Counterfeit Medicine
In America: 2020

The partnership is a coalition of over 40 healthcare, manufacturer, and patient organizations dedicated to fighting counterfeit medicines.

Shabbir Imber Safdar
Executive Director, PSM
shabbir@safemedicines.org
415-630-3736

February 2020 Anchorage
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?
- **States do not regulate foreign wholesalers.**
- **Thousands of criminal organizations across the world produce counterfeit and substandard medicines.**
- **U.S. regulators cannot prosecute rogue, foreign drug manufacturers, leaving them accountable to no one.**
- **In a survey of 11,686 online pharmacy websites, less than 500 met regulators’ standards for safe pharmacies.**
- **Americans will be left wondering: “Is my medicine working? Is it even medicine?”**
- **Result**: Patients cannot rely on the quality, sterility or effectiveness of their medication.
First wave: Before scanned codes and paper pedigrees: Counterfeits from 1999 to 2005

Timothy Fagan (above left) obtained Procrit as part of his post-kidney transplant regimen.

Maxine Blunt (not pictured) obtained Procrit as part of cancer treatment.
Even twenty years ago, counterfeits were near perfect.
Katherine Eban’s book spurred calls for change.

Katherine Eban’s 2005 book chronicled the lawless secondary market of criminal pharmaceutical wholesalers operating in Florida, the cops and prosecutors who chased them, and the patients that suffered from the crime.
From this crisis was born the need for Track and Trace

With tracking affixed on the manufacturing floor, Track and Trace is how we eliminate shadowy middlemen.
Second wave: The rise of the Canadian entrepreneurs: 2001-present

Kris Thorkelson, Canada Drugs
Andrew Streampler, RXNorth
Blister packs of counterfeits: 2001-present

Andrew Strempler, Canadian pharmacist / entrepreneur

1999: Founded Canadian web pharmacy Mediplan / RxNorth
2005: Manitoba Pharmacists Association sanctions Strempler and orders him to surrender his license. He has sales of $100mm / yr.
2006: US FDA warns Americans Strempler’s company is shipping counterfeit product.
2007: Strempler sells Mediplan / RxNorth to CanadaDrugs.com and opens PharmaCheck in the Bahamas. He continues selling to Americans but also to Europe. Canadian authorities frustrated that he still claims his medication is “Canadian” despite coming from elsewhere.
2012: Strempler is arrested when his plane makes a stop in Florida. He is sentenced to 4 years in prison and fined $325,000
2015: Strempler is released.
"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)

Daren Jorgensen opened one of the first Canadian Internet fake pharmacies in 2001, and exited in 2008.
Illinois’ Experience With ISaveRX, 2003–2006

A “white listed” online pharmacy program of 28 online drug sellers dispensing from Canada, the United Kingdom, Australia, and New Zealand to IL, WI, KS, MO, and VT.

Select IG findings
• Operating in violation of federal law with unapproved federal funds.
• Dispensing entities in the program in violation of IL pharmacy practice law.
• 40% of the inspections records (32 of 80) were not completed.
• State did not monitor that only approved pharmacies participated.
• Significant labor costs of $488,000 for 26 employees (19 months).
• High expenses, incl. $111,000 for international travel and over $350,000 for contract management, marketing, and legal services.
• Uptake of the program was small and it was eventually cancelled.
An online pharmacy regulation program started by Gov. Tim Pawlenty. After launch, the FDA cited a number of patient safety issues, including several found during a pre-announced visit by Minnesota’s own inspectors:

- Pharmacy techs, not pharmacists, entering prescriptions.
- Having pharmacists check 100 prescriptions / hour or refill 300 prescriptions / hour.
- Cold-chain drugs shipped not refrigerated / no historic thermometers in refrigerators.
- Allowing pharmacy techs instead of pharmacists contact U.S. medical providers
- Allowing faxed prescriptions.
- Failed to meet minimum lighting standards as set by MN pharmacy law.
- Uptake of the program was small and it was eventually cancelled.
Maine’s passage of LD 171 in 2013

In 2013 Maine passed a law facilitating foreign mail order pharmacies from Canada, the UK, Northern Ireland, Australia, and New Zealand.

Dr. McCall ordered three medications from Canada Drug Center, operated by Quantum Solutions. They all arrived from other countries not on the approved list, and lab testing showed them to have insufficient API. The Maine Board of Pharmacy asked the AG to shut them down. The AG was powerless.
Breaking the supply chain - Florida example

Martin Paul Bean of **Boca Raton, FL** purchased US$7mm oncology medications from Pakistan, India, and Turkey and repackaged them to appear to be FDA approved medications.

When pressed by physicians who worried about the medicine’s integrity, he would assure them they were Canadian. He was sentenced to two years in prison in 2013.
Wholesale size lots of counterfeits: 2008-present
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 2017, Dr. Ona Colasante of Gainesville, FL was finally convicted and sentenced for 162 counts including purchasing black market non-FDA-approved medicines at a discount and administering them to her patients. She received one year in prison and three years probation.

Dr. Colasante at her clinic in 2012 (Photo credit Gainesville Sun)
Dr. Norbergs of *Palm Harbor, FL* bought oncology products from a ring of unlicensed wholesalers operating out of Canada with offices in Montana and Tennessee at a steep discount, gave them to at least 66 of her patients, and billed insurance for higher amounts.

Wanda Colgan, a patient, passed away in 2011 during the time of the crime. Her daughter Lori Ann Reed said at sentencing, “I’ll spend the rest of my life wondering if my mother would have lived longer if she’d gotten the treatment she deserved.”
Select medical clinics that received FDA warnings letters
Doctors and clinics in AK have been warned by the FDA for doing business with unlicensed Canadian wholesalers.
Wave of wholesale counterfeit medicines in America: 2008-present

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
Wave of wholesale counterfeit medicines in America: 2008-present
One of many convictions over a multi-year period.
Difficult prosecutions of foreign actors

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 bargain approved
Terms of plea deal

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

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 began his house arrest and subsequent probation while still holding his pharmacy license.

America prosecutors accuse CanadaDrugs.com and CEO Kris Thorkelson, affiliated companies and associates of selling 756,000 unapproved and counterfeit cancer drugs to U.S. doctors. (CBC)

CanadaDrugs.com sold off most of the rest of their inventory to Americans for many more months while “shutting down”
Counterfeit discovered February 2019 by WHO in North America, Malaysia, Switzerland, Turkey, Argentina, and online websites. Contains only acetaminophen.

Internet sales are one of the ways that the WHO listed these pills were being distributed around the world. Takeda and Incyte are the legitimate manufacturers of Iclusig, but neither produced the counterfeits currently on the market. The batch numbers for the fakes, which do not correspond to the genuine manufacturing records, are as follows:

- Iclusig 45-milligram: Batch number PR072875 (30 tablets per bottle)
- Iclusig 15-milligram: Batch number 25A19E09 (60 tablets per bottle)
Fentanyl ad beyond: the fourth wave

Photo originally created by New Hampshire Public Radio photographer Paige Sutherland
Fentanyl is driving overdose deaths

Drugs Involved in U.S. Overdose Deaths, 1999 to 2017

- Synthetic Opioids other than Methadone, 29,406
- Heroin, 15,958
- Natural and semi-synthetic opioids, 14,958
- Cocaine, 14,556
- Methamphetamine, 10,721
- Methadone, 3,295

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

Counterfeit OxyContin
Source: Atlanta Law Enforcement / DEA

Counterfeit Oxycodone
Source: Public Health Seattle & King County

Counterfeit Xanax
Source: Yakima Police Department

Counterfeit Percocet
Source: Georgia Bureau of Investigations
Maggie DiVita Crowley, Wellington, FL
On the evening of September 1, 2016, in Wellington, Florida, 34-year-old restaurant manager Margaret DiVita Crowley took a single oxycodone pill she had purchased from an acquaintance to deal with her chronic back pain. She died almost instantly of furanyl fentanyl poisoning.

Orthopedic surgeon Johnny Benjamin, Jr. of Vero Beach, FL made the pill that killed Maggie, using drugs and a pill press he ordered on the internet.
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.
The remaining three quarters of the counterfeit Xanax Tosh Ackerman took. *Photo courtesy of Carrie Luther and Santa Cruz, CA County Coroner’s office.*
Charles Joseph Kordsmeier, 34, of Conway, went to be with the Lord on Thursday, February 21, 2019. He was born August 25, 1984 in Conway to David and Melinda Kordsmeier. C. J. is preceded in death by his grandparents, Florence Kordsmeier, Catherine and Andrew Seiter and Olena Seiter.

Left to cherish his memory are his parents, David and Melinda Kordsmeier of Conway, sister, Kristen (Michael) Uffenbeck of Weare, NH, two brothers, Clark Kordsmeier of Edmond, OK and Luke (Brooke) Kordsmeier of Conway, grandfather, Clement "Pops" Kordsmeier, niece, Karoline, nephews, Nathan, Jaxon, and Grayson, and numerous aunts, uncles, cousins, and friends.

C. J. was a lifetime member of St. Joseph Catholic Church and attended St. Joseph Catholic School. He was employed as a Pipeline Engineering Technician in the Oil and Gas Industry. C. J. helped his dad often with remodeling projects and was his right-hand man. He was a Godfather to Nathan Kordsmeier and showed infinite love for his nieces and nephews. He was especially fond of his grandpa "Pops" and enjoyed spending time with him. C. J. will be greatly missed by all of his family and friends.

Rosary and visitation will be at 9am, Tuesday February 26, 2019 at St. Joseph Catholic Church with Mass of Christian Burial following at 10:30am. Burial will be at Crestlawn Memorial Park.

Counterfeit oxycodone pills made with fentanyl

(Photograph: U.S. Drug Enforcement Administration)
California + Arizona + Arkansas = Bad news for criminals

The Arkansas Postal Inspectors walked right into an active investigation in Arizona triggered by a Dark Web purchase of heroin in November 2018 shipped to Sacramento, CA.

Surveillance footage from inside a post office (this is not an image of the suspects in this case)
Email/first initial plus birthday = Booking photo

Once they obtained photos of both suspects, they began search their social media presences for more photos to match to surveillance footage, and that included them with each other.

Logo of the Paul Nava Jiu-Jitsu Gym on clothing seen in both surveillance photo and social media photos.
Packages being mailed by the subject and her daughter had the return address of two strip clubs in Phoenix, AZ on them.
ABC 15 (AZ) covered the arrest March 29, 2019

- Count 1: Conspiracy to possess with intent to Distribute Fentanyl
- Count 2: Possession with intent to distribute fentanyl
- Count 3: Possession of a Firearm in furtherance of/use of a firearm during and in relation to a drug trafficking offense
- Count 4: Possession with intent to distribute 100 grams or more of fentanyl.
Fake pills in 48 states, 33 states have fatalities

Source data current as of August 2019
Counterfeit enforcement challenge

Scott Gottlieb, M.D. @SGottliebFDA

Last week #FDA investigators at the JFK Airport’s International Mail Facility in New York intercepted and destroyed counterfeit and/or misbranded drugs totaling more than a half ton of illegal products.

#OnTheJob #MissionCritical
Evolved international criminal vendors

The vendor brags about their success at clearing customs, and when challenged, breaking the pill press into three parts and shipping those parts separately to get past U.S. Customs and Border Patrol.

https://www.safemedicines.org/pill-presses-an-overlooked-threat
From fentanyl to counterfeit pill

2017: CBP LA seized 396 pill presses

Illegal molds exist for all pills
The next threat: 3D printed pill presses and molds

https://www.safemedicines.org/pill-presses-an-overlooked-threat
Law enforcement risk: officer exposure

- Small amounts (2-3mg) ingested can cause injury and death
- New procedures for law enforcement
- Suspension of field tests

Source: KEPRTV.com

First Responder Fentanyl Exposures

Source: SAFEMEDICINES.org® ©2020

This much fentanyl will kill you.
Are we doing Canadian drug importation yet?

- Where is importation today?
- What do the Canadians think about it?
## Importation federal rulemakings

<table>
<thead>
<tr>
<th>Approach</th>
<th>Pathway #1: Consider proposals to import medicines from wholesalers or pharmacists (or states on behalf of those two).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pathway #2: Provide new NDC codes to existing manufacturers of FDA-approved medication for foreign markets.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Governed by</th>
<th>2003 Medicare Modernization Act</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unknown. There are testing and equivalency standards that are referenced but have not been cited yet.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who can apply to import?</th>
<th>Pharmacists and Wholesalers (or states on their behalf like FL, VT, CO, and ME)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manufacturers</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Restrictions?</th>
<th>Only certain types of drugs allowed, statistical sampled testing for purity, proper labels, documentation for all transactions, affirmations for cost and safety, and ongoing oversight.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>
### States doing importation

<table>
<thead>
<tr>
<th>State</th>
<th>State law</th>
<th>Stakeholder input sessions</th>
<th>RFI</th>
<th>Designed a plan</th>
<th>Formal state rulemaking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vermont</td>
<td>Passed</td>
<td>No</td>
<td>No</td>
<td>Outline only.</td>
<td>No</td>
</tr>
<tr>
<td>Colorado</td>
<td>Passed</td>
<td>Nov 2019</td>
<td>Yes</td>
<td>Outline only.</td>
<td>In process</td>
</tr>
<tr>
<td>Maine</td>
<td>Passed</td>
<td>Jan-Jun 2020</td>
<td>First due 12/12</td>
<td>Outline only.</td>
<td>In process</td>
</tr>
<tr>
<td>Florida</td>
<td>Passed</td>
<td>Some</td>
<td>Yes</td>
<td>Outline only.</td>
<td>In process</td>
</tr>
</tbody>
</table>
But what’s happening in Canada?

Respective population - 2018

37 million

327 million
Canada’s government has said No.

"Canada does not have a large enough supply of prescription drugs to meet U.S. demand, and importing medicines from Canada would not significantly lower U.S. prices[..]

Not only are we too small of a market, Canada cannot increase its domestic pharmaceutical drug supply to meet U.S. demand"

Delivered to White House advisor Joe Grogan, 
October 22, 2019.

Statement of Kirsten Hillman, 
Acting Ambassador of Canada to the United States
Law Enforcement has soundly rejected importation
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.
Generics lower prices. We need more of them.
Adding more generic manufacturing to the market drives down prices.

In 2018, 90% of all prescriptions filled were a generic drug, up from 88% in 2016.
Discount cards and patient assistance programs

Also the encyclopedia of patient assistance programs is Partnership for Prescription Assistance: www.pparx.org
Systemic solutions: Follow the dollar along the supply chain and address the players adding cost.

The Secret Drug Pricing System
Middlemen Use to Rake in Millions

By Robert Langreth, David Ingold and Jackie Gu
September 11, 2018
Adding more FDA-regulated manufacturers to the market
Solutions operating inside the legal supply chain

Starting in 2019, Louisiana will pay a single, annual flat fee for unlimited access to the Hepatitis C cure medication. Washington State also.
We must speak up now to focus our leaders on solutions to the healthcare cost problem that can actually work.

What can we do?

**Individuals**
Send a letter to your elected officials at all levels:
https://safedr.ug/takeaction

**Organizations (contact Shabbir)**
- Sign our ongoing letter against importation to the White House and Congress
- Join PSM