Counterfeit Medicine In America: 2018

9th Annual Drug Abuse Symposium

October 29, 2018
The Partnership for Safe Medicines

Americans are largely unaware of this threat. PSM awareness tools:

- Comprehensive reporting on counterfeit incidents online
- Explaining the risks in a variety of mediums
- Telling the stories of people who have been hurt by fake medicine
Closed Secure Drug Supply

- FDA-approved supplier
  - FDA regulates U.S. manufacturers & facilities globally
- State rules
  - Each state regulates U.S. wholesalers with individual rules and cross-licenses
- License
  - State regulated doctors and pharmacies purchase from licensed wholesalers
- Result: Closed secure drug supply chain for patients

Unregulated Foreign Drug Supply

- Unknown conditions of manufacture
  - Safe? Sterile? Effective?
  - Thousands of criminal organizations across the world produce counterfeit and substandard medicines.
- No rules
  - States do not regulate foreign wholesalers.
  - U.S. regulators cannot prosecute rogue, foreign drug manufacturers, leaving them accountable to no one.
- Fake pharmacies online
  - Fake pharmacies already sell Americans unregulated drugs online.
  - In a survey of 11,688 online pharmacy websites, less than 500 met regulators' standards for safe pharmacies. (4%)
- Result: Patients cannot rely on the quality, sterility or effectiveness of their medication.
  - Americans will be left wondering: "Is my medicine working? Is it even medicine?"

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Working together to protect the safety of your prescription drugs
The United States has the safest drug supply in the world…

…but as many as 19 million Americans buy medicines outside that supply chain, from foreign online pharmacies or other unlicensed sources.
"Basically, all my competition started selling drugs they were sourcing overseas from, in my opinion, unsafe countries and marketing them as Canadian. I couldn't compete with that," he said. (CBC 6/20/2017)

Canada’s drug supply would be drained in 201 days, should just 20% of U.S. prescriptions shift to dispensing out of Canada. (Shepherd, Health Econ Outcome Res Open Access 2018, 4:1)
Since 2012, smugglers caught selling fake drugs sold up to 63 medications to over 3,000 doctors, clinics and hospitals across the U.S.
In 2012, the FDA discovered 2 lots of an imported counterfeit cancer drug (Avastin) with no active ingredient.

The agency launched a massive recall and a lengthy investigation.
Public health threat is real

Late stage lung cancer Betty Hunter was treated with counterfeit Avastin in 2011. Ms. Hunter died three months later.

Source: Medicin der Dræber

Source: FDA
Figure 1: Visual depiction of a total of 949 FDA safety notifications that were sent to 932 physicians and/or clinics in 795 zip codes from 2012 to 2013.
Case Study: Path of Fake Avastin

The fake Avastin traveled through a series of overseas suppliers before reaching the Canada Drugs' network. Companies controlled by Canada Drugs procured the counterfeit cancer medicine, marketed it to U.S. doctors and shipped it through a contractor in Tennessee, court records and business documents show. Doctors identified by the FDA as the network's customers were warned that they may have bought the fake Avastin.

Graphic courtesy the Wall Street Journal
Lack of prosecution

Prosecuting foreign nationals for selling counterfeit drugs is hard, which makes a poor deterrent.

2014: DOJ indicted 5 CanadaDrugs.com executives for selling $78 million of fake cancer drugs


2018: Plea approved - no jail time ($34mm penalty)

2018: CanadaDrugs.com shut down, but license was transferred
The criminals - Where are they now?

Internet pharmacy pioneer's licence reinstated, just days after it was suspended

Kris Thorkelson’s Manitoba licence was pulled on same day his Canada Drugs reached tentative plea deal in U.S.

By Karen Pauls, CBC News  Posted: Dec 21, 2017 8:03 PM CT  |  Last Updated: Dec 21, 2017 8:14 PM CT

Thorkelson’s company, CanadaDrugs, continues to hold provincial wholesale pharmacy licenses and a Canadian Federal manufacturing pharmacy license.

Terms of pending plea deal with U.S. Department of Justice for Kris Thorkelson

- Six months house arrest and four and a half years of probation;
- a $250,100 fine; and
- Turn over records and cooperate in future investigations.

The plea agreement does not require him to:

- serve any jail time;
- surrender his pharmacy license;
- enter a guilty plea of selling counterfeit drugs.

He is not prohibited from holding any kind of pharmacy license or starting a new pharmacy business to export to America.
FENTANYL 101
An introduction to the Fentanyl crisis in the U.S.

What are fentanyl and fentanyl analogues?
Fentanyl is a synthetic opioid that is 50–100 times more potent than morphine. Doctors prescribe fentanyl in medical settings, but drug traffickers manufacture black market fentanyl and sell it illegally.

Fentanyl
Furanylfentanyl
5-Methylfentanyl

Morphine
Oxycodone

1 1.5x 15x

POTENCY compared to MORPHINE
50–100x 10,000x

Acetyl Fentanyl

Carfentanil

There are over 40 analogues (variations) of fentanyl.

To evade prosecution, chemists alter the fentanyl molecule to create new analogues.
Fentanyl-laced counterfeits

First reports of counterfeit Xanax and fake opioids laced with fentanyl and analogues in late 2015.
Fentanyl-laced counterfeits

Counterfeit Xanax
Source: Yakima Police Department

Counterfeit Oxycodone
Source: Public Health Seattle & King County

Counterfeit Percocet
Source: Georgia Bureau of Investigations
Pills have been found in 43 states, with deaths reported in 22 – March 2018

Full report: “Forty Three States and Counting” at www.safemedicines.org
Select fentanyl-laced counterfeit seizures
Fentanyl is driving overdose deaths

Fentanyl-laced counterfeits in Indiana

Fake pills bringing risk to youths

Police warn of pills designed to look like Xanax

THPD: Counterfeit oxycodone pills could prove fatal

Pills may be laced with potent and possibly deadly fentanyl.

.
All fentanyl is imported

Since 2015, counterfeit pills that are laced with deadly imported fentanyl have been killing Americans across the U.S.
Fentanyl is cheap and readily available online

Investigators for the US Permanent Subcommittee of Investigations communicated with online vendors who sold fentanyl. They provided the following price list to the investigators.

A kilo of fentanyl costs roughly $11,000 when paid through Western Union. A fatal dose of fentanyl for an adult is as little as 2-3mg.

That’s enough for 333,333 fatal doses.

Read the entire report: Combatting the Opioid Crisis: Exploiting Vulnerabilities In International Mail, Staff Report, Permanent Subcommittee on Investigations, US Senate.

Law enforcement and journalists working on this issue report fentanyl for sale for $3.5k-$5k/kg.
Fentanyl is cheap and readily available online

During the committee’s investigation, they tracked five sellers in China for a short time period. During the time of that investigation, they tracked their sales and shipments to purchasers in 43 different states.

Read the entire report: Combatting the Opioid Crisis: Exploiting Vulnerabilities In International Mail, Staff Report, Permanent Subcommittee on Investigations, US Senate.
How does it get here? 

Source: Twitter 

“..many Americans are purchasing fentanyl and other illicit opioids online and having them shipped here through the international mail system.” Jan. 23, 2018
Die molds are readily available for any kind of pill.
Fentanyl to counterfeit pill

2017: CBP LA seized 396 pill presses

Illegal molds exist for all pills
Aaron Shamo and 5 others allegedly manufactured and sold hundreds of thousands of fake prescription pills across the U.S. via the Darknet.

They used pill presses, dies, and stamps and illegally imported fentanyl and alprazolam from China.

In the November 2016 raid, the DEA seized $1.2 million and 95,000 pills that could have been sold for as much as $2.2 million. His trial is set for August 2018.
Just one criminal ring can have a huge impact on the country

The Shamo ring out of Utah had many of their shipments traced to cities all over the country. This map shows where they sent pills after investigators finished combing through their sales records.

Locations That Shamo Drug Ring Shipped Pills
Source: U.S. Immigration and Customs Enforcement
The evening of October 27, 2015, 29-year-old Aptos, California resident Tosh Ackerman took a benadryl and part of a Xanax pill to help him sleep. He never woke up, and his girlfriend found him dead the next day.

Investigation showed that Ackerman’s Xanax was counterfeit. It contained a fatal dose of fentanyl.

Carrie is an active speaker to schools and the media. You can reach her at ToshsStory@gmail.com
Betty Jean Collins of Macon, Georgia

A 60-year-old Macon resident recovering from open-heart surgery took one of her husband’s Percocets and ended up in the hospital with an overdose. The medication was counterfeit—made with fentanyl—and Collins was one of a series of poisoning cases across Georgia.

Source: gbi.georgia.gov
Fentanyl trade attracts organized crime
What does a fatal dose look like

Photo originally created by New Hampshire Public Radio photographer Paige Sutherland
Law enforcement risk: officer exposure

- Minuscule (2-3mg) exposure can cause injury and death.
- New procedures for law enforcement
- Suspension of field tests

Source: KEPRTV.com
Law enforcement risk: officer exposure

Law enforcement exposure reported in Massachusetts, Wisconsin, Ohio, New Hampshire, Rhode Island, New York, Pennsylvania, Florida, Georgia, Michigan, Maryland, Connecticut, New Jersey, Kentucky and Colorado
Law enforcement risk: officer exposure

First Responder Fentanyl Exposures

First Responder Exposure, as reported, May, 2018

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How do we address this problem?

There are steps we can take to make the drug supply safer including resources for law enforcement, consumer education, and regulatory enhancement.

AND

There are steps we can avoid taking that would make the drug supply more dangerous.
What can we do?

We teach consumers that licensed pharmacies and pharmacists are the only safe sources of medication.

Friends and relatives, even ones you trust, are not as safe as a licensed pharmacist.
What can we do?

Teach consumers how to save money safely so they don’t buy off the black market.

47 of the 50 most frequently prescribed medications in the U.S. are available in cheaper generic form.

Americans **pay less** for most commonly prescribed generic medications than Canadians do.
What can we do?

We always tell consumers to consolidate their prescriptions at a single pharmacy when recommending they shop around. Patients should have a single dispensing pharmacist, preferably a community pharmacist who knows the patient well.
Support efforts to remove gag clauses that prevent pharmacists from helping patients save money.
Support the FDA’s generic staffing levels through advocacy

FDA staffing is funded through a combination of user fees on generic drug makers and Congressional appropriations. When the FDA approves generics, especially multiple ones, prices go down and the market for counterfeits evaporates.
What can we do?

Support enhancement to border security through advocacy

More resources for package inspection at International Mail Facilities

Sen. Rob Portman introduces the Synthetics Trafficking & Overdose Prevention (STOP) Act

Require electronic data on international mail to facilitate more efficient inspections
New legislative threat: Importation

• Allows non-FDA approved medication into the U.S.
• No increased CBP resources for package inspection
• Does not require prescription for foreign sellers to dispense any medication
• Contains no enforcement mechanism to punish foreign sellers of counterfeit or controlled substances
• Will create an enormous and nearly legitimate pathway for opioids and fentanyl analogues to enter the United States
Importation enforcement challenge
Importation enforcement challenge

Unregulated Online Sellers

Package Inspection

Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages.
Every head of HHS and FDA for the last 18 years refused to certify the safety of drug importation.

- Donna Shalala
  “flaws and loopholes...make it impossible for me to demonstrate that it is safe and cost effective.”

- Tommy G. Thompson
  “It’s impossible for us to certify that these drugs are safe.”

- Kathleen Sebelius
  “The last thing we need is open borders for unsafe drugs in search of savings that can’t be safely achieved. You can’t improve competition and choice in our drug markets with gimmicks like these.”

- Alex M. Azar II

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- Margaret A. Hamburg, M.D.
  “Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies. Unfortunately, these drugs are often counterfeit, contaminated, unapproved products or contain an inconsistent amount of active ingredient. Taking these drugs can pose a danger to consumers.”

It’s not a Republican or Democrat issue. It’s a safety issue.

To see all of the HHS and FDA quotes go to https://safedrug/FDA-HHS.
Opposition by four former FDA commissioners
Key Findings:

- Increase counterfeits and illegal activity
- Worsen the opioid crisis
- Overburden law enforcement resources
- Endangers law enforcement
Law enforcement opposition

2017 – 07
NATIONAL SHERIFFS' ASSOCIATION OPPOSES DRUG IMPORTATION LEGISLATION WHICH JEOPARDIZES LAW ENFORCEMENT'S ABILITY TO PROTECT THE PUBLIC HEALTH AND ENDANGERS THE SAFETY OF LAW ENFORCEMENT AND OTHER FIRST RESPONDERS

WHEREAS, the number of drug overdose deaths in 2016 likely exceeded 59,000, representing the largest annual increase in the drug overdose death count ever recorded in the United States, and which are the consequence of an escalating public health crisis: opioid addiction, and.

WHEREAS, the Drug Enforcement Administration (DEA) reported in 2016 that the sudden arrival of wholesale amounts of counterfeit prescription drugs containing fentanyl (dosed by China-sourced fentanyl into the United States via Canada and Mexico) will result in an increase in overdoses, deaths, and opiate-dependent individuals.

WHEREAS, local law enforcement officials in more than 1000 counties representing 60 million people have expressed their support for the resolution passed by the National Sheriffs' Association (NSA) opposing drug importation legislation which jeopardizes law enforcement's ability to protect the public health and that endangers the safety of law enforcement and other first responders.

NOW, THEREFORE, the National Sheriffs' Association opposes the passage of legislative drug importation proposals, which if implemented, would overextend and divert law enforcement resources and jeopardize law enforcement's ability to protect the public health, threaten the safety of our drug supply, and endanger the safety of law enforcement officers, their K-9 companions and first responders across America.” - International Association of Chiefs of Police (IACP), December 2017

The Partnership for
SAFE MEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS
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Law enforcement opposition

NATIONAL SHERIFFS’ ASSOCIATION

August 8, 2018

Dear President Trump:

I write on behalf of more than 3,000 Sheriffs’ Associations, as well as the Sheriffs’ Association of America, to request your Administration carefully weigh the potential harmful impact of drug importation legislation which jeopardizes the public health and undermines the safety of law enforcement officers. This is not the first time that Sheriff’s Associations have raised concerns about the importation of prescription drugs.

...
What can we do?

Provide enhanced authority and capabilities to the U.S. Food and Drug Administration (FDA) to more effectively enforce against counterfeit, misbranded or adulterated pharmaceuticals

- Provide FDA to destroy seized counterfeit
- Increase budgetary resources and FTEs
- Permanently schedule all fentanyl analogues
- Increase penalties and fines for counterfeit medicines production, distribution and sale
What can States do?

- Authorize and expand participation in federal taskforces
- Increase penalties and fines for counterfeit medicines production, distribution and sale
- Increase funding for county and local law enforcement to have rapid access to drug testing laboratories to get drug testing results for prosecutions
What can we do?

Materials to help educate consumers and healthcare professionals that interact with them.

Distribute our materials to consumers and pharmacists (we print them at cost for you!)

Re-share our materials on social media

Print materials: editors@safemedicines.org
Thank you