TUESDAY, JANUARY 9:
TOOLS TO PROTECT PATIENTS FROM COUNTERFEIT MEDICATION
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Counterfeit Medicine In America: 2019

Iowa Pharmacy Association

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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
- State regulations
- License
- 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.
- 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%
- 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?"

The Partnership for SafeMedicines.org ©2018
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)

Daren Jorgensen opened one of the first Canadian Internet fake pharmacies in 2001, and exited in 2008.
Since 2012, smugglers caught selling fake drugs sold up to 63 medications to over 3,000 doctors, clinics and hospitals across the U.S.
Midwest medical clinics that received FDA warnings letters
Iowa medical practices doing business with black marketers

Black Market and Counterfeit Cancer Drugs

November 2016: An Iowa cancer clinic and oncologist were required to pay more than $176,000 in fines to settle False Claims Act allegations. Hematology and Oncology Center of Iowa purchased medication from convicted counterfeit drug distributor, Medical Device King.6

March 2016: Four Iowa doctors, Mark O. Carlson, of Siouxland Adult Medicine Clinic, John Hoffman of Orthopaedic Specialists, Val O. Lyons of Pharmacy Medical Associates, and Ellen Shepler of Pharmacy Medical Associates, were among more than 1,227 doctors nationwide who received warning letters from the FDA to stop buying infusion drugs from TC Medical Group, which sold more than $33 million worth of non-FDA approved medications, including counterfeit Botox.7

May 2013: The FDA warned 780 medical practices, including three Iowa doctors offices, Hematology & Oncology Center of Iowa, Metro Anesthesia & Pain Management, and The Dental Center, to stop doing business with unlicensed drug seller Medical Device King, which had sold 31 non-FDA approved medications, including counterfeit Avastin.8

2012–2013: The FDA warned two Iowa medical practices, Mona Alqualali of Infinity Medical Group and Medical Associates of Clinton, Iowa, and more than 500 across the country to stop buying from CanadaDrugs.com subsidiaries that had sold American doctors counterfeit Avastin.9

This is from our two page PDF about counterfeit and black market medicine in Iowa that will be sent to attendees after the webinar.
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.
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
Difficult prosecutions

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 5:03 PM CT  |  Last Updated: Dec 21, 2017 5:14 PM CT

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.

Thorkelson’s company, CanadaDrugs, continues to hold provincial wholesale pharmacy licenses and a Canadian Federal manufacturing pharmacy license.
Across all therapeutic areas, the FDA has traced criminal wholesaler drug importation businesses to at least 3,000 medical practices across the United States.

Importation is not safe, even at a wholesale level. Only licensed U.S. wholesalers selling FDA-approved medicines are safe for American patients.

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.

There are over 40 analogues (variations) of fentanyl.

To evade prosecution, chemists alter the fentanyl molecule to create new analogues.
What does a fatal dose look like

Photo originally created by New Hampshire Public Radio photographer Paige Sutherland
Fentanyl-laced counterfeits

Three deaths now may be tied to counterfeit Xanax in San Francisco

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
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
Select fentanyl-laced counterfeit seizures

Police say residence in Utah was home to one of the largest fentanyl operations in the U.S.

20,000 fentanyl pills seized at border in San Diego, beating record set last week

3 Summit County men indicted in large seizure of fentanyl pills

U.S. Attorney Justin Herdman believes the arrests helped save at least 1,500 lives.

CLEVELAND (AP) - Federal prosecutors say three Summit County men have been indicted in a seizure of 1,500 fentanyl pills marked as the less potent opioid oxycodone.
Fentanyl is driving overdose deaths

An Even Deadlier Opioid, Carfentanil, Is Hitting The Streets

UPDATE: Counterfeit opioids on the rise in Iowa
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?

Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages

“..many Americans are purchasing fentanyl and other illicit opioids online and having them shipped here through the international mail system.” Jan. 23, 2018

Source: Twitter

**COMBATTING THE OPIOID CRISIS: EXPLOITING VULNERABILITIES IN INTERNATIONAL MAIL**

STAFF REPORT
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
UNITED STATES SENATE
Die molds are readily available for any kind of pill.
From 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.

Source: www.deseretnews.com
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.
Fentanyl trade attracts organized crime

Suspected Mexico cartel leader charged with smuggling 44 pounds of fentanyl into the city

Francisco Quintero-Zamora is charged with smuggling 44 pounds of fentanyl into the city. (Drug Enforcement Administration Handout)

A high-level drug trafficker from Mexico was arrested and charged with smuggling more than 44 pounds of fentanyl into the city, authorities announced Tuesday.

Francisco Quintero-Zamora, 41, a suspected leader of the powerful Sinaloa cartel, faces drug-trafficking conspiracy charges.

Major Bust Brings Down Drug Ring Selling Sinaloa Cartel Drugs – Including Fentanyl And Fentanyl Pills

October 19, 2018

The Ventura County Star reported on a press conference announcing the bust of a major drug trafficking ring operating in the area with ties to the Sinaloa cartel and the seizure of $10.8 million worth of drugs. At the press conference, Ventura County Undersheriff Gary Pentis said it was the discovery of fentanyl pills that started this whole investigation: “Early on, one of the first seizures was fentanyl, bogus prescription counterfeits made with synthetic fentanyl to stimulate the high of opiates.” Those pills looked like Oxycodone pills.

On multiple tables behind the sheriff were all the drugs seized during this year-long operation: 285 pounds of methamphetamine, 121 pounds of cocaine, 13.2 pounds of heroin, 6.6 pounds of powdered fentanyl, and the 600 counterfeit Oxycodone. Pentis stated that the powdered fentanyl was seized in the city of Camarillo. For the Ventura County Sheriff’s Office.

Expert: Sinaloa cartel moved to fentanyl to meet demand

Joe Dwinell Friday, February 09, 2018

Click here to learn about other counterfeit drug incidents in California

Operación HIGH HOPES

Credit: Courtesy
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
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.
What can we do?

Regulatory enhancement

Support efforts to remove gag clauses that prevent pharmacists from helping patients save money.
Support the FDA’s efforts to bring more generics to market faster.

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.
Support enhancement to border security through advocacy

Scott Gottlieb, M.D.  
@SGottliebFDA

Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages

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.
- Removes local pharmacist from the care team.
- 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.

Sen. Grassley has a history of work on reducing drug pricing, advocating many different policy methods of bringing down prices including increasing generic competition.

Only one approach sacrifices drug safety and cuts local pharmacists out of the patient care team: foreign drug importation.
Importation enforcement challenge
Overburdening Law Enforcement

Unregulated Online Sellers

Package Inspection

“in fiscal year (FY) 2017, 86 percent of the packages that the FDA reviewed [at ports of entry] contained illegal, illicit, unapproved, counterfeit and potentially dangerous drugs. These products come in all different shapes and forms – some with sophisticated packaging and others in nondescript plastic bags.” FDA Commissioner Scott Gottlieb, M.D., Oct. 24, 2018
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.htm
Every head of HHS and FDA for the last 18 years refused to certify the safety of drug importation.

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

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

"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

To see all of the HHS and FDA quotes go to https://safedrug.com/FDA-HHS.
Opposition by four former FDA commissioners
Law enforcement opposition
What can we do?

Tell your elected officials in Congress and the White House personally that you support efforts to lower pharmaceutical costs, but not at the expense of safety:

SPEAK UP AT: https://www.safemedicines.org/speak-up-to-the-white-house-about-importation

Have your organization join dozens of others on our joint letter to Congress and the White House. Tell them your organization supports efforts to lower health care costs, but not at the expense of safety. This letter will be delivered in early Q1 2019.

SIGN ON AT: https://www.safemedicines.org/action-speak-up-for-patient-safety

These links will be sent out in a followup email after this webinar.
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

Order bulk print materials: editors@safemedicines.org

Contact us to find out if we have materials about counterfeit drug investigations in your state: editors@safemedicines.org
Thank you

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THANKS FOR ATTENDING!

JOIN US TUESDAY, FEBRUARY 12:
IMPACT OF NEW EPA RULES ON YOUR PRACTICE

Questions? Contact David Schaaf at dschaaf@iarx.org or 515-270-0713