

#### Testimony of Shabbir Imber Safdar North Dakota Health Care Committee, Aug. 4, 2021

#### Serious Flaws Plague Canadian Drug Importation Plan Savings Estimates

Past Canadian drug importation attempts failed to deliver on program promises of safety and affordability. Below are some key elements that savings estimates for Canadian drug importation plans have thus far neglected to address. The inaccurate savings projections resulting from these flaws should be considered in light of the serious safety risks that third-party drug importation poses to patients in North Dakota.

## Importation program savings estimates fail to account for state expenditures for compliance and enforcement.

Fake Canadian online pharmacies already exist and endanger American patients every day. The development of a Canadian drug importation program will bring new scammers targeting North Dakota patients, and law enforcement will need to deal with them.

To address this significant safety risk, states will have to conduct inspections of entities in Canada that wish to sell medicine into North Dakota, just as they do with local drug wholesalers. Experience has shown that these inspections will be more time-consuming and costly because of two factors. First, foreign travel costs were a problem in Governor Rod Blagojevich's failed i-SaveRX Canadian drug importation program. Second, inspectors do not have legal access to foreign vendor premises or a legal right to records which will require significant scrutiny.

Cost estimates that exclude the costs of increased law enforcement of businesses illegally profiting from the idea that all Canadian drug importation is safe, such as fake Canadian strip-mall pharmacies, illegal buyers clubs, etc., cannot provide a realistic projection of actual costs to the state of administering an importation program.

- Illinois Auditor General Management Audit of the Flu Vaccine Procurement and the I-SaveRX Program
- PSM case study of illegal businesses profiting off Maine's brief attempt at Canadian drug importation.
- "American Perceptions and Use Of Online Pharmacies" (Alliance for Safe Online Pharmacies Global Foundation) "45% of Americans erroneously believe all websites offering healthcare services/prescription medications to Americans via the internet have been approved by the FDA or state regulators"

Importation program savings estimates use unrealistic price comparisons between U.S. and Canadian medications.

#### Serious Flaws Plague Canadian Drug Importation Plan Savings Estimates

Cost comparisons between U.S. and Canadian drugs often vastly overestimate savings from importation. Many cost comparisons use the U.S. list price, rather than the net price. The U.S. net price includes rebate savings, which significantly reduce the price patients pay at the pharmacy counter for their medications.

Further, cost comparisons often fail to compare the most cost-effective U.S. product (brand or generic) with the Canadian equivalent and thus cannot provide an accurate forecast of potential savings. It is not equivalent to compare U.S. brand drug prices to Canadian generic prices. When a generic is available in the U.S., a comparison between the U.S. brand product and the Canadian drug overestimates cost savings from importation.

Further, only Canadian purchasers are entitled to Canadian prices. Many cost comparisons incorrectly assume that U.S. importers can purchase medicine from Canadian wholesalers at the negotiated provincial price when calculating savings.

Colorado published a list of medicines they wanted to import from Canada with desired quantities.
 <u>PSM's analysis</u> shows many examples of flawed comparisons, including comparisons using the U.S. brand product price when a generic is available.

#### Importation program savings estimates fail to account for important program costs.

Many savings estimates fail to use actual costs. Blanket percentage markups are not accurate. Statutory requirements include set up, storage, testing, cGMP quality repackaging, re-shipping, and record-keeping. These costs, especially repackaging and testing, can vary on a per-medicine basis and can be quite high.

Any savings estimate will not realistically account for these costs unless the state has consulted several repackagers about the cost of preparing foreign medicines for U.S. patients and obtained estimates based on *specific* medications intended for import and estimate quantities based on state patient populations.

Further, any estimate of actual testing costs will not be accurate unless it includes the cost of testing for subtherapeutic medication (not enough active ingredient) rather than just the presence or absence of the ingredient, using estimates from real testing labs. Testing would need to be performed to achieve statistical standard of confidence and reliability, and costs will be underestimated if this element is not incorporated. Dr. Acri below cites 99.99% and 99.999% to maintain safety.

- <u>"State Pharmaceutical Importation Programmes: An Analysis Of The Cost-Effectiveness"</u> (Journal of Pharmaceutical Health Services Research, 2020) presents a detailed cost of testing model with actual estimates.
- Florida has contracted with a vendor in Texas (Life Science Logistics) to manage its as yet unapproved
  importation program. <u>The LSL contract lays out the significant costs required to start up a program in
  great detail</u>.

Importation program savings estimates fail to incorporate additional real-world costs.

#### Serious Flaws Plague Canadian Drug Importation Plan Savings Estimates

Importation program savings estimates often ignore the possibility that importation programs could actually increase healthcare costs. Two different expert models predicted increased costs of healthcare due to counterfeit medicines from Canadian drug importation programs.

Further, the risk of wholesaling or dispensing counterfeit medicines will increase insurance costs for the supply chain, including pharmacists. Given the history of counterfeits in the pandemic, any estimates that do not account for medical adverse events due to counterfeiting and subtherapeutic products and the increased supply chain costs caused by this risk, will be inaccurate.

<u>Dr. Acri's paper, mentioned above</u>, also includes a model for estimating increased medical adverse
event costs from a Canadian drug importation program. The Healthcare Distribution Association
Research Foundation's "<u>The Risks and Realities of Commercial Drug Importation</u>" also examines the
topic.

# Importation program savings estimates fail to consider the overall risk to state fiscal expenditures.

Canadian stakeholders, including pharmacists, patients, wholesalers, and even the Canadian federal government, have all opposed U.S. plans to import Canadian medicine. If importation cannot move forward, for example, because of a prohibition under Canadian law, any state dollars that are committed to an importation program risk being wasted. Indeed, Wyoming studied and rejected Canadian drug importation, citing, among other concerns, the state's lack of control over the pricing of medicine through the supply.

- Prescription Drugs In Wyoming: Evaluating State Policy Options for Lowering Costs (October 2020).
- "What are Canadians Saying About Drug Importation?" quotes compiled by PSM.
- <u>Letter to Sen. Howard Anderson</u> (ND) from Canadian consul general Ariel Delouya regarding concerns about North Dakota's proposed program to import medicine from Canada.

# Studying Canadian drug importation

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Academy of Managed Care Pharmacy **ADAP Advocacy Association** Alabama Pharmacists Association Alaska Pharmacists Association American Pharmacists Association Arizona Pharmacy Alliance (AzPA) Association for Accessible Medicines Biotechnology Innovation Organization Colorado BioScience Association Colorado Pharmacists Society Community Access National Network Connecticut Pharmacists Association **Delaware Pharmacists Society** Florida Pharmacy Association Healthcare Distribution Association HealthCare Institute of New Jersey HealthHIV Illinois Pharmacists Association Indiana Pharmacists Association Institute for Safe Medication Practices International AntiCounterfeiting Coalition

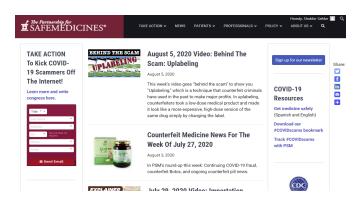
International Health Facility Diversion **Association** Kansas Pharmacists Association Maine Pharmacy Association Maryland Pharmacists Association Men's Health Network Minnesota Pharmacists Association Mississippi Pharmacists Association Missouri Pharmacy Association National Alliance of State Pharmacy **Associations** National Alliance On Mental Illness National Association of Boards of Pharmacy National Association of Chain Drug Stores National Association of Drug Diversion Investigators National Association of Manufacturers National Consumers League National Grange of the Order of Patrons of Husbandry Nebraska Pharmacists Association

NeedyMeds New Hampshire Pharmacists Association New Mexico Pharmacists Association Ohio Pharmacists Association Oklahoma Pharmacists Association Oncology Managers of Florida, Inc. Oregon State Pharmacy Association Pennsylvania Pharmacists Association Pharmaceutical Industry Labor-Management Association (PILMA) Pharmaceutical Researchers and Manufacturers of America Pharmaceutical Security Institute RetireSafe Rx Outreach Rx Partnership Texas Pharmacy Association Virginia Pharmacists Association Washington State Pharmacists **Association** 

PSM's membership is the entire supply chain: manufacturers, distributors/wholesalers, pharmacists, and patient advocates.



# 18 years studying safety (and counting!)



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# Importation program savings estimates fail to account for state expenditures for compliance and enforcement.

- Maine scammers quickly took advantage of their flawed program, victimizing patients.
- Foreign inspection costs are often overlooked and expensive. (IL, MN)
- FDA has not committed to do this.



# Importation program savings estimates use flawed price comparisons between U.S. and Canadian medications.

- Savings estimates erroneously compare U.S. list prices instead of prices NET of rebates.
- Savings estimates erroneously compare U.S. list prices for brands when cheaper U.S. generics are available.
- U.S. purchasers are not entitled to Canadian pricing from Canadian vendors.



# Importation program savings estimates fail to account for important program costs.

- 45% markup is not enough for set up, storage, testing, cGMP quality repackaging, re-shipping, recall management, and record-keeping.
- Use real quotes from wholesalers and other vendors.
- Pull specific quotes from testing labs and repackagers for each medication, it will be different.



"While pharmaceutical importation plans are politically attractive, the numbers demonstrate that they fail to deliver cost savings when implemented safely. These schemes can be cheap, or they can be safe, but not both."

State pharmaceutical importation programmes: an analysis of cost effectiveness, Kristina M. L. Acri née Lybecker, Journal of Pharmaceutical Health Services Research, March 18, 2020, Royal Pharmaceutical Society



# State Pharmaceutical Importation Programs: An Analysis of the Cost Effectiveness

Colorado College Working Paper 2019-02 June 2019

58 Pages • Posted: 19 Jun 2019 • Last revised: 26 Jun 2019

#### Kristina M.L. Acri née Lybecker

Colorado College - Department of Economics & Business

Date Written: June 12, 2019

#### Abstract

Recently proposed legislation in Colorado, Connecticut, Florida, Maine, Missouri, Oklahoma, Oregon, Utah, Vermont and West Virginia aims to reduce spending on pharmaceuticals by importing them from Canada. To examine the cost effectiveness of importation, this study analyzes 24 drugs from an online Canadian supplier, accounting for the cost savings, the cost of testing, the medical consequences of treatment failure, and the cost of treating an adverse medical event. For a "Representative State", given an adverse medical event, the presumed savings from an online Canadian supplier are exhausted in the treatment of only one patient in the case of Nexium, to 24,318 adverse events for patients in the case of Advair. The analysis shows the cost of testing (99.999% confidence level with 99.999% reliability) exceeds the presumed cost savings in all cases. Pharmaceutical importation plans are politically attractive, but the numbers demonstrate that they fail to deliver cost savings.

Keywords: pharmaceutical importation, drug prices, Canadian pharmacy, cost effectiveness

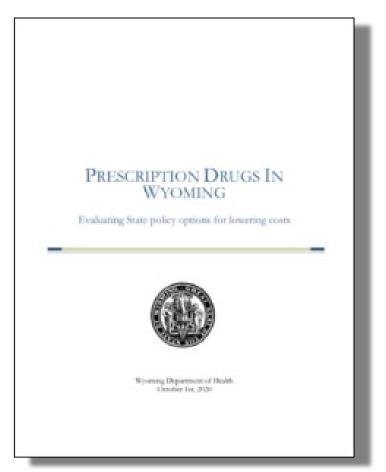
JEL Classification: F13, F14, H21, I11, I18, L51, L65

Suggested Citation:



# Importation program savings estimates fail to consider overall risk to state fiscal expenditures.

- Wyoming's study said the state lacks control over pricing to ensure importation saved money.
- No state has received federal approval.
- Canadian government actions could terminate program after it starts.



# Questions



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#### Significant Cases Involving Black Market Cancer Drugs

**CANCER TREATMENTS LISTED IN THE PROSECUTIONS:** Abraxane, Aclasta, Alimta, Aloxi, Altuzan, Anzemet, Aranesp, Arimidex, Avastin, Camptosar, Casodex, Dacogen, Daxotel, Docemil, Docetax, Doxil, Eloxatin, Eprex, Erbitux, Espogen, Farmorubicina, Faslodex, Gemzar, Grafeel, Grastim, Herceptin, Hycamtin, Irnozen, Kytril, Leucovorin, Mabthera, Methotrexate, Neulasta, Neulastim, Neupogen, Oxidach, Reclast, Ribomustin, Rituxan, sodium dichloroacetate, Taxotere, Treanda, Velcade, Venofer, Vidaza, Zometa

#### **APRIL 2018**

Montana: CanadaDrugs.com and 2 subsidiaries will pay \$34 million in fines and forfeitures for selling \$78 million in non-FDA approved medicines to U.S. doctors, including counterfeit Avastin. CEO Kris Thorkelson received 6 months house arrest, 4.5 years probation, and a \$250,000 fine for concealing a felony. In 2012, the FDA warned more than 500 medical practices to stop buying misbranded medication from subsidiaries of CanadaDrugs.com.

#### **MARCH 2018:**

NEW YORK: Dr. Vincent Koh and his wife/office manager received a \$10,500 fine for buying and treating patients with imported oncology drugs. The couple also paid \$500,000 for submitting false claims to Medicare for the drugs.

#### **AUGUST 2017:**

FLORIDA: Dr. Diana Anda Norbergs received a nearly 6-year sentence for importing non-FDA approved cancer drugs from multiple unlicensed suppliers.

#### **MAY 2016:**

ILLINOIS: Dr. Ann Kinnealey relinquished her medical license to avoid prosecution for allegedly treating patients with illegal cancer drugs obtained through a CanadaDrugs.com subsidiary, Quality Specialty Products (QSP).

#### **AUGUST 2015:**

VIRGINIA: Canadian TC Medical Group and SB Medical, Inc received a \$75 million fine for selling imported orthopedic, rheumatology, ophthalmology, and oncology drugs and cosmetic devices to over 1,000 U.S. medical practices.

#### **JULY 2015:**

MISSOURI: Dr. Robert L. Carter received 5 years probation and more than \$2 million in fines and restitution payments for purchasing non-FDA approved medications from QSP.

#### **APRIL 2015:**

TEXAS: South Texas Comprehensive Cancer Centers received 5 years probation and forfeited \$900,000 for buying imported cancer drugs from Montana Healthcare Solutions, which sold American medical practices counterfeit Avastin.

UTAH: Cache Valley Cancer Treatment and Research Clinic received 6 months probation and nearly \$1 million in fines and forfeitures for purchasing misbranded oncology drugs from QSP.

#### **FEBRUARY 2015:**

NEW YORK: Shahrad Rodi Lameh received 6 months home detention, 3 years probation, and forfeited \$500,000 after his company, Medical Device King, distributed non-FDA approved prescription drugs, including counterfeit Avastin. In May 2013, the FDA warned 781 doctors to stop buying medicines from Medical Device King.

#### **NOVEMBER 2014:**

TEXAS: Dr. Eduardo Miranda received 5 years probation and a \$1 million fine for importing and treating patients with non-FDA approved oncology drugs and fraudulently billing Medicare and private insurers for them.

**NEW MEXICO:** Dr. Mohamed Basel Aswad received 3 years probation and a \$2 million fine for importing

and treating his patients with non-FDA approved oncology drugs.

#### **OCTOBER 2014:**

MISSOURI: Ozay Pharmaceutical executive Ozkan Semizoglu received a 27-month sentence for smuggling misbranded, adulterated and counterfeit cancer treatments, including fake Avastin. Owner Sabahhadin Akman received a 30-month sentence and a \$150,000 fine in January 2015.

#### **JUNE 2014:**

KENTUCKY: Hematology and Oncology Center (HOC) and former office manager, Natarajan Murugesan received probation for charges related to buying and treating patients with imported cancer drugs from QSP. In a parallel civil case, HOC, Murugesan, and an oncologist, N. Mullai, agreed to pay \$2 million plus interest for billing Medicare fraudulently for the illegal medicines.

#### **FEBRUARY 2014:**

CALIFORNIA: Alvarado Medical Plaza Pharmacy received a sentence to pay \$1 million in fines and restitution for billing Medicare for unapproved oncology drugs it purchased from QSP. Pharmacist William Burdine received 8 months home confinement, 5 years probation and 240 hours community service.

#### MAY 2013-MAY 2014:

VIRGINIA: 12 employees of Gallant Pharma International, which sold smuggled counterfeit and misbranded chemotherapy and cosmetic injectables to U.S. doctors, cumulatively received sentences of 108 months in prison and more than \$8 million in fines and forfeitures.

#### (significant cases, cont.)

2 additional defendants, believed to be in Canada, cannot be prosecuted. In April 2015, the FDA warned more than 270 doctors nationwide to stop buying drugs from Gallant Pharmaceuticals.

### **SEPTEMBER 2013– JANUARY 2014:**

OHIO: 7 oncologists who imported non-FDA approved cancer medications received probation and paid a cumulative \$2.6 million in restitution.

#### **SEPTEMBER 2013**

FLORIDA: Martin Paul Bean, III; received a 2-year sentence and a \$19,000 fine and forfeited a luxury car after selling \$7 million in unapproved foreign oncology drugs to American medical practices. Coconspirator Maher Idriss, received 3 years supervised release, 8 months home detention, and a \$2,000 fine in October 2013.

#### **AUGUST 2013:**

UTAH: Michael Lawrence O'Donnell received a 12-month sentence after distributing diverted, non-FDA approved cancer drugs and Botox without a license. He pleaded guilty to I count of shipping Botox to a New York practice.

#### **JULY 2013**

MONTANA: Montana Healthcare Solutions founder Paul Bottomley received 5 years probation, 200 hours of community service and owed \$4.4 million in restitution for concealing the importation of non-FDA approved drugs, including counterfeit Avastin.

MISSOURI: Richards Pharma owner Richard J. Taylor received an 18-month sentence and forfeited almost \$4 million after distributing imported, adulterated cancer medicines, including drugs damaged by poor temperature control.

#### **JUNE 2013**

CALIFORNIA: Oncologist Joel I. Bernstein received a year of probation and over \$2 million in fines and penalties for fraudulent billing and introducing a foreign drug into interstate commerce.

TENNESSEE: Dr. William Kincaid, the owner of McCleod Blood and Cancer Center, received a 2-year sentence and paid a \$2.6 million settlement for receiving imported Rituxan with intent to defraud. His plea agreement revealed a much larger scope of illegal importation. Kincaid's business manager, Michael Dean Combs, received 3 years and a \$4,000 fine in September 2012.

#### **JANUARY 2013:**

FLORIDA: Canadian pharmacist Andrew Strempler received a 4-year sentence and a \$25,000 fine and forfeited \$300,000 after misrepresenting the source of medicines —some of them counterfeit—to customers.

#### **AUGUST 2012:**

CALIFORNIA: Ban Dune Marketing owner James Newcomb received a 2-year sentence and forfeited \$1.4 million for distributing imported cancer medications that were adulterated as a result of poor storage and shipping.

#### **MAY 2012**

MISSOURI: Dr. Abid Nisar received 2 years probation, 200 hours of community service and owed more than \$1 million in restitution for receiving and distributing a foreign version of Rituxan imported through Ban Dune Marketing.

#### **JULY 2011**

MARYLAND: Dr. Isabella Martire pleaded guilty to introducing a misbranded drug into interstate commerce after purchasing nearly \$200,000 of misbranded drugs and treating patients with them.

#### **AUGUST 2010**

ARIZONA: Canadian Hazim Gaber received a 33-month sentence and owed \$150,000 in fines and restitution after selling a counterfeit version of an unapproved cancer drug to at least 65 U.S. patients.

#### **SEPTEMBER 2009**

CALIFORNIA: Vinod Chandrashekm Patwardhan, MD received 5 years probation, 9 months of house detention, 1,000 hours of community service and owed more than \$1.3 million in fines and restitution after importing unapproved oncology drugs and fraudulently billing government healthcare programs.

#### **JANUARY 2009**

TEXAS: Kevin Xu received a 78-month sentence for trafficking in misbranded and counterfeit pharmaceuticals, including medicines that treated prostate cancer. Xu realized \$1.5 million in profits in 2007 alone.

### DOCTORS WHO HAVE PAID TO SETTLE ALLEGATIONS THAT THEY IMPROPERLY BILLED MEDICARE FOR ILLEGALLY IMPORTED CHEMOTHERAPY DRUGS:

TENNESSEE: Dr. Anindya Sen, \$1.2 million (June 2017)

NEW JERSEY: Dr. Kenneth D. Nahum, pay \$1.7 million (February 2017)

IOWA: Hematology and Oncology Center of Iowa, P.C. and Dr. Magdy Elsawy, \$176,000 (November 2016)

**CALIFORNIA:** Dr. John F. Kiraly, \$300,000 (*May 2016*); Dr. Neelesh Bangalore, \$736,000 (*July 2015*); Dr. Prabhjit S. Purewal, \$550,000 (*February 2014*)

# HOW CAN PATIENTS AND MEDICAL PRACTICES PROTECT THEMSELVES?



**HEALTHCARE PROVIDERS** can be prosecuted for buying drugs from unlicensed sellers. Patient medications should only be purchased from wholesale drug distributors licensed in the United States.

The FDA keeps a list of verification sites by state: http://safedr.ug/fdalicense.

In addition to sourcing medicines safely, health care professionals can spot therapeutic failure and teach patients how to buy medications from safe sources. Learn more about protecting patients at <a href="http://safedr.ug/healthcare\_pros">http://safedr.ug/healthcare\_pros</a>.



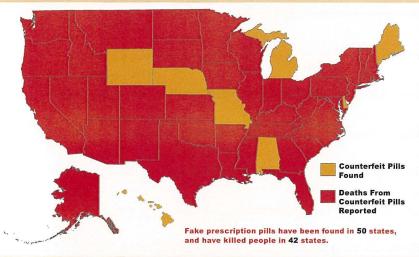
**PATIENTS** treated in medical offices should ask to see medication packaging. Check the packaging for accurate labeling, package condition, and labeling in English. When in doubt, ask your doctor for the name of the medicine distributor. All legitimate wholesalers are licensed by your state and can be verified online.

Use **http://safedr.ug/fdalicense** to find your state licensing agency.

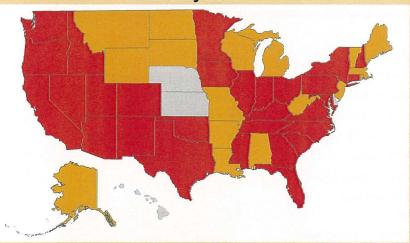




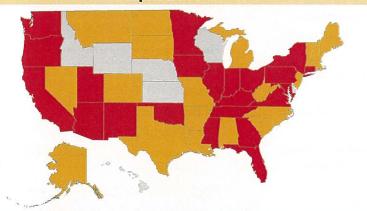
#### OCTOBER 2020



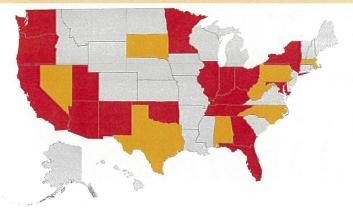
#### January 2019



April 2018



October 2016



## **ALL 50 STATES HAVE REPORTED** DEADLY COUNTERFEIT **PILLS MADE WITH FENTANYL**

#### Fake, fentanyl-laced pills have left a trail of bodies in the U.S.

A father-to-be in Georgia. A Californian who took a Xanax when he couldn't sleep.2 A Peace Corps volunteer staying with his parents in Connecticut.<sup>3</sup> A restaurant manager in Florida who just wanted her back to stop

hurting.4 A Major League Baseball pitcher winding down after a game.5 **Unsuspecting Americans** like these have died in 42 states—all because of counterfeit pills made with fentanyl.



FATAL DOSE OF FENTANYL

#### Where do these pills come from?

Criminals smuggle cheap, illicitlymanufactured fentanyl powder and fentanyl pills en masse across U.S. borders, but the drug also comes in the mail. A first-class envelope can conceal enough powdered fentanyl that a person with an inexpensive pill press can make over 120,000 deadly fake pills.6

#### How do we stop it?

Educate Americans about the existence of these dangerous counterfeits and oppose efforts to weaken the closed, secure drug supply through importation.

Only purchase medicine from licensed U.S. pharmacies selling FDA-approved products.



#### **Footnotes**

- I. "Counterfeit Pill Made With Fentanyl Killed Young Father-To-Be," The Partnership for Safe Medicines, December 4, 2017, <a href="http://safedr.ug/JPGeorgia">http://safedr.ug/JPGeorgia</a>.
- 2. "Young Californian Dies After Accidentally Taking Counterfeit Xanax," The Partnership for Safe Medicines, September 27, 2017, <a href="http://safedr.ug/ToshA">http://safedr.ug/ToshA</a>.
- 3. Niki and Wally Beddoe, "Opinion: Talk to family about dangers of street drugs," *Greenwich Time*, August 15, 2020, <a href="https://bit.ly/373UMgS">https://bit.ly/373UMgS</a>.
- 4. "In Florida, a Beloved Wife, Sister, Daughter, and Aunt Was Felled by Fake Oxycodone," The Partnership for Safe Medicines, May 31, 2018, <a href="https://bit.ly/374muKy">https://bit.ly/374muKy</a>.
- 5. "Former Angels Employee Charged in Pitcher's Fatal Fentanyl Overdose," U.S. Department of Justice, August 7, 2020, <a href="https://bit.ly/2GNkPOR">https://bit.ly/2GNkPOR</a>.
- 6. Counterfeit Prescription Pills Containing Fentanyls: A Global Threat, U.S. Drug Enforcement Administration, July 2016, <a href="http://bit.ly/2EzoNmU">http://bit.ly/2EzoNmU</a>.

#### **PSM MEMBERS:**

Academy of Managed Care Pharmacy

ADAP Advocacy Association

Alabama Pharmacy Association

Alaska Pharmacists Association

American Pharmacists Association

Arizona Pharmacy Alliance (AzPA)

Association for Accessible

Medicines

Biotechnology Innovation Organization

California Pharmacists Association

Colorado BioScience Association

Community Access National Network

Connecticut Pharmacists

Delaware Pharmacists Society

Healthcare Distribution

Association

Association

HealthCare Institute of New Jersey

Illinois Pharmacists Association

Institute for Safe Medication

**Practices** 

International AntiCounterfeiting Coalition

International Health Facility
Diversion Association

Kansas Pharmacists Association

Maine Pharmacy Association

Maryland Pharmacists Association

Men's Health Network

Minnesota Pharmacists Association

Mississippi Pharmacists

Association

Missouri Pharmacy Association

National Alliance of State

Pharmacy Associations

National Alliance On Mental Illness

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National Association of Boards of

Pharmacy

National Association of Chain

Drug Stores

National Association of Drug Diversion Investigators

National Association of

Manufacturers

National Consumers League

National Grange of the Order of Patrons of Husbandry

Nebraska Pharmacists Association

NeedyMeds

New Mexico Pharmacists

Association

Ohio Pharmacists Association

Oklahoma Pharmacists Association

Oncology Managers of Florida, Inc.

Pennsylvania Pharmacists

Association

Pharmaceutical Industry Labor-Management Association (PILMA)

Pharmaceutical Researchers and Manufacturers of America

Pharmaceutical Security Institute

RetireSafe

Rx Outreach

Rx Partnership

Texas Pharmacy Association

University of New England College of Pharmacy

Virginia Pharmacists Association





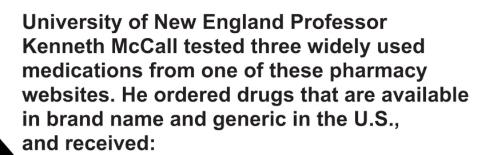


# MYTH: "WE ARE GETTING THE SAME DRUGS CANADIANS TAKE."

Testing proves they are not getting the same medicine. They are risking ineffective and dangerous drugs from other countries.

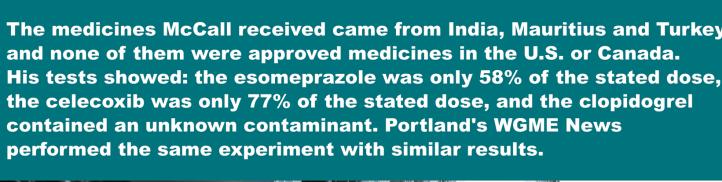
From 2013 until 2015, Maine law allowed the importation of foreign prescription drugs from online "pharmacies" associated with licensed retail pharmacies in Canada, the U.K., Australia and New Zealand, exclusively.

# However, the cost savings came with some surprising results.



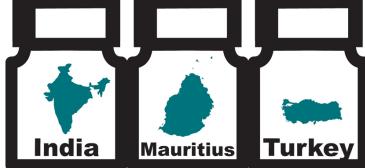
- A non-FDA approved generic of Nexium, esomeprazole (which treats acid reflux disease)
- A non-FDA approved generic of Celebrex, **celecoxib** (an anti-inflammatory)
- A non-FDA approved generic of Plavix, clopidogrel (a blood thinner)

The medicines McCall received came from India, Mauritius and Turkey His tests showed: the esomeprazole was only 58% of the stated dose,

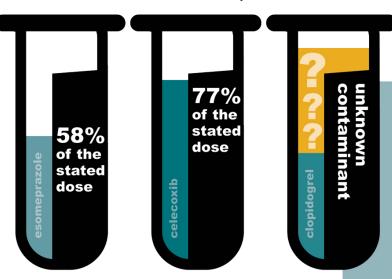




**INSTEAD OF COMING FROM CANADA'S DRUG SUPPLY.** THESE CAME FROM . . .



#### ON TESTING THEM, HE FOUND:



#### What happens if patients take black market medicine that is weaker than the stated dose?

Treatment will be ineffective and potentially dangerous. Patients with chronic illnesses such as diabetes and hypertension may get sicker as doses vary between unregulated batches of medicine. Their doctors may presume that treatment is ineffective for that patient instead of realizing that their imported medication is unreliable. When patients take substandard medicines they could suffer serious harm.

Because the medications come from foreign sources not supervised by the FDA, patients have no legal protection when they receive dangerous or ineffective drugs.



- The online "pharmacy" was NOT licensed and does NOT dispense prescriptions to Canadians.
- None of the 4 prescriptions from these websites were manufactured, approved for use or filled in Canada.
- All 4 prescriptions were unapproved FDA products.

