Maine
PHARMACY ASSOCIATION
PO Box 7033 Ocean Park Maine 04063

February 19, 2013

Dear Senator Patrick, Representative Herbig and members of the LCRED Committee,

INTRODUCTION:

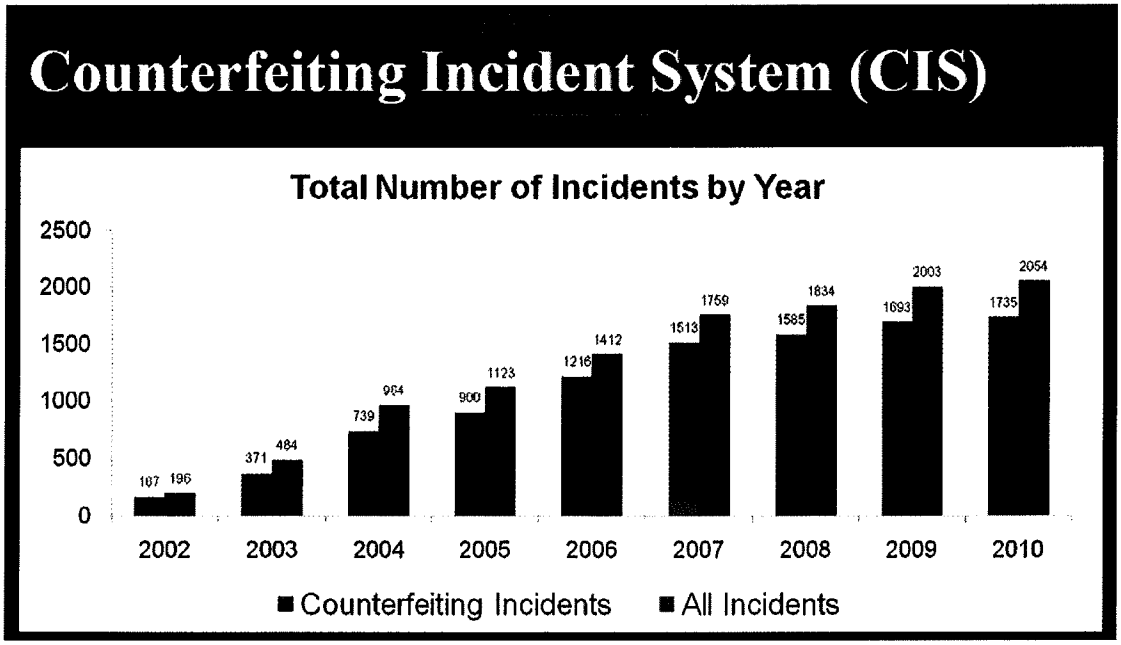
On behalf of the Maine Pharmacy Association, I am writing in opposition to LD 171: An Act To Facilitate the Licensing of International Mail Order Prescription Pharmacies by the Maine Board of Pharmacy. Last year, the Attorney General ruled that CanaRx had violated state laws by dispensing prescription drugs without a license and ordered the company to cease operations in Maine. This bill amends the Maine Pharmacy Act in order to authorize the licensing of international mail order pharmacies and authorize the importation of prescription medications to residents of Maine. LD 171 elicits a strong response from individuals both for and against the bill because it affects the fundamental aspects of our healthcare system; access, cost, quality and safety.

Seventy-five years ago, Congress responded to widespread instances of unsafe drugs by enacting the Food, Drug, and Cosmetic Act to create a strong drug regulatory system requiring that drugs be tested before marketing, manufactured under exacting standards, prescribed by licensed physicians, and dispensed by state licensed pharmacies and pharmacists. In 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent counterfeit, adulterated, misbranded, subpotent and expired drugs from entering the United States. Under these laws, it is illegal to import unapproved foreign versions of US approved prescription drugs and it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the US. These laws were enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the US in large volumes. In one instance, over 2 million unapproved and ineffective Ovulen-21 contraceptive tablets were distributed into the US from Panama.

The US regulatory system has enabled our citizens to have the safest, most advanced prescription drug supply in the world. Every day, millions of Americans are successfully treated by safe and effective medications. The efficient distribution of safe and effective drugs in the United States is commonplace and often taken for granted. Subsequently, many urban myths have evolved about the safety of our drug supply system and the importation of drugs from outside that system. I appreciate the opportunity to discuss these misconceptions and the facts regarding the importation of prescription drugs.

MYTH: People in Maine are not at risk from counterfeit, substandard and ineffective drugs

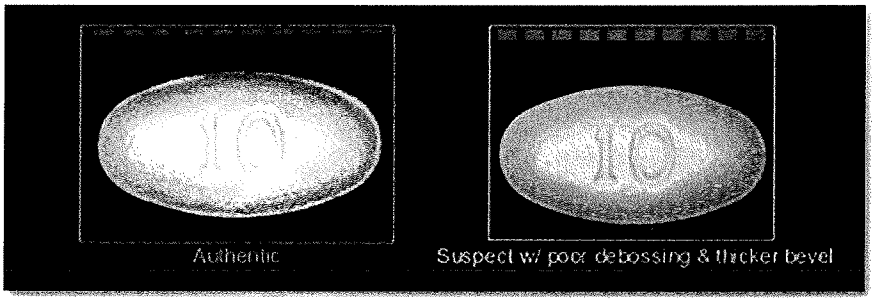
This myth is largely true because of the layers of regulatory safeguards in the US drug supply chain. However, our system is under increasing attack from a sophisticated international network of counterfeit drug suppliers. According to the Partnership for Safe Meds, the number of counterfeiting incidents rose by over 900% in just eight years from 167 in 2002 to 1,735 in 2010.



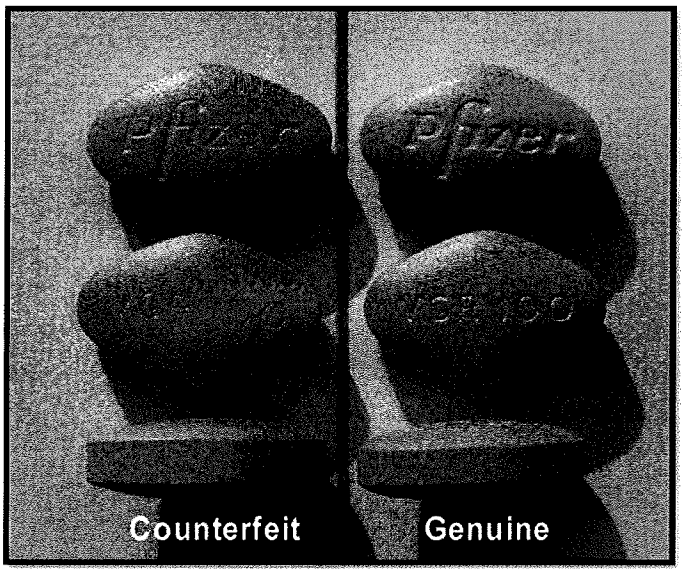
Examples of counterfeit prescription medications that have entered the US through international mail order pharmacies according to FDA press releases include Ortho Evra contraceptive patches that contained no active ingredient, contaminated Procrit used to treat severe anemia, substandard Lipitor tablets for cholesterol, substandard Viagra tablets for erectile dysfunction, injectable Avastin chemotherapy that contained no active ingredient for cancer treatment, Ambien tablets for insomnia that contained a powerful antipsychotic drug – haloperidol, Xenical capsules that contained a central nervous system and cardiac stimulant – sibutramine, and many other counterfeit and adulterated drugs. At a time when the United States faces an unprecedented risk from international networks which sell and distribute counterfeit medications for profit, LD 171 would circumvent the FDA safety system in Maine and open the floodgates to substandard and unsafe medications.

MYTH: I know that my imported prescriptions are the real thing.

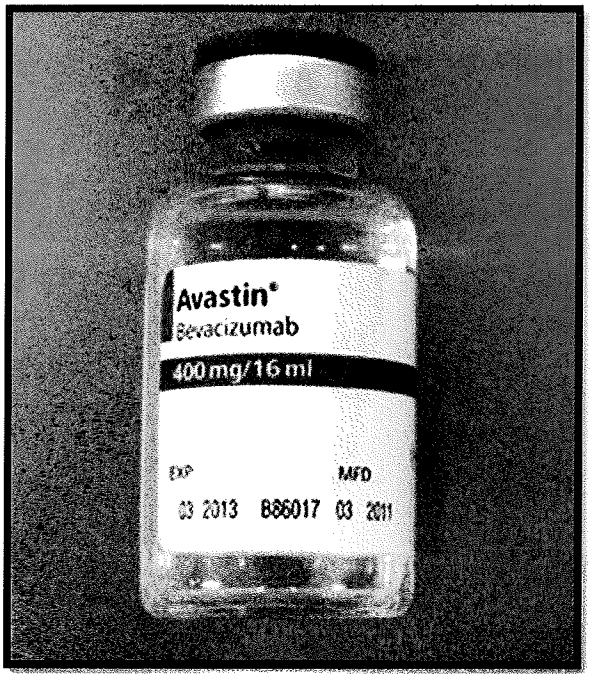
Counterfeiters use very advanced means to produce their products. It can be difficult, if not impossible, to tell the real product from an imposter without sophisticated equipment. Here are several examples of authentic and counterfeit prescription medications.



Lipitor 10mg: http://www.fda.gov/Drugs/DrugSafety/ucm180912.htm



Viagra 100mg: http://www.fda.gov/Drugs/DrugSafety/ucm180905.htm



Avastin 400mg/16ml vial: http://www.fda.gov/drugs/drugsafety/ucm291960.htm

Even if a pharmacist, much less a consumer, could detect the physical and visual differences, they would not be able to tell if the correct active ingredient was present and in what amount. In the case of counterfeit Avastin for cancer treatment, this substandard product entered the US via an unlicensed distributor in England (one of the countries utilized for pharmaceutical distribution by CanaRx). The CanaRx website provides the following reassurance, *"Although the drugs you receive may look slightly different or have a different name than the one you are used to, for all intents and purposes they are identical."*

MYTH: Although the drugs from international mail order pharmacies often are labeled by different names than the US approved versions, patients will know what they are taking and patients will take these meds correctly.

Filling US prescriptions at an international pharmacy may inadvertently contribute to harmful pharmacy errors by giving patients the wrong drug for treating their health condition. According to the Institute for Safe Medication Practices and an FDA Public Health Advisory, at least 18 foreign drug products use the same brand name as an FDA-approved medication but contain a different active ingredient. For example, a US citizen filled a prescription for Dilacor XR (diltiazem extended release in the US) at a Serbian pharmacy and was given digoxin because in Serbia, Dilacor is brand name for digoxin. The patient continued taking digoxin rather than diltiazem until he suffered life-threatening drug toxicity and was hospitalized.

The FDA has also found 105 US brand names that look or sound so much like foreign brand names that consumers are at significant risk for medication errors. For example, Ambien is brand name for zolpidem (a treatment for insomnia) in the United States while Ambyen is brand name for amiodarone (a treatment for abnormal heart rhythms) in England. When, not if, a citizen of Maine takes the wrong medication or takes his/her medication incorrectly and suffers harm because the prescription is labeled by the international mail order pharmacy with a different name, who is responsible? What recourse for injuries does the citizen in Maine have under these circumstances?

MYTH: The solution to safely importing prescription drugs is as simple as licensing the international mail order pharmacy.

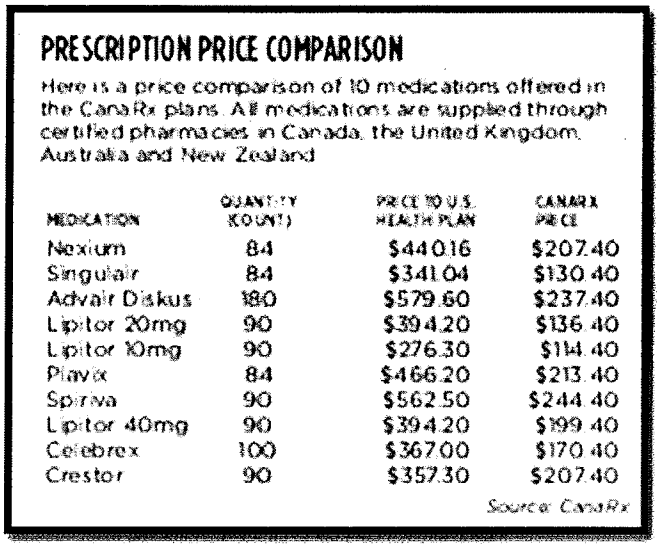
This myth has three significant fallacies. First, The US drug supply system is one of the safest in the world because of the many layers of safeguards in the drug manufacturing, monitoring and distribution process. Licensing the pharmacy is only one link in the drug supply chain. Without licensing and oversight of each step in the drug supply chain, counterfeit and substandard drugs would break through the weakest link and into the US healthcare system. For example, LD 171 does not address the licensing and oversight of international pharmaceutical wholesalers and pharmaceutical distributors. Neither does this bill address licensing and oversight of manufacturing quality by international pharmaceutical companies. Neither does LD 171 address the licensing of pharmacists who dispense medications at international mail order pharmacies or the licensing of physicians who rewrite US prescriptions as reported on the CanaRx website. Licensing international mail order pharmacies and expecting safe prescription drugs without licensing the international wholesalers, manufacturers, pharmacists and physicians is an unrealistic expectation.

Secondly, authorizing the Maine Board of Pharmacy to enter into reciprocal inspection agreements with any country assumes that the department has adequate resources to monitor and enforce these international agreements. The key difference between a reciprocal inspection agreement between the Maine Board of Pharmacy and another state versus the Maine Board of Pharmacy and another county is that the latter is outside the regulatory scope and safety of the Federal Government and US FDA. The regulatory oversight of these international agreements by the Maine Board of Pharmacy would be enormous. In fact, John Taylor (former US Associate Commissioner for Regulatory Affairs) in a 2004 letter to the Senate Committee on Government Affairs stated "States face many obstacles when it comes to regulating online pharmacies. State pharmacy and medical boards have limited resources for enforcement."

Third, authorizing the importation of prescription medications violates federal law. Several municipalities and states including Maine have initiated programs whereby their employees or constituents could be directed to Canadian pharmacies to purchase Canadian drugs. The largest program to date was initiated by Illinois ex-Governor Rod Blagojevich. This program was the I-Save Rx program administered by CanaRx. Before the I-Save Rx program ceased operation, it grew to include residents of Illinois, Wisconsin, Missouri, Kansas, Vermont and Rhode Island. In September, 2006, the Illinois Auditor General issued a report concluding that the program was in violation of federal law. The report also concluded that program safety inspections were inadequate.

MYTH: Companies like CanaRx provide brand-name medications at discounts of about 50 percent.

Companies like CanaRx often make false claims about the potential savings to patients and employers. For example, CanaRx provided a price comparison of ten brand name drugs to the Portland Press Herald in a September 14, 2012, article titled, "Why are drugs from CanaRx cheaper than those in Maine."



PRESCRIPTION PRICE COMPARISON

Here is a price comparison of 10 medications offered in the CanaRx plans. All medications are supplied through certified pharmacies in Canada, the United Kingdom, Australia and New Zealand

MEDICATION	QUANTITY (COUNT)	PRICE TO U.S. HEALTH PLAN	CANARX PRICE
Nexium	84	$440.16	$207.40
Singulair	84	$341.04	$130.40
Advair Diskus	180	$579.60	$237.40
Lipitor 20mg	90	$394.20	$136.40
Lipitor 10mg	90	$276.30	$114.40
Plavix	84	$466.20	$213.40
Spiriva	90	$562.50	$244.40
Lipitor 40mg	90	$394.20	$199.40
Celebrex	100	$367.00	$170.40
Crestor	90	$357.30	$207.40

Source: CanaRx

Source: CanaRx – Portland Press Herald, September 14, 2012

Of these ten prescription drug products, five (Singulair, Lipitor 10mg, Lipitor 20mg, Lipitor 40mg and Plavix) were already available generically to patients and health plans in the United States at significantly lower prices. Furthermore, two other prescription products (Nexium and Crestor) in the CanaRx comparison have multiple US generic counterparts in the same drug class. Additionally, the "Price to US Health Plans" according to CanaRx for these products was inflated and did not reflect true US market prices. Therefore, the entire price comparison provided by CanaRx was disingenuine and misleading. For example, CanaRx claimed that the US price of #84 Singulair tablets was $341.04 versus the CanaRx price of $130.40. When, in fact, the price of #84 generic Singulair tablets in the US was less than $50 at the time of this publication. These inaccurate price comparisons by CanaRx have also been provided to states and municipalities as a justification for their program.

Sometimes, US FDA approved drugs are more affordable than their counterparts. Sometimes, foreign, unapproved versions of US prescription drugs shipped through Canada are cheaper, but at what true cost?

MYTH: Imported drugs from Canada are safe. If it's good enough for Canada, then it's good enough for Maine.

The FDA reports that spot examinations of mail shipments of foreign drugs to US consumers often contain dangerous or unapproved drugs that pose potentially serious safety problems. Of the 1,153 shipments examined in 2003, the overwhelming majority (1,109 prescriptions or 88%) contained unapproved drugs. These drugs arrived from many countries including 16% from Canada. A second set of spot examinations of 3,375 prescriptions revealed that 2,256 (69%) were unsafe. Canadian parcels accounted for 80% of those prescriptions. Examples of potentially dangerous products included unapproved drugs such as lti-azathioprine, controlled substances including diazepam, drugs withdrawn from the US market for safety reasons such as dipyrone, improperly packaged drugs, animal drugs not intended for human use such as Clenbuterol, and drugs which require risk management or restricted programs like isotretinoin.

In 2004, the FDA purchased generic Viagra, Lipitor and Ambien from two websites titled "Canadian Generics". The drugs received were tested in an FDA laboratory. All three samples failed. While all three had some level of the active ingredient, the generic Lipitor and Viagra were determined to be subpotent while the generic Ambien was found to be superpotent. Two samples also failed purity testing and all three samples failed content uniformity testing.

A 2005 FDA operation discovered that most drugs ordered from so-called 'Canadian' pharmacies originated from other countries. Of the drugs being promoted as "Canadian," 85 percent actually came from 27 countries around the globe. Thirty two of the pharmaceuticals sampled also were determined to be counterfeit.

Many 'Canadian pharmacies' like CanaRx operate under multiple names and internet links which makes investigations much more complex and resource intensive. Furthermore, most 'Canadian pharmacies' such as CanaRx are not licensed pharmacies in Canada. In fact, CanaRx does not provide prescription medications to Canadians.

In 2003, the FDA issued a warning letter to CanaRx which documented specific concerns about supplying prescription drugs from unregulated sources and making unwarranted and misleading assurances to consumers about the safety of its drugs.

CONCLUSION

This bill would amend the Maine Pharmacy Act with a mere 13 words and yet would have enormous implications on public safety by circumventing the US Food and Drug Administration and 75 years of federal and state regulations designed to protect our communities from unapproved drugs, adulterated and misbranded drugs, prescription drugs and controlled drugs without a valid prescription and/or physician relationship, and counterfeit drugs. The brevity of this bill belies the complexity of this issue and the dangerous public health consequences. Yes, this bill would "facilitate the licensing of international mail order prescription pharmacies" but would do absolutely nothing to ensure the safety and effectiveness of imported dangerous prescription drugs.

Healthcare access and cost are very important considerations but should not compromise quality and safety. There are many other ways that the state could pursue providing affordable and safe medications to our citizens. The Maine Pharmacy Association would welcome the opportunity to discuss these alternatives and would look forward to working with you to implement better policy for the people of Maine. These approaches include improved chronic disease management through collaborative practice agreements and promoting access to FDA-approved generic drugs, which are proven safe and effective, account for the majority of prescriptions filled in the US, and generally cost less than the generic drugs sold in Canada.

Thank you for the opportunity to testify. I look forward to responding to any questions you may have.

Most Sincerely,

Kenneth L. McCall III, BSPharm, PharmD
President | Maine Pharmacy Association