.

Although McCall said he filed his complaint independently, it follows a federal lawsuit filed last fall by several interest groups that want to overturn Maine’s new law – including the Maine Pharmacy Association.

“For me, I think it’s important that Mainers know what they are getting,” McCall said in an interview. “It’s a matter of safety.”

It’s not clear yet how the Board of Pharmacy will respond to McCall’s complaint, but the outcome will interest thousands of Mainers who turn to Canadian sources for more affordable prescription medications, despite warnings from the Food and Drug Administration and consumer groups about the risks of online drug purchases.

The exact number of Mainers who are buying drugs from outside the U.S. is not known.

A lawyer for Canada Drug Center, which has filed a formal response with the Board of Pharmacy, questioned McCall’s motives in an interview.

“In his position as president of the Maine Pharmacy Association, he has a vested interest in the campaign that is attempting to prevent citizens of the state of Maine from having access to safe and affordable medications from sources outside the United States,” said John Myers, an attorney in Winnipeg, Manitoba.

The pharmacy association is the state’s professional trade group for licensed pharmacists, pharmacy technicians and pharmacy students.

McCall said his curiosity was piqued when he noticed a newspaper ad for lower-priced prescription drugs in November, not long after the law took effect to allow retail pharmacies in Canada, the United Kingdom, Australia and New Zealand to sell drugs to Mainers.

The newspaper ad offered consumers less expensive, generic forms of popular prescription drugs such as Celebrex (an anti-inflammatory used to treat arthritis), Nexium (to treat heartburn) and Advair (a steroid used to treat asthma, emphysema and chronic obstructive pulmonary disorder).

“Are you still paying too much for your medications?” the ad asked. The company selling the drugs was not identified, but there was a toll-free number, which McCall called.

He was directed to a website, CanadaDrugCenter.com, where he ordered three medications: Cobix, the generic equal of Celebrex; Izra, the generic version of Nexium; and Clopivas, the generic equivalent of the popular blood thinner Plavix.

When McCall’s order arrived, the labels showed that the drugs had been manufactured not in Canada but in India, and that the prescriptions had been filled in Turkey, India and Mauritius, an island in the Indian Ocean off the coast of Madagascar.

McCall says Canada Drug Center is a pass-through company that doesn’t produce or manufacture anything. He said it merely provides a mechanism for Mainers to gain access to cheaper medications from abroad.
IMPORTS FROM SELECTED COUNTRIES

In his complaint to the Board of Pharmacy, McCall quotes from Maine law, which says: “A licensed retail pharmacy that is located in Canada, the United Kingdom of Great Britain and Northern Ireland, the Commonwealth of Australia or New Zealand that meets its country’s statutory and regulatory requirements may export prescription drugs by mail or carrier to a resident of this state for that resident’s personal use.”

The Legislature passed the law last year in response to a decision in 2012 by the attorney general at the time, William Schneider, who concluded that Canadian pharmacies were not legally licensed to do business in Maine.

Schneider’s decision was a blow to another Canadian company, CanaRx, which had been providing low-cost medications since 2003 through the MaineMeds program, which served employees of the city of Portland and the state government.

The law was meant to allow CanaRx to continue operating, but it was written to allow pharmacies in Canada, Australia, New Zealand and the United Kingdom to export prescriptions by mail through unlicensed entities. As long as those pharmacies meet their own countries’ statutory and regulatory requirements, they do not need separate licenses in Maine.

Jessica Grondin, spokeswoman for the city of Portland, said employees can order brand-name medications through the voluntary Portland Meds program, which receives mail order prescriptions from pharmacies in Australia, the United Kingdom and New Zealand.

“We are satisfied with the program, given the cost savings that we’ve seen,” Grondin said.

The FDA generally urges consumers to be wary of buying drugs online, including from Canadian companies. The agency notes on its website that it does not have the authority to regulate drugs sold in Canada, and that its counterpart, Health Canada, may not have control over drugs that are sold only for export to the United States.

The FDA recommends buying only from licensed pharmacies in the United States.

ATTORNEY DEFENDS CANADA CENTER

Myers, the lawyer for Canada Drug Center, said the company’s customers are “fully informed” about where their pharmaceuticals come from. He said McCall was told at several stages in the placement of his order and never objected.

In a formal response to McCall’s complaint to the Board of Pharmacy, Myers noted that the Canada Drug Center website lists several nations where orders may be filled and shipped, including the countries from which McCall received his medications. The company said all pharmacies that fill its orders are certified by PharmacyChecker, an independent company in New York that evaluates online pharmacies.

McCall said that even though Canada Drug Center discloses where its drugs come from, their sale in Maine may be illegal.

He also noted that Canada Drug Center is on the National Association of Boards of Pharmacy’s list of “not recommended sites.” The association is the national organization for state pharmacy associations, including Maine’s.

Its list of approved Internet pharmacies includes 35 pharmacies, all of which appear to be operated by U.S. companies. Its list of “not recommended sites” runs into the thousands and includes numerous foreign companies.

The association says the sites it doesn’t recommend “appear to be out of compliance with state and federal laws” or the organization’s patient safety and pharmacy practice standards.

McCall said it’s worth noting that Canada Drug Center does not offer its prescriptions to Canadians, only to consumers in the U.S. and elsewhere.

“That is telling,” McCall said. “Maine people should know that information.”

ETHICS OF PLAINTIFF QUESTIONED

McCall said he went to his primary care physician to get the prescriptions that he ordered from Canada. He would not identify the doctor.
Myers criticized McCall for acting as “a detective of some sort” and obtaining prescriptions “under false pretenses.”

He said in his response to the complaint that “Mr. McCall’s unethical behavior is the only thing that the committee considering this complaint should be concerned about.”

As president of the Maine Pharmacy Association, McCall represents one of several plaintiffs in a federal lawsuit filed last fall that aims to overturn the new law. In their 23-page complaint, the plaintiffs argue that the law could threaten patient safety.

“Prescription drugs shipped to Maine by foreign pharmacies pursuant to the (law) are not subject to any of the quality and safety controls put in place by the federal government in order to protect persons who rely on prescription medications,” the complaint says. “The (law) therefore puts Maine residents at risk of serious harm.”

The lawsuit is still pending. Oral arguments could begin as soon as this month.

URL: http://www.centralmaine.com/2014/04/08/complaint_challenges_legality_of_canadian_company_s_medication_sales_to_mainers/
AUGUSTA, Maine — The hunt for cheaper prescription drugs long has led consumers to reach beyond U.S. borders, but under a Maine law set to take effect Wednesday, their search now will have the state's blessing.

The law, the first of its kind, sanctions the direct purchase of mail-order drugs from some foreign pharmacies. It has ignited a court battle with the pharmaceutical industry and set the stage for a broader fight over access to less-costly medication.

“If Maine can do this, other states will do this. It could have a big impact on pharmaceutical companies' long-term profits and desire to invent new medications,” said Boston University economics professor Laurence Kotlikoff, who researches drug imports. “On the other hand, in some areas, they [drug makers] need to be brought back in line.”

Drug makers argue in a lawsuit that the practice could expose residents to tainted or counterfeit medication, and that it interferes with U.S. Food and Drug Administration oversight. Supporters say the industry is worried about a hit to its bottom line. “It’s not a safety issue,” Republican Gov. Paul LePage said in an interview. “It’s turf.”

For years, some companies and municipalities in the Canadian border state have been setting up drug plans with foreign pharmacies. For Portland, the practice saved Maine's largest city $3.2 million between 2004 and 2012 for employees' drugs, Mayor Michael Brennan said. There were no safety issues, he said.

Using the broker CanaRx, Portland pays $200.90 for a 90-day supply of 40 mg tablets of the heartburn drug Nexium, and it waives any employee copay. For the same order as negotiated by Portland's health insurer, Aetna Inc., the city says it pays $621.08, with the employee contributing 25% of that, or $155.27.

More than a dozen states, including Illinois and Kansas, have explored importing medications at the urging of older residents, but a prescription-drug benefit added to Medicare in 2006 quieted the movement.

Americans generally pay more for drugs than residents of countries where the government imposes pricing caps or negotiates prices with drug makers.

The FDA prohibits importing medication by any means, but the agency rarely enforces the ban among consumers. An FDA spokesman, citing the federal government shutdown, said the agency was unable to comment.

One Maine company that already imports drugs is Hardwood Products Co., which makes wooden sticks used in frozen treats and corn dogs, and employs 440 people around the rural community of Guilford. Access to international pharmacies cuts its annual health-care costs up to $600,000, company officials said.

Without the benefit, they said, copays can run hundreds of dollars a year each for factory workers. “I can afford to do that. But many of our employees cannot, and that really hurts,” said general manager Terry Young.

Local pharmacists grew alarmed in 2012 after the Maine State Employees Association, which represents thousands of workers, contracted with CanaRx, said Kenneth McCall, head of the Maine Pharmacy Association. He said the contract would have hurt the pharmacies' revenue, but also was concerning because CanaRx wasn't subject to Maine's oversight. In response, then-Attorney General William Schneider halted drug-importation programs last year by all employers, saying they violated state law.

CanaRx was issued two FDA warning letters in 2003. Chief Executive G. Anthony Howard said the issue concerned a shipment of insulin, which needs to be kept at a certain temperature range, that wasn't delivered in a timely way. The
company since has stopped shipping temperature-sensitive drugs, he said. “We're very proud of our safety record and we'll stand behind our products 110%,” he said.

In June, Maine legislators stepped in, removing the state licensing requirement for accredited pharmacies in Canada, the U.K., New Zealand and Australia. Major drug companies, including Pfizer Inc., Eli Lilly & Co. and Johnson & Johnson, as well as retail drug chain Rite Aid Corp., opposed the move. A Pfizer spokesman said drug imports raise “serious safety concerns,” because tracking them for safe handling or validity is difficult.

The law triggered a challenge in U.S. District Court in Portland from Maine pharmacy groups and the Pharmaceutical Research and Manufacturers of America, the first lawsuit from the drug-industry trade group against a state over drug importation.

Pharmacists want the court to clarify that drug importation is illegal, said Joe Bruno, CEO of Community Pharmacies, a Maine chain. He said they have been disappointed in the response from the FDA, which in a recent letter indicated it would concentrate its efforts on educating the public about the potential hazards of imported drugs.

“We wanted the FDA to step in and say it's against the [Maine] law, but they kind of did a little soft-shoeing around it,” he said.

Maine officials say they are confident residents are getting legitimate medication through well-regulated supply chains. But some Canadian pharmacies have outsourced prescriptions from Americans to operations in Turkey and India, said John Horton, president of Portland-based LegitScript LLC, which vets online pharmacies and works with the FDA and Google Inc. to identify rogue operators. Some drugs ultimately were found to be misbranded or counterfeit, he said.

Americans have crossed the Canadian border for prescription drugs since the 1950s and would have stopped if the drugs were unsafe, said Tim Smith, a general manager at the Canadian International Pharmacy Association, which represents drugstores that ship to Americans.

URL: http://online.wsj.com/news/articles/SB10001424052702303442004579123613325473946