

Webinar: Crime and Policy III

June 30, 2021, 12:30-1:30pm Eastern

Federal and state legislation on importation, pill presses, and fentanyl

Recent 2021 counterfeit drug prosecutions

A panel discussion with survivors of counterfeit medicines



Host

Shabbir Imber
Safdar
Executive
Director

Register at safedr.org/CP21

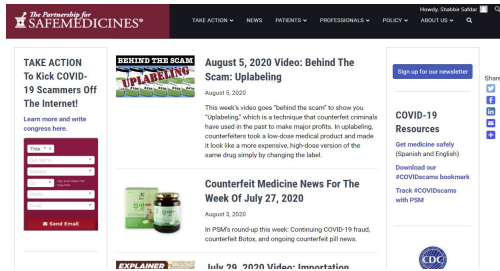


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Academy of Managed Care Pharmacy	Kansas Pharmacists Association	New Mexico Pharmacists Association
ADAP Advocacy Association	Maine Pharmacy Association	Ohio Pharmacists Association
Alabama Pharmacists Association	Maryland Pharmacists Association	Oklahoma Pharmacists Association
Alaska Pharmacists Association	Men's Health Network	Oncology Managers of Florida, Inc.
American Pharmacists Association	Minnesota Pharmacists Association	Pennsylvania Pharmacists Association
Arizona Pharmacy Alliance (AzPA)	Mississippi Pharmacists Association	Pharmaceutical Industry
Association for Accessible Medicines	Missouri Pharmacy Association	Labor-Management Association (PILMA)
Biotechnology Innovation Organization	National Alliance of State Pharmacy Associations	Pharmaceutical Researchers and
California Pharmacists Association	National Alliance On Mental Illness	Manufacturers of America
Colorado BioScience Association	National Association of Boards of Pharmacy	Pharmaceutical Security Institute
Colorado Pharmacists Society	National Association of Chain Drug Stores	RetireSafe
Community Access National Network	National Association of Drug Diversion	Rx Outreach
Connecticut Pharmacists Association	Investigators	Rx Partnership
Delaware Pharmacists Society	National Association of Manufacturers	Texas Pharmacy Association
Healthcare Distribution Association	National Consumers League	University of New England College of
HealthCare Institute of New Jersey	National Grange of the Order of Patrons of	Pharmacy
Illinois Pharmacists Association	Husbandry	Virginia Pharmacists Association
Institute for Safe Medication Practices	Nebraska Pharmacists Association	Washington Pharmacists Association
International AntiCounterfeiting Coalition	NeedyMeds	
International Health Facility Diversion	New Hampshire Pharmacists Association	
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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What we watched states for this year so far:

Legislation or executive actions that touched on:

Pill press regulation

Drug-assisted homicide

Counterfeit medicine

Foreign drug importation

Medical / drug tourism

States legislatures and importation

- 25 bills were introduced in 17 states
- Four dealt with medicines beyond Canada (CA, CO, OK, OR)
- 2 states passed legislation (ND, CO), 3 states still have live bills (OR, WI, PA) and 12 are not viable (AZ, CA, CT, HI, IL, MN, MO, MT, OK, RI, TN, WV)

States legislatures and importation

- ND: 2 bills introduced: SB2212 became an importation study that passed. SB2209/HB1250 did not pass.
- CO: Passed legislation (S123) to allow importation from any country in the world as long as FDA approves it.
- Many other states are likely to end session with bills failing to “cross over” or see movement.

Follow our state legislative importation tracker

Current Bills In State Legislatures (See Date Of Last Action For Last Updated Date)

State Legislation Tracking for Importation : 2021				
State/Bill	Hearings	Status	Date of last action	Notes
North Dakota/ SB 2209	Jan. 27, 2021: testimony submitted , video	Failed to pass this session.	4/26/2021	Text , bill actions
North Dakota/ SB 2212	Jan. 27, 2021: testimony submitted , video	Passed into law. Will conduct a study of importation.	4/26/2021	Text , bill actions
Colorado / S 123 to expand importation beyond Canada		Signed into law. Allows the state to import from any country in the world with HHS approval.	4/16/2021	Text , Status
Oregon / SB 12	Mar. 24, 2021: Senate Committee on Health Care	Referred to Ways and Means Committee.	4/16/2021	Text & status
California/ A 458		Amended to include importation from other countries.	3/23/2021	Text , bill history
Montana / HB 679		Introduced and referred to committee	3/22/2021	Text & Status
Illinois / HB 3867		Referred to Committee	3/20/2021	Text & Status
Rhode Island / SB 499	Mar. 18, 2021: Health and Human Services (Webex)	Committee recommended bill held for further study.	3/18/2021	Text
West Virginia / HB 3170		Introduced and sent to House Health and Human Services committee	3/15/2021	Status
Pennsylvania / H833		Referred to Committee	3/8/2021	Text
Connecticut / SB 1006	Scheduled for Mar. 11, Insurance and Real Estate	Referred to Committee	3/5/2021	Text (Sections 11-15)
Rhode Island / H 5249	Mar. 1, 2021: Health and Human Services	Recommended held for further study	3/2/2021	Text , Status
Missouri / HB 4957		Assembly, 2nd read	2/24/2021	Text , Status

<https://www.safemedicines.org/legislative-tracking-for-canadian-drug-importation>

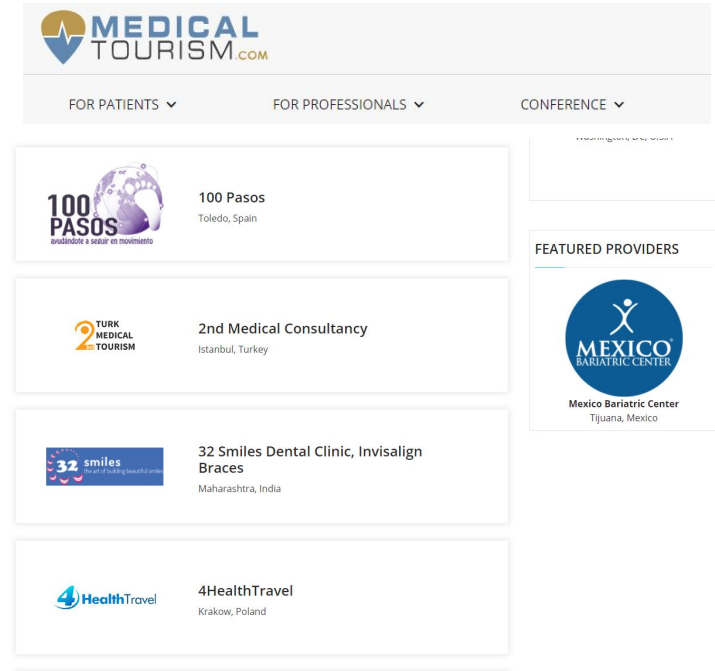
Medical tourism policy action

- Medical tourism: OR legislation SB 12 (2021), WA legislation SB 6111 (2020)
- Oregon bill is a study bill for Mexico & Canada medical tourism and importation. Bill passed Senate but not House.
- Utah's program was temporarily suspended due to the pandemic.

Medical tourism entrepreneurs abound

An industry of facilitators and recommendation services has sprung up around medical tourism.

Clients include not just patients but companies trying to reduce employee health insurance premiums.



Drug-related / drug-induced homicide

Multiple efforts to hold drug dealers accountable for the death of individuals killed by products they sold.

Federal law already covers both distribution of a counterfeit controlled substance and distribution of controlled substance resulting in death / serious injury.



Alexandra's Law (CA SB350) is named for Alexandra Capelouto. The bill failed to move in the CA state Senate this year.

Drug-related / drug-induced homicide

Both federal charges were successfully prosecuted in district court in Grand Junction, Colorado to convict Bruce Holder by Assistant U.S. Attorney Jeremy Chaffin and Special Assistant U.S. Attorney Jaime Peña.



Jonathan Ellington (left) died from one of the counterfeit pills Bruce Holder smuggled and was the basis for the “controlled substance distribution resulting in death” charge. Ashley Romero (left) also died in this wave of fake pills in Grand Junction.

Drug-related / drug-induced homicide

Two proposals from previous years have also not passed their state legislatures, including Joe's Law in Georgia (2017) and Taylor's Law in Oregon (2019).



Joe's Law in Georgia was named for Joe Patterson, son of PSM Advisory board member Lisa Hicks.

Drug-related / drug-induced homicide

Riverside County DA Mike Hestrin filed second degree murder charges against a man who sold counterfeit pills that allegedly resulted in the death of Angel Vazquez and at least one other near-fatal poisoning.



Yolo County DA Jeff Reisig is formally warning every convicted drug dealer that they could face future homicide charges.

Oklahoma has also been aggressively using murder charges.

Other state legislation

- Pill press regulation: No known proposed bills
- Counterfeit medicine: NJ (A-5037) increased penalties in 2020.

What we watched federally for this year so far:

Legislation or executive actions that touched on:

Penalties for pill press misuse

Require platforms to report illegal drug sales

Domain name transparency

Fentanyl analogue scheduling

Foreign drug importation



PSM Legislative Agenda for the 117th Congress

Protect Consumers

Stakeholders must work together to improve enforcement and regulations and increase penalties to combat online sales of counterfeit, misbranded and adulterated pharmaceuticals. In addition, PSM rejects proposals which call on HHS to allow foreign drug importation because they will open the U.S. drug supply to unsafe and counterfeit drugs. PSM supports policies such as increasing approvals of generics to help Americans receive safe U.S. medications at prices they can afford without sacrificing safety.

We SUPPORT

Requiring Registries/Registrars to Lock & Suspend Domain Names That Facilitate Illegal Online Drug Sales

- PSM supports legislation that would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require credible parties (e.g., law enforcement, domain name registrars and registrars) to immediately lock and suspend any domain name used to facilitate illegal medicine sales.
- The FDA should be given injunctive authority to seize and reassign domain names that facilitate the illegal online sales of medicines and illicit drugs.
- Failure to comply with such policies should be added to the FDA's Prohibited Acts and Penalties.

Requiring Online Search/Social Media/Marketplace Platforms to Report Illegal Online Drug Information to Federal/State Authorities ("duty to report")

- PSM supports internet companies having a duty to report communications requisite to tackling illegal content.
- Oversight authorities should be able to assess whether additional measures are needed to ensure swift and proactive detection and removal of illicit drug sales online.
- Search engines, social media platforms and online marketplaces should submit data including computer-mediated messages, posts, comments, interactions, and multimedia.

We OPPOSE

117th Congress Legislation: H.R. 832/S. 259, the Safe and Affordable Drugs from Canada Act; and the HHS

Safe Importation Action Plan; S. 920, the Affordable and Safe Prescription Drug Importation Act

116th Congress Legislation: S. 1801, The Affordable Medications Act; H.R. 1478, the Affordable Insulin Act

- PSM opposes any legislation or administrative action that would legalize the importation of prescription drugs from other countries.
- Foreign drug importation would weaken our borders and open more loopholes for criminals trafficking dangerous drugs into the U.S.
- Importation will lead to the proliferation of counterfeit pharmaceuticals, including fentanyl-faced counterfeit drugs. This creates a significant interior enforcement issue and an unfunded mandate for law enforcement at the federal, state and local levels.

Updated: April 2021

safemedicines.org/policy-page
Contains our entire federal policy platform

Supported Policies - Safeguarding Therapeutics Act

116TH CONGRESS
2D SESSION

H. R. 5663

IN THE SENATE OF THE

SENATE

Received; read twice and referred to the Committee on Health, Education and Labor

To amend the Federal Food, Drug, and Cosmetic Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, to provide for the destruction of counterfeit drugs, and for other purposes

Department of Health and Human Services, acting through the Commissioner of Food and Drugs

Be it enacted by the Congress of the United States of America in Congress assembled,

SECTION 1.

This Act may be cited as the "Safeguarding Therapeutics Act".

SEC. 2. AUTHORITY TO SEIZE AND DESTROY COUNTERFEIT DEVICES.

BECAME LAW

Supported Policies - The CAST Act

116TH CONGRESS
1ST SESSION

H. R. 4510

To amend the Controlled Substances Act to prohibit the knowing possession of a pill press mold with intent to manufacture in violation of such Act a counterfeit substance in schedule I or II in a capsule, tablet, and other form intended for distribution, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2019

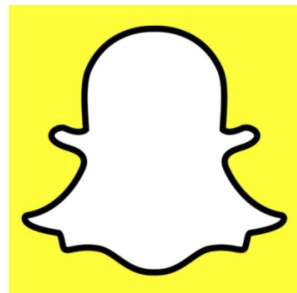
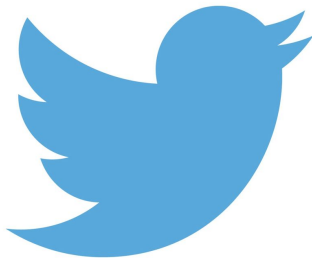
Mr. KUSTOFF of Tennessee (for himself and Ms. SPANBERGER) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Controlled Substances Act to prohibit the knowing possession of a pill press mold with intent to manufacture in violation of such Act a counterfeit substance in schedule I or II in a capsule, tablet, and other form intended for distribution, and for other purposes.

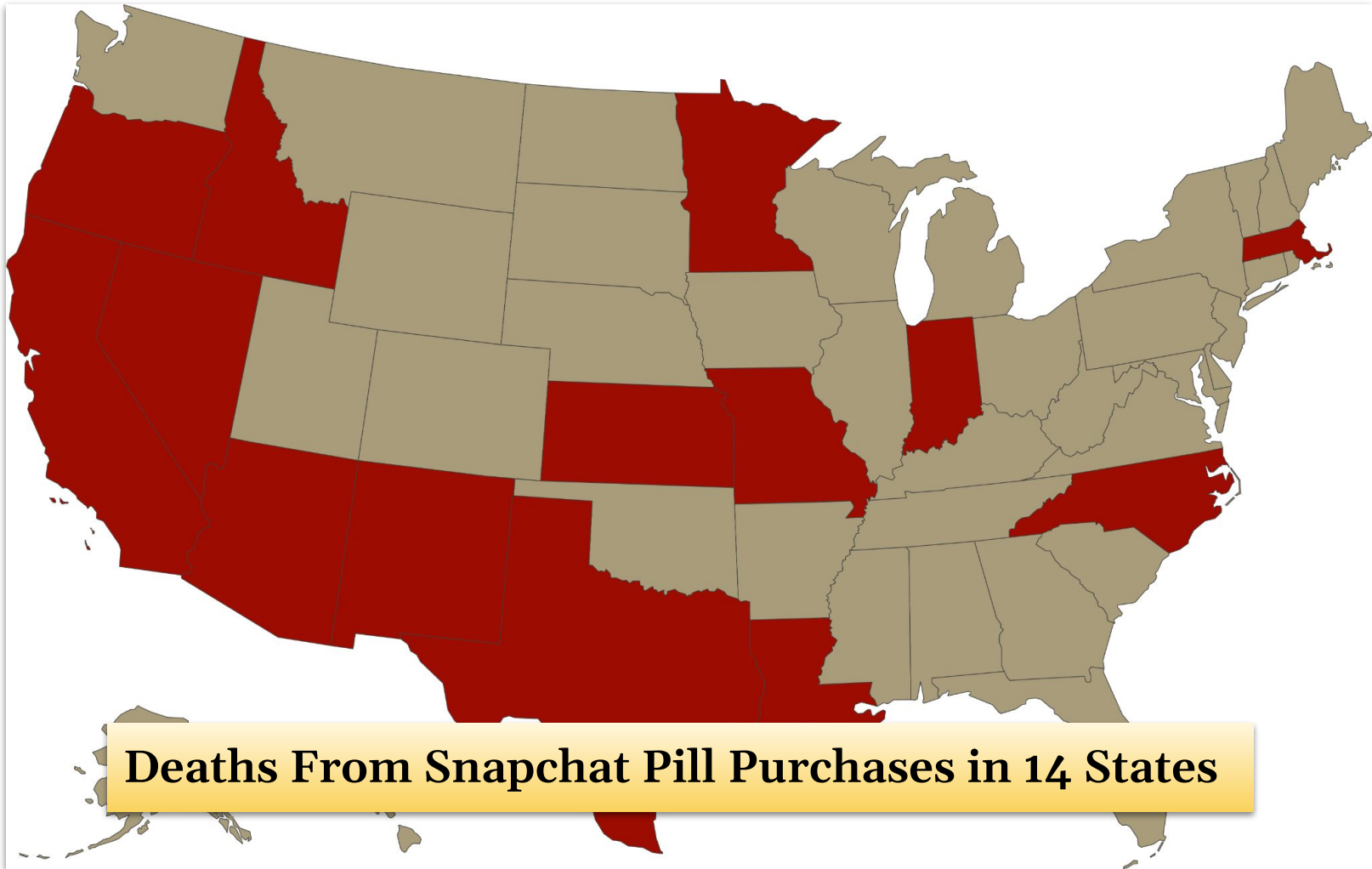
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Supported policy: Requiring online marketplaces, social media or search engine to report illegal online drug content



Bing





Deaths From Snapchat Pill Purchases in 14 States

Protest at Snapchat



Snapchat
Is An Accomplice
To My Murder



WHY A
DRUG DE
ETT
Snapchat
Is An Accomplice
To My Murder
Forever 16

Ray Mascolo
FOREVER 37
Snapchat
Is An Accomplice
To My Murder
Forever

Ray Mascolo
FOREVER 37
Snapchat
Is An Accomplice
To My Murder
Forever 17

Snapchat
Is An Accomplice
To My Murder

 SAFEMEDICINES.org® **June 14, 2021**

Supported Policies - Domain name transparency and lock and suspend

Criminals operating internationally online are difficult to shut down.

Law enforcement and the public should be able to see who owns domain names and, with proof of criminal activity, have them locked and suspended.

Additionally there are a few domain name sellers favored by criminals who rarely suspend customers.



PSM belongs to and supports CSTI which is working to change national policy on criminal use of domain names.

Supported Policies - Permanent fentanyl analogue scheduling

Many analogues are only controlled substances because of emergency actions.

Lack of controlled status means lack of access to LEO resources, and criminal statutes for prosecution.

Policy balance: research access, criminal justice reform, reduction of epidemic, and justice for victim families.



Sneaky Fentanyl Variants

April 19, 2021

The Partnership for
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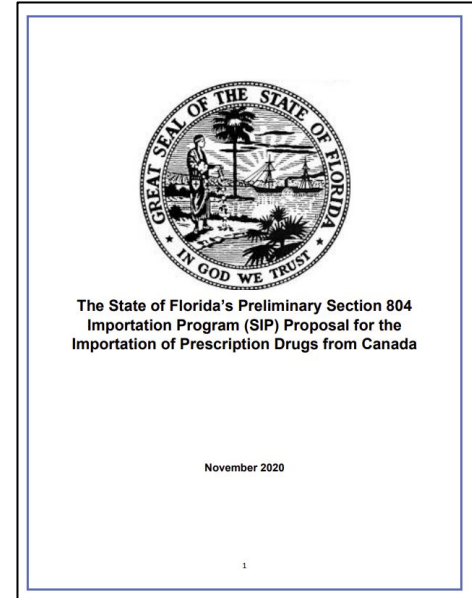
PSM supports permanent scheduling of fentanyl analogues.

Opposed Policies - Foreign drug importation

Two states have submitted applications to FDA:
New Mexico and Florida

One state is working on their proposal: Colorado

Six states have a stalled implementation:
Connecticut, Maine, New Hampshire, and
Vermont.



Read both applications from FL
and NM on our website.

Opposed Policies - Foreign drug importation

PSM, PhRMA, and the Council for Affordable Health Coverage have filed suit against HHS to overturn the federal rules finalized by the Trump Administration.

Case 1:20-cv-03402-TJK Document 26 Filed 05/28/21 Page 1 of 3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Pharmaceutical Research & Manufacturers
of America, *et al.*,

Plaintiffs,

v.

U.S. Department of Health and Human
Services, *et al.*,

Defendants.

Case No. 1:20-cv-03402-TJK

Opposed Policies - Foreign drug importation



Under Gov. DeSantis, Florida has hired an importer, secured a warehouse and a Canadian seller, developed IT systems for order tracking and recall management, and hired personnel.

Total Estimated Cost So Far: \$9 million dollars.



Under Gov. Polis, Colorado is developing their importation program, and has expanded it to include importation from any country in the world.

Total Estimated Cost So Far: \$2 million dollars.

Crime!

Major criminal trends in
counterfeiting

Interesting
investigations/prosecutions

Open investigations /
crimes we're tracking



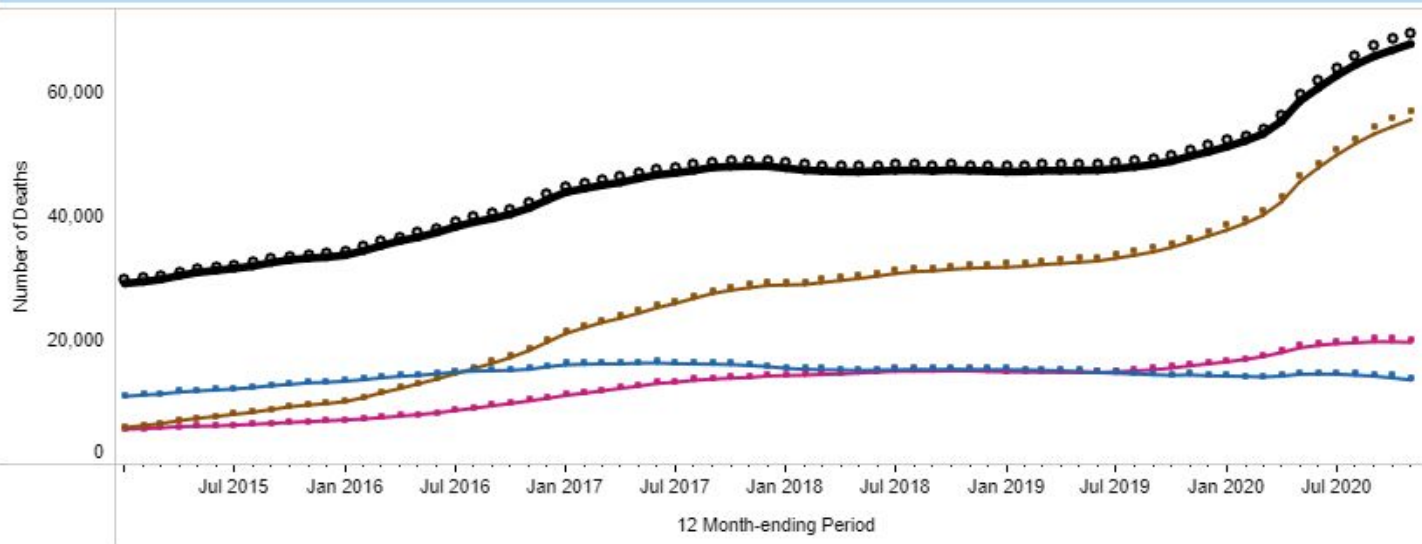
Source: www.xdpedia.com

Fentanyl is driving deaths

November 2020



Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: United States



Opioids:
67,574

Fentanyls:
55,363

Cocaine:
19,945

Heroin:
13,444

Legend for Drug or Drug Class

Opioids (T40.0-T40.4,T40.6)

Heroin (T40.1)

Synthetic opioids, excl. methadone (T40.4)

Cocaine (T40.5)

--- Reported Value

○ Predicted Value

Fentanyl is an additive to illicit drugs



tracey helton mitchell MPA (she/her/hers)

@traceyh415



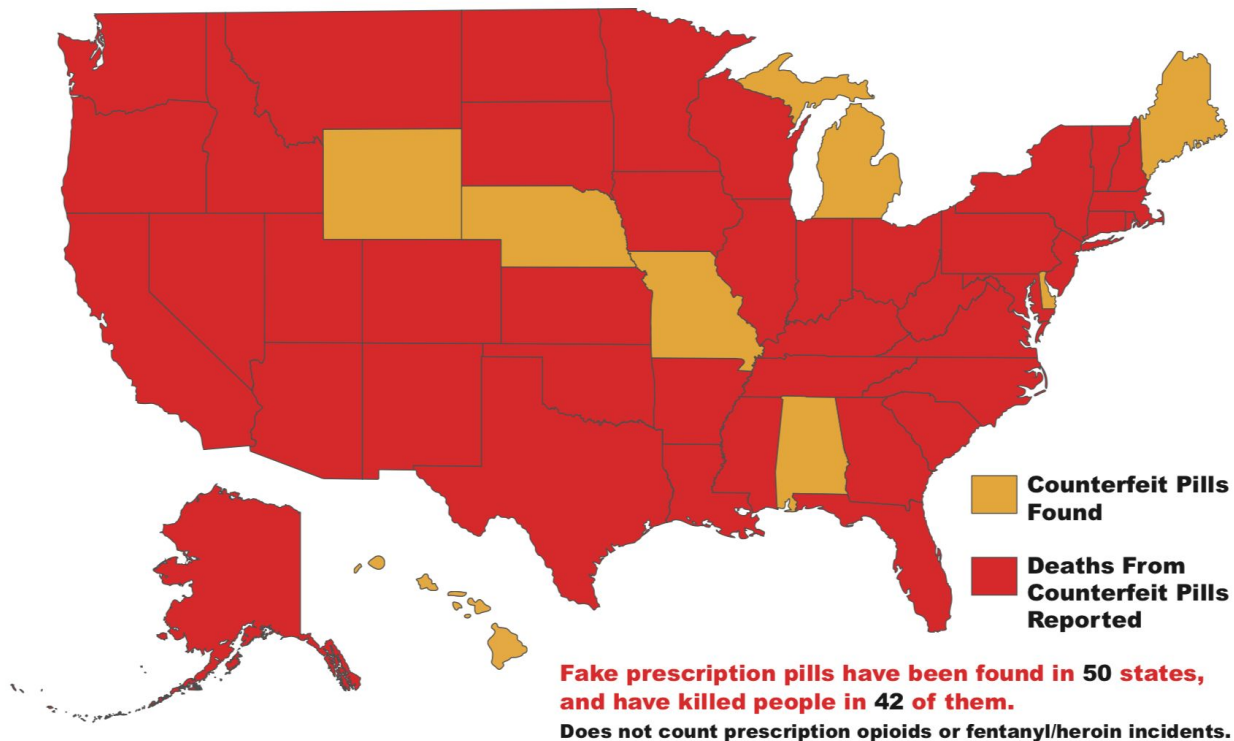
My friend's roommate died this week from fent in his cocaine. The person was an occasional user of drugs so his circle of friends are blindsided.

This seems to be common now in the Bay Area. While there are narcan and test strips, either way you have to go slow.

3:12 PM · Jun 25, 2021 · Twitter Web App

Fentanyl has been found in cocaine, heroin and methamphetamine but we haven't seen credible stories of it in cannabis.

Trend: Fake pills with fentanyl



Some new analogues
and other emerging
substances to watch

para-fluorofentanyl

isotonitazene

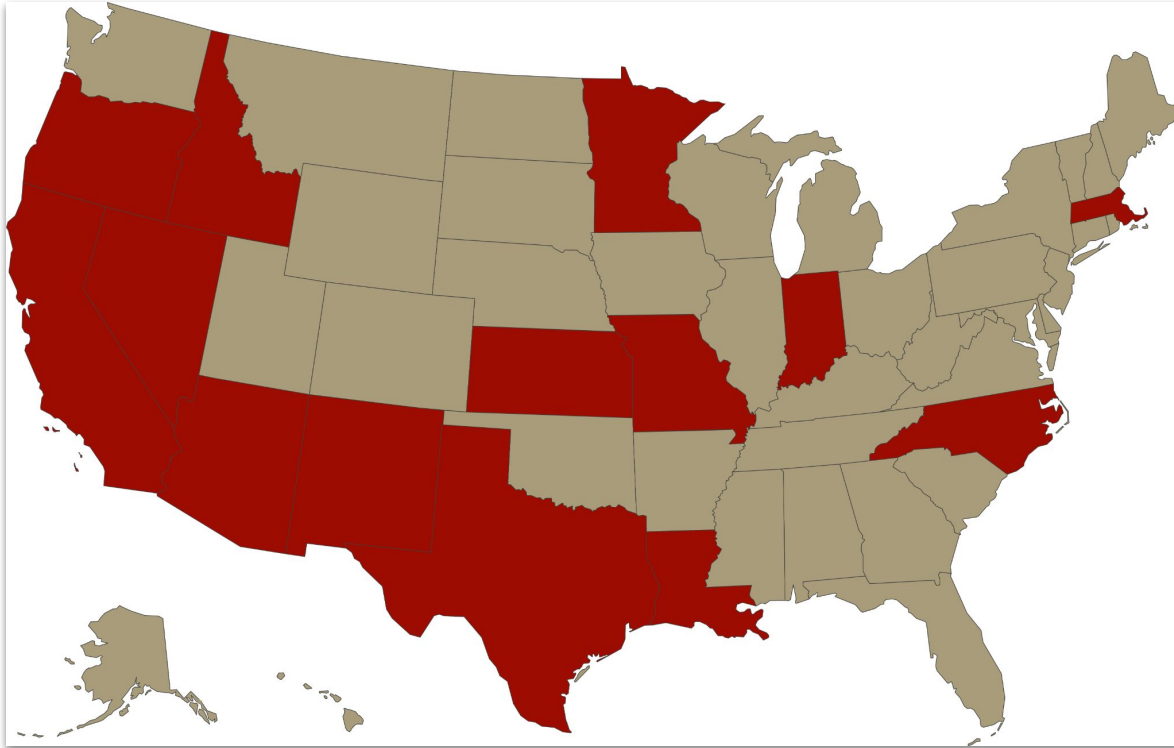
xylazine

etizolam

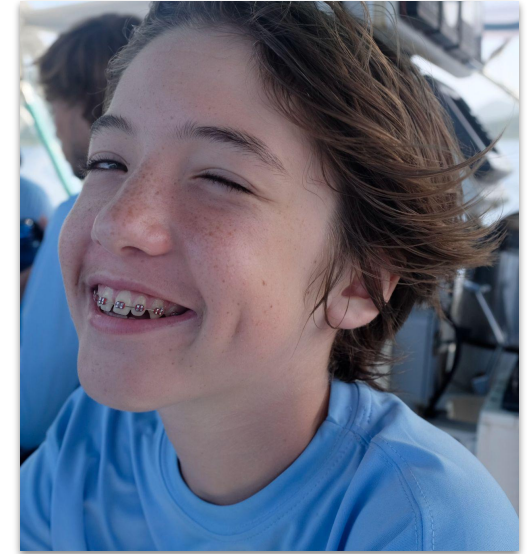


Protest at Snapchat headquarters, Santa Monica, CA

Trend: Younger victims

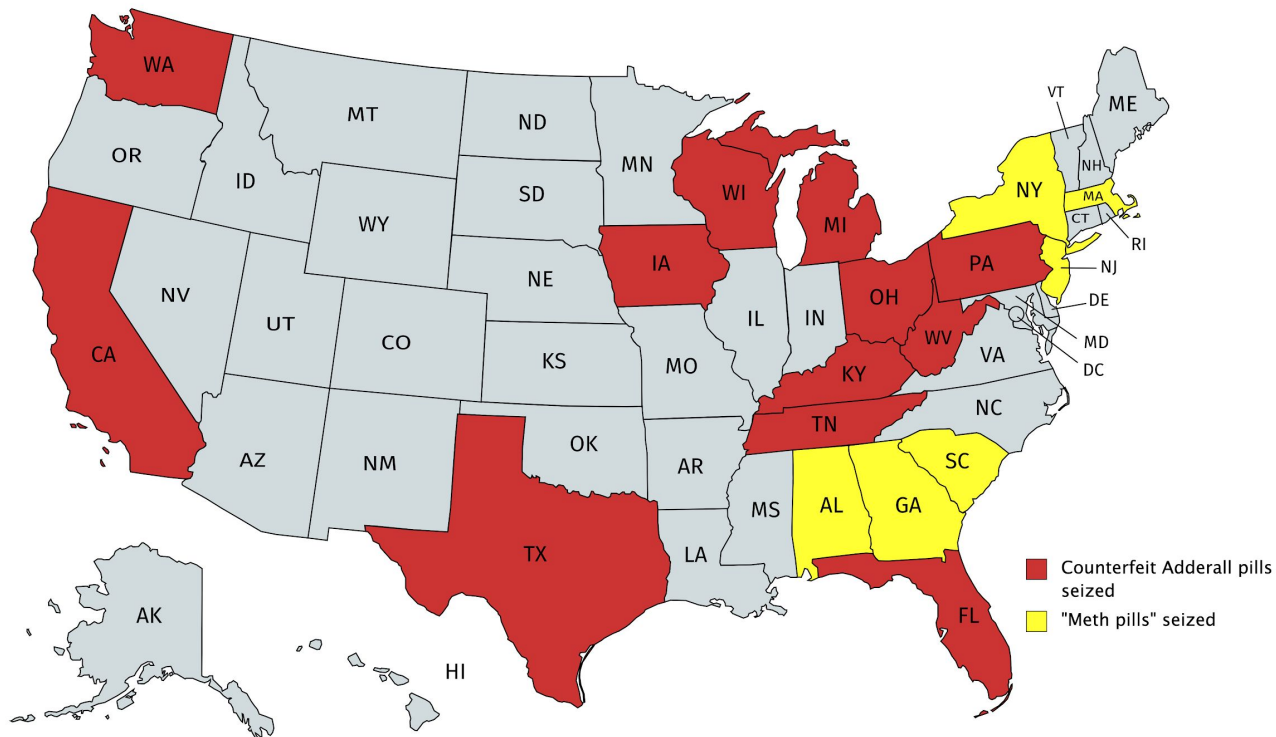


Deaths From Snapchat Pill Purchases in 14 States



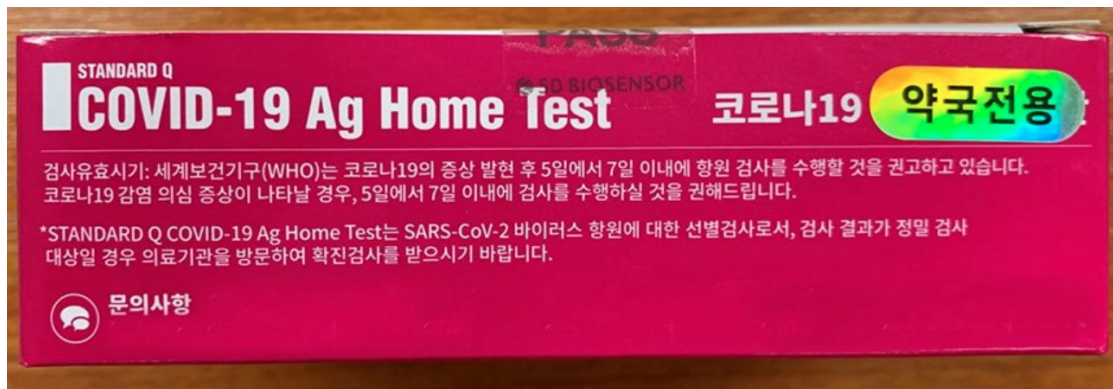
Alexander Neville, 14

Trend: Fake Adderall with meth

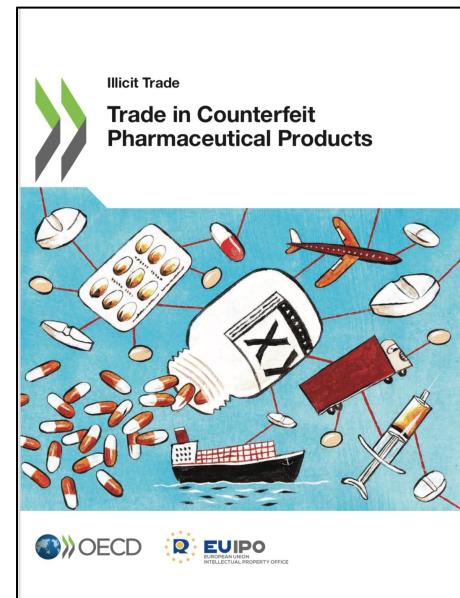


Since October 2020, we've gone from 7 states to 18 states.

Trend: Fake medical devices / products



This year Interpol conducted Operation Pangea XIV and seized 9 million counterfeit medical products in 92 countries. **Half of the items seized were counterfeit or black market COVID-19 diagnostic tests.**

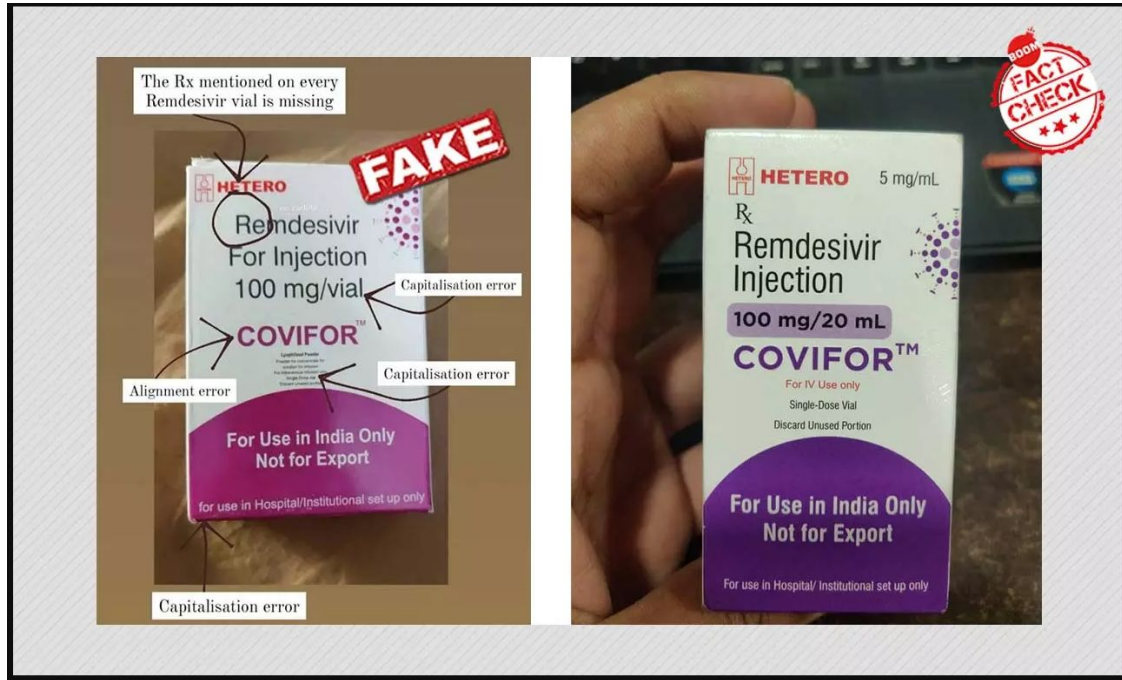


“In 2016, international trade in counterfeit pharmaceuticals reached USD 4.4 billion”

(Photo: Interpol)
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Trend: Global counterfeiting not resting



Other products

Hand sanitizer made with methanol has been subject to over 200 recalls and an import alert for dangerous Mexican product by the FDA.

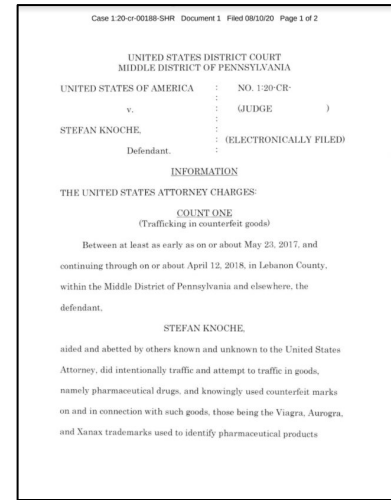
Incidents of fake masks, sanitizer, PPE, and diagnostics persist today, and will probably continue for years to come.

Prosecution: U.S. v Stefen Knoche

U.S. repackager / reshipper for foreign counterfeiters who shipped Viagra, Aurogra, Xanax, Levitra, Cialis, Valium, and others.

Knoche was shipping to fulfill online sales of others. Sometimes he never even examined contents before shipping.

Not surprisingly it was far easier to convict Knoche, who was in the U.S., than his upstream partners who are outside the U.S.



Key facts

April 15, 2021 plea

US\$3.6mm restitution

70 month sentence

Prosecution: U.S. v Vincent Decaro

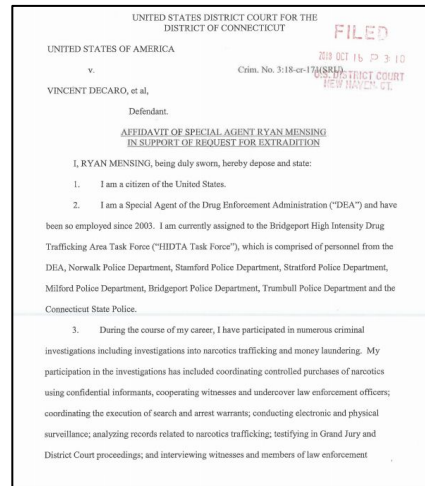
Purchased fentanyl analogues, pressed counterfeit oxycodone pills, sold via Dark Web from a private home in Stamford, CT.

Pill presses **legally** sold by LFA Tablet Presses (TX).

Search turned up equipment and directions to make carfentanil.

Arrested in Albania with another conspirator. An apartment searched there also had manufacturing equipment.

Both extradited back to the U.S.



Key facts

June 15, 2021 plea

Sep. 21, 2021 sentencing

Physicians buying black market medicine

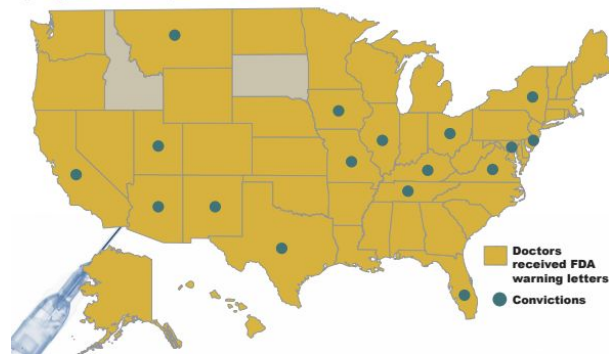
Over the past twelve years there have been incidences of black market oncology medicine in forty eight states, with convictions in seventeen states.

This wave of counterfeits covered dozens of therapeutic medicines.

Many patients have no idea their physician was warned by the FDA.

Black Market Cancer Drugs In the U.S. 2007–2018

Wholesale importation backfired resulting in thousands of patients endangered and physicians prosecuted



Find this publication on our website under Policy->Publications

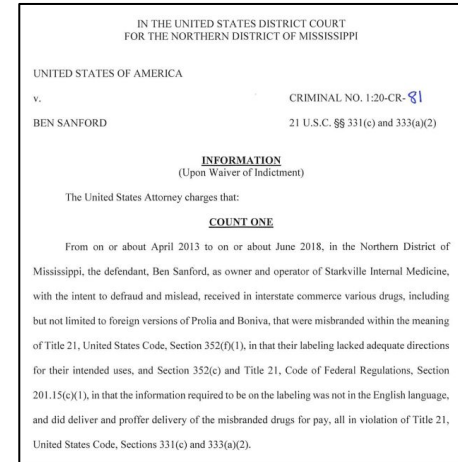
Prosecutions: Doctors still importing their own meds

Benjamin Franklin Sanford, Jr - Prolia,
Boniva, and Aclasta

Stanley Rossman - Altuzan

Mark Goldstein - Altuzan

Lindsay Marie Clark - Botox and Juvederm



These prosecutions are rare for a variety of reasons. Full court docs on our website.

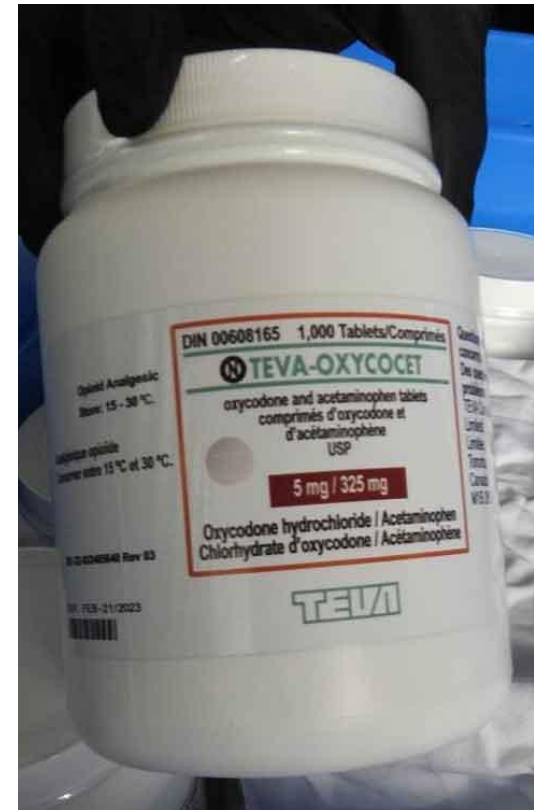
Prosecution: Ontario Teva-Oxycocet counterfeits

Two rings in Ontario have been **caught** counterfeiting Teva-Oxycocet pills with fentanyl.

The innovation is they make near perfect looking wholesale packaging.

PSM has found footage of one buyer on social media showing off his bottle.

No product has been detected in Canadian pharmacies yet. We suspect it will never get past Canadian pharmacists.



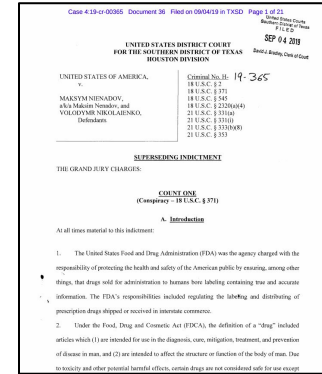
Prosecution: U.S. v Maksym Nienadov, Volodymyr Nikolaienko

Two Ukrainians selling counterfeit Keytruda, Abraxane, and Eplclusa around the world via Whatsapp.

Did not contain necessary active ingredient.

Lured to the U.S. for business meeting to work around lack of extradition treaty.

Counterfeit packaging for Iclusig found amongst their belongings after arrest in Texas.



Key facts

Sentenced Mar. 2021.

71/33 month sentences

Fine waived.

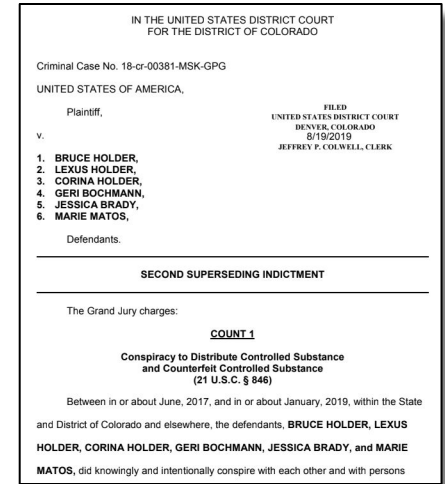
Prosecution: U.S. v Bruce Holder et al

Charged with conspiracy to distribute controlled substance or counterfeit controlled substance.

Also distribution of a controlled or counterfeit substance resulting in death. (unusual!)

Some fatal victims of these pills did not rise to the burden of proof and were excluded from the case.

Five other co-defendants in the case awaiting legal action.



Key facts

Guilty verdict Apr. 2021

Sentencing in fall.

Other prosecutions we think are interesting

Johnny Stine allegedly created his own COVID-19 vaccine.

George Kuiper sold illegally imported drugs for 14 years.

Tymalk Love ran a meth, heroin and fentanyl pill ring from prison.

4 Hartford, CT men allegedly sold fentanyl pills out of local grocery stores.

Nitica Lee fled the country after her silicone injections killed a woman.



Watch this video about this case and many more at youtube.com/safemedicines

Giving voice to victims



Rick Roberts
San Francisco, California



Lisa Hicks
Dacula, Georgia



Andrea Thomas
Grand Junction, Colorado

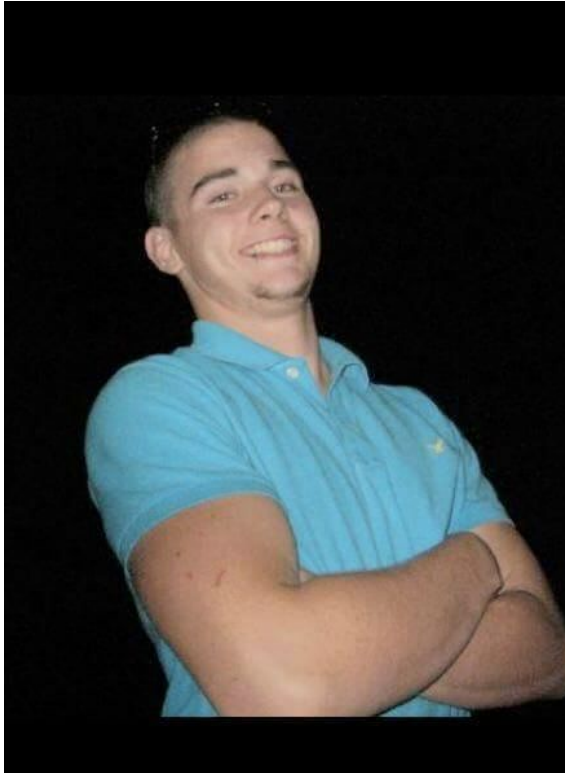
Rick Roberts



In 2000, a wholesaler smuggled fake HGH injections into the legitimate drug supply. After many transactions, they landed at Rick's pharmacy.

The fake drugs were a threat to his then-precarious health and his peace of mind.

Lisa Hicks, mother of Joe Patterson



Lisa's son Joe died in February 2015 after taking oxycodone for a pulled muscle.

Joe had no idea the pills were counterfeit, and made with fentanyl.

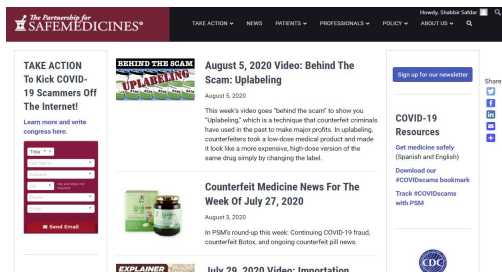
Andrea Thomas, mother of Ashley Romero



Andrea lost her daughter to fentanyl poisoning in June 2018.

Ashley had taken half an oxycodone that her boyfriend gave her.

18 years studying safety (and counting!)



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