

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.

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.



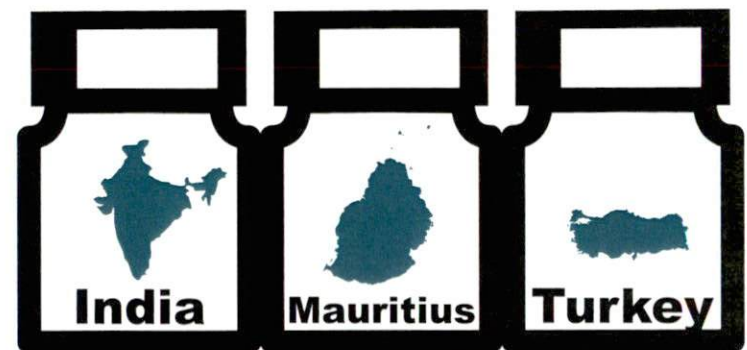
University of New England Professor Kenneth McCall tested three widely used medications from one of these pharmacy websites. He ordered drugs that are available in brand name and generic in the U.S., and received:



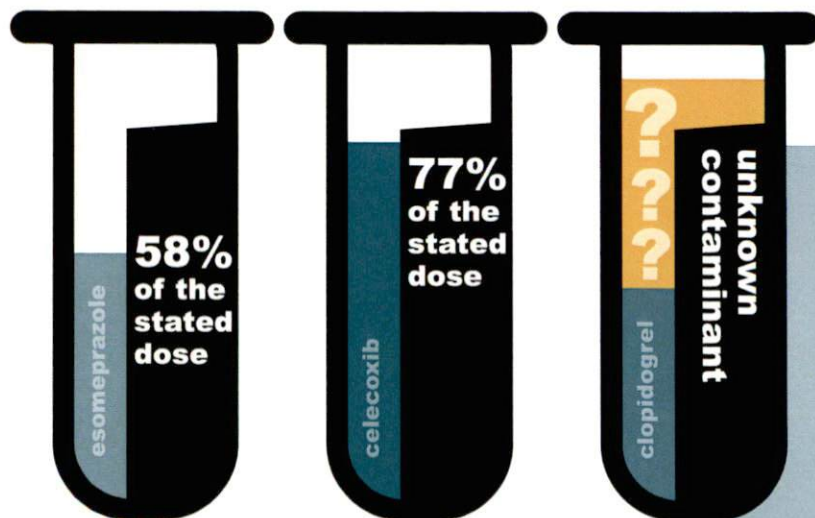
- A non-FDA approved generic of Nexium, **esomeprazole** (which treats acid reflux disease)
- A non-FDA approved generic of Celebrex, **celecoxib** (an anti-inflammatory)
- A non-FDA approved generic of Plavix, **clopidogrel** (a blood thinner)

The medicines McCall received came from India, Mauritius and Turkey and none of them were approved medicines in the U.S. or Canada. His tests showed: the esomeprazole was only 58% of the stated dose, the celecoxib was only 77% of the stated dose, and the clopidogrel contained an unknown contaminant. Portland's WGME News performed the same experiment with similar results.

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

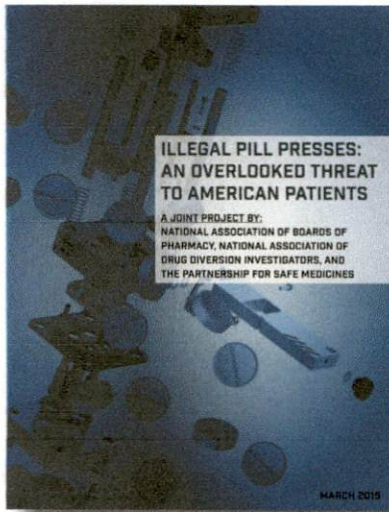


ON TESTING THEM, HE FOUND:



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.



ILLEGAL PILL PRESSES: AN OVERLOOKED THREAT TO AMERICAN PATIENTS

**A JOINT PROJECT BY:
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY,
NATIONAL ASSOCIATION OF DRUG DIVERSION
INVESTIGATORS AND
THE PARTNERSHIP FOR SAFE MEDICINES**

RELEASED MARCH 19, 2019.

EXECUTIVE SUMMARY

For less than \$500, an individual with ill intent can purchase a pill press and a counterfeit pill mold that allows them to turn cheap, readily available, unregulated ingredients into a six-figure profit. Criminals rely upon these pill presses to create dangerous counterfeit medications with toxic substances such as cheaply imported fentanyl (analogues). Their deadly homemade products have reached 46 states in the United States. Of grave concern is the significant lack of manufacturing control utilized in the making of these counterfeit products.

The inexperience of these “garage manufacturers” has killed unsuspecting Americans in 30 states.

Counterfeit medications that can kill someone with a single pill are a reality that is increasing at an alarming rate. This is a critical health issue that all three of our organizations are urgently striving to stay on top of.

How do these criminals get their hands on pill presses? How are they evading customs inspections? Is possession of these presses illegal and if so, why are more people not charged with it?

Recently, the National Association of Boards of Pharmacy, National Association of Drug Diversion Investigators and The Partnership for Safe Medicines joined together to research the extent of the pill press challenge for law enforcement and other first responders. Key findings include:

- 1. Pill presses are broadly available for sale on the Internet and virtually untracked.** These devices are successfully smuggled through customs because the enormous volume of packages makes compliance challenging. Data from Customs and Border Protection shows pill press seizures at International Mail Facilities are increasing every year, growing 19 fold from 2011 to 2017.
- 2. The broad availability and sale of pill presses allow novice criminals to make millions of doses of nearly perfect-looking counterfeits that can have deadly consequences.**
- 3. Possession of a pill press, while not well regulated, is at most a violation of a Drug Enforcement Administration registration requirement carrying no jail time.** It only becomes a crime once you add a counterfeit pill mold. However, the prosecution of individuals for possession of a pill press with a counterfeit pill mold is also a rare occurrence and does not carry a sentence high enough to be a deterrent.
- 4. Disrupting the availability of pill presses will be a challenging process.** Our research suggests that increasing criminal penalties for the possession or non-registration of a pill press alone is not likely to provide a sufficient deterrent because it relies on a change in charging behavior by prosecutors. Note: Some law enforcement interviewed suggested adding a sentencing enhancement that increases penalties for committing a drug-related crime with a pill press and suggested exploring serialization or registration as a technique to increase the frequency of indictments for illegal possession and manufacturing operations.

Read the full report here: <https://safedr ug/pill-press-threat>.

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For 19 Years Canadian and American Public Servants, Healthcare Experts and Law Enforcement Have Said Foreign Drug Importation Is Dangerous

Law Enforcement

Louis Freeh, director of the FBI from 1993 to 2001, 2019 and 2017
Nevada Sheriffs' & Chiefs' Association, 2018
National Sheriffs' Association, 2018 and 2017
International Association of Chiefs of Police, 2017
Nevada Sheriffs' and Chiefs' Association, 2017

Pharmacist Associations

Canadian Pharmacists Association, 2019
American Pharmacists Association, 2019 and 2017
The Oregon Pharmacy Coalition, 2019
Alaska Pharmacists Association, 2017
American Society of Health-System Pharmacists, 2017

Trade Associations

Healthcare Distribution Alliance, 2019
National Association of Chain Drug Stores, 2019
Oregon Bioscience Association and Biotechnology Innovation Organization, 2019
Northwest Association for BioMedical Research, 2019
National Association of Chain Drug Stores, 2019 and 2017
Healthcare Institute of New Jersey, 2007

Canadian Regulators, Patient Groups and Health Care Professionals

Canadian Pharmacists Association (CPhA), 2019, 2007
Alliance for Safe Online Pharmacies Canada, 2019
Newfoundland and Labrador Pharmacy Board, 2017
The College of Pharmacists of Manitoba, 2017
The Best Medicines Coalition, 2016
The Canadian Arthritis Patient Alliance, 2016
The Ontario Pharmacists' Association, 2007
The Canadian Association for Pharmacy Distribution Management, 2007

Healthcare and Patient Advocates

Alliance for Safe Online Pharmacies, 2018
The Pew Charitable Trusts, 2017
More than 150 patient advocates

State and Federal Regulators

Secretary of Health and Human Services Alex Azar, 2018
California State Board of Pharmacy, 2017
Louisiana Board of Pharmacy, 2017
The Kentucky Board of Pharmacy, 2017
The Arizona State Board of Pharmacy, 2017
The Oklahoma State Board of Pharmacy, 2017
Former FDA Commissioners, Drs. Robert Califf, Margaret B. Hamburg, Mark B. McClellan, and Andrew Von Eschenbach, 2017
The Virginia Board of Pharmacy, 2017
The West Virginia Board of Pharmacy, 2017
The National Association of Boards of Pharmacy, 2017
FDA Commissioner Robert Califf, 2015
The National Association of Boards of Pharmacy, 2014
Health and Human Services Secretary Kathleen Sebelius, 2009
FDA Commissioner Lester M. Crawford, 2005
William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, 2004
The National Association of Boards of Pharmacy, 2004
FDA Commissioner Mark B. McClellan, 2003
The National Association of Boards of Pharmacy, 2003
Tommy Thompson, Secretary of Health and Human Services, 2001
Donna Shalala, Secretary of Health of Human Services, 2000

 *The Partnership for*
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