FORTY STATES AND COUNTING:

The Deadly
Combination of
Imported Fentanyl and
Counterfeit Medicines





Introduction

In recent weeks, authorities in New York have seized nearly 200 pounds of fentanyl, which experts believe could produce 32 million lethal doses of the illegal substance.

Counterfeit prescription pills are poorly made in rogue manufacturing facilities with illegally obtained fentanyl, most often imported from China. And they are infiltrating communities across America.

Increasingly, toxicology screens and autopsies are revealing that the pills found next to overdose victims are counterfeits, and the chemical in the pills responsible for death is fentanyl or one of its analogues. Consider the example of world-famous musician Prince. He died from a counterfeit painkiller made with too much fentanyl in an unidentified illegal lab. A fractional piece of a counterfeit Xanax made with too much fentanyl killed Tosh Ackerman in California. By our analysis, counterfeit pills made with illegal fentanyl have killed people in at least 16 states. The counterfeit pill epidemic is so new and fast-moving that even the experts we work with don't appreciate how widespread it is.

As PSM's research staff started tracking these incidents in media reports in 2015, we became alarmed. A few isolated incidents became a dozen, and then suddenly 25 states were affected. Then 30 and 35.

As of the date of this publication, we have documented the spread of counterfeit pills made with illegal fentanyl throughout 40 states. There is documentation that counterfeits made with fentanyl have killed Americans in at least 16 of those states. The other 24 states probably have deaths attributable to counterfeits made with fentanyl, but because of limited awareness of the problem, those deaths may not have been investigated for counterfeit drugs.

How did we get here?

How we got here isn't hard to understand. Criminals like trafficking prescription drugs. Instead of stealing or buying them in small quantities from the legitimate supply chain, they



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



9:33 AM - 25 Aug 2017

I. Rogue manufacturers are finding new ways to tweak the fentanyl molecule all the time. For the sake of simplicity in this report, when we say "fentanyl", we mean "fentanyl and its analogues".



can easily make fake ones with pill presses after purchasing illegal fentanyl from Chinese manufacturers. Or they can just resell finished counterfeit pills made outside the U.S. borders smuggled through the mail or carried across the border by drug mules. Mexican cartels and their peers have moved into this line of business as well.

What does this have to do with importation?

Seizures and criminal cases show us that a great deal of fentanyl in its raw and finished counterfeit pill forms come from outside the United States. The sheer volume of packages shipped into the U.S. containing unidentified pharmaceuticals is so great that it is impossible for Customs and Border Protection to inspect, intercept and seize all of the illegal shipments. Without any electronic tracking information and with reduced resources, the ability for an inspector to effectively detect counterfeit pharmaceuticals becomes almost a random chance. An estimated one million packages enter the U.S. every day through the Jamaica, Queens NY international mail facility, which is just one of over a dozen such sites. There simply aren't enough inspectors to check them all.

Proposals in Congress to open the floodgates to importation from unlicensed foreign sources for pharmaceuticals will increase the volume of unidentified packages containing pharmaceuticals even more, and make the problem even worse.

The volume that we have today is a result of impediments to enforcing existing laws and Americans' lack of understanding that counterfeits exist and are dangerous. It is illegal for you to go online and buy uninspected medical products from a foreign supplier, and yet people do it every day. Every day hundreds of thousands of packages come into the U.S. Many of them are tested and found to be counterfeit, either containing no active ingredient, the wrong active ingredient, or a tiny amount that isn't sufficient to treat your disease. CBP and the U.S. Food and Drug Administration (FDA) can destroy packages at the border that are tested as counterfeits. However, excessive regulatory and bureaucratic requirements and processes significantly hamper CBP's ability to seize and destroy counterfeit drugs. The seizure of one small parcel of counterfeit drugs requires the same paperwork as the seizure of a 40 ft. container. In an analysis done by former FBI Director Louis Freeh studying the impact of importation, he said, "[destruction] still requires the FDA to follow a burdensome, multi-step notification and hearing process that delays the destruction." In addition, CBP has to store seized packages at their facilities until destruction is allowed. CBP is required to store seized counterfeit pharmaceuticals in secured locked cages, and the sheer volume of seizures exceeds the storage capacity at many International Mail Centers.

The result is that those small batches have added up to an enormous volume of products that cross the border and provides ample places to hide deadly fake pills and dangerous ingredients such as counterfeit pills made with illegal fentanyl.

How do we stop this?

To stop the importation of fentanyl in finished form, we need to sufficiently resource our CBP officers. That includes both making their job easier by requiring electronic data on packages before they arrive at international mail facilities, as well as giving them the resources to handle the volume. We need to clamp down on illegal but currently unprosecuted importation of medicine and stop making CBP and the FDA jump through hoops to destroy packages of verified counterfeits.



We also need to handle the problem of domestic illegal pill manufacturing. A good first step would be to ensure that anyone without the legitimate licenses to manufacture medication, such as drug manufacturers or specific types of pharmacists, doesn't have the right to purchase or own a pill press or other forms of manufacturing equipment. Only licensed professionals should be able to purchase and own such equipment. In addition, old or seized equipment should have a restriction requirement, so it cannot be used and reused for counterfeit production.

Like all broad public policy issues, this one will not have easy, fast, or cheap fixes. Some of them are cheaper than others though. Allowing CBP to destroy counterfeit pharmaceuticals without onerous bureaucratic processes is one of them. Disallowing purchase or possession of a pill press without a compounding pharmacy or manufacturing license is another. Requiring the destruction of old, obsolescent and seized equipment is yet another.

Screening all fatalities that present as an overdose for toxic compounds will cost money, as will giving CBP officers additional resources they've been lacking. Implementing a global tracking system for medicine as is being put into place right now is yet another.

In the end, ensuring a safe drug supply costs money, but it's absolutely worth it.

Mary Shepherd

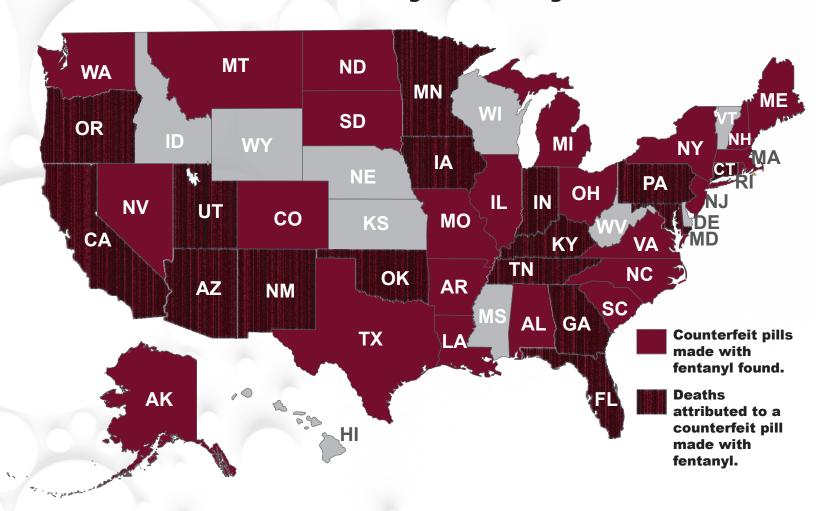
President, Partnership for Safe Medicines

Shabbir Safdar Executive Director, Partnership for Safe Medicines





40 States Have a Deadly Fentanyl Pill Problem



States with confirmed counterfeit fentanyl pills

Montana

Nevada

Illinois

Indiana

otates with commed counterfeit fentally, pins				
Alabama	Iowa	New Hampshire	Ohio	South Dakota
Alaska	Kentucky	New Jersey	Oklahoma	Tennessee
Arizona	Louisiana	New Mexico	Oregon	Texas
Arkansas	Maine	New York	Pennsylvania	Utah
California	Maryland	North Carolina	Rhode Island	Virginia
Colorado	Massachusetts	North Dakota	South Carolina	Washington
Connecticut	Michigan	Counterfeit fentanyl pill deaths may have been misattributed to opioids due to insufficient post-mortem testing.		
Florida	Minnesota			
Georgia	Missouri			

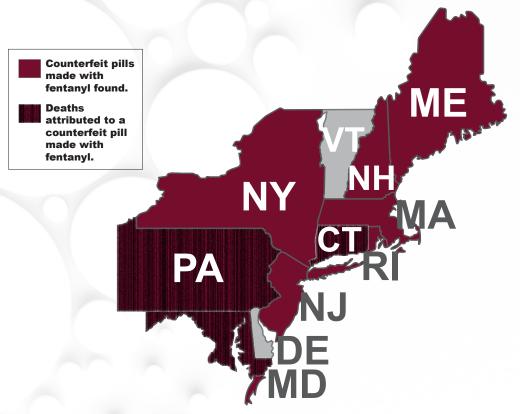
insufficient post-mortem testing.

On 9/5/17 the CDC recommended that all labs

screen for fentanyl in any overdose death.



Incidents of note in the Northeastern region



Connecticut ➤ A 30-year-old man in Hamden died of a fentanyl overdose when he inadvertently purchased <u>fake oxycodone pills</u> (March 2017).

Maine ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to Maine (November 2016).

Maryland ➤ A Baltimore man <u>overdosed and died</u> after taking a fentanyl-laced oxycodone (September 2015).

Massachusetts ➤ Salem police found <u>counterfeit "oxycodone" pills containing lethal doses of fentanyl</u> (September 2016).

New Hampshire ➤ State police <u>seized large quantities of fentanyl tablets</u> that resembled 30-milligram oxycodone pills (August 2017).

New Jersey ➤ DEA agents seized two pill presses and an unstated amount of fentanyl from a home in Carneys Point Township (June 2017).

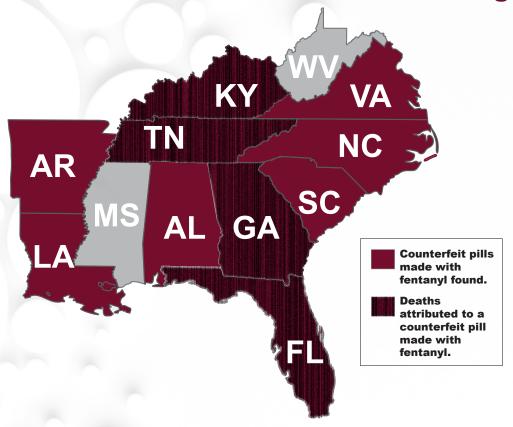
New York ➤ The DEA <u>raided a Long Island</u> home and arrested two men in the act of <u>manufacturing fake oxycodone pills</u> made of fentanyl (July 2017).

Pennsylvania ➤ A Bucks County man and a Montgomery County man died <u>after taking fake</u>, <u>fentanyl-laced Percocet</u> (November 2015).

Rhode Island ➤ State police <u>arrested an East Providence man</u> for possession of fentanyl pills and cocaine (July 2017).



Incidents of note in the Southeastern region



Alabama ➤ The Russell County Sheriff's Office arrested a man for possession of fentanyl pills disguised to look like Percocet (June 2017).

Arkansas ➤ Arkansas's crime laboratory identified 56 samples of fentanyl—in powder and counterfeit pill form—in the first three months of 2017 (July 2017).

Florida ➤ At least <u>nine Pinellas County residents died</u> after taking fake Xanax laced with fentanyl (March 2016).

Georgia Eight people overdosed in Bibb and Houston Counties after taking fake Percocets (August 2017). A similar outbreak in June 2017 killed four and prompted the hospitalization of nearly 20 people. Counterfeit pills first reported April 2015.

Kentucky ➤ A woman <u>died after taking a counterfeit oxycodone pill</u> that contained fentanyl (July 2015).

Louisiana ➤ The Natchitoches Drug Task Force reported that dealers were selling counterfeit hydrocodone <u>laced with fentanyl</u> (April 2017).

North Carolina ➤ A traffic stop in Iredell County resulted in police seizing 5,000 counterfeit OxyContin pills made of fentanyl (November 2016).

South Carolina ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to South Carolina (November 2016).

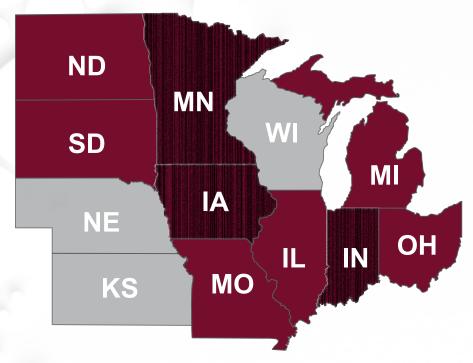
Tennessee ➤ A 37-year-old woman died after taking <u>counterfeit Xanax</u> (January 2016).

Virginia ➤ A state police officer reported "seeing fentanyl-laced pills" in the southwest part of the state (July 2017). Counterfeit pills first reported November 2016.



Incidents of note in the Midwestern region





Illinois ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to Illinois (November 2016).

Indiana ➤ A 19- and a 20-year-old in Fort Wayne died after <u>taking fake Xanax pills</u> (March 2016).

Iowa ➤ Four Iowa health and public safety agencies <u>reported</u> that counterfeit oxycodone is in circulation in Iowa and that Iowans had died after taking the drug (July 2017).

Michigan ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to Michigan (November 2016).

Minnesota ➤ Minneapolis-area musician <u>Prince Rogers Nelson</u> died after taking counterfeit painkillers laced with fentanyl (April 2016).

Missouri ➤ Utah-based drug trafficker Aaron Shamo <u>shipped counterfeit oxycodone pills</u> made with fentanyl to Missouri (November 2016).

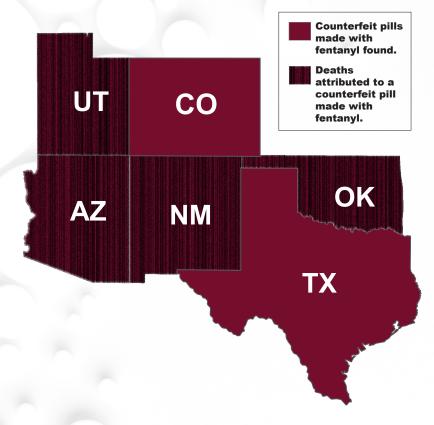
North Dakota ➤ Police <u>seized 500 counterfeit oxycodone pills</u> at a traffic stop in Grand Forks (March 2017). Law enforcement attributed as many as three overdoses to the pills.

Ohio ➤ Franklin County Police <u>seized</u> hundreds of oxycodone pills laced with fentanyl during a drug bust (November 2016). Counterfeit pills <u>first reported</u> in March 2016.

South Dakota ➤ Investigators intercepted a package containing 20,000 fentanyl pills at the Chamberlain post office (June 2017). Counterfeit pills first reported October 2016.



Incidents of note in the Southwestern region



Arizona ➤ Federal and Arizona authorities <u>seized 30,000 counterfeit pills</u> that contained fentanyl (August 2017). 32 <u>Maricopa County residents died</u> after taking fake prescription pills laced with fentanyl between May 2015 and February 2017.

Colorado ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to Colorado (November 2016).

New Mexico ➤ Authorities reported that at least 20 people have died after taking black-market oxycodone made of fentanyl (October 2016).

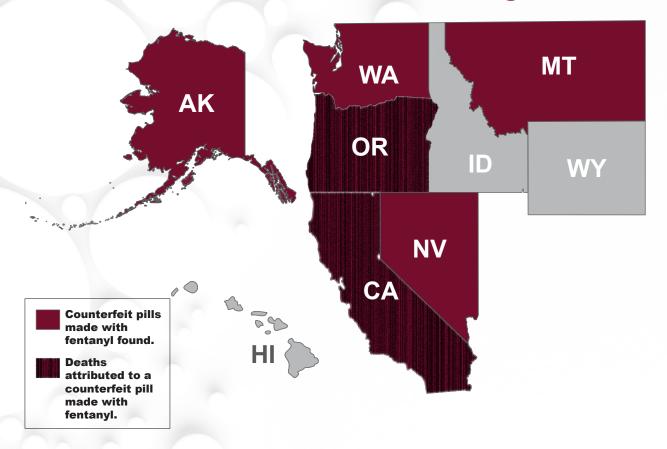
Oklahoma ➤ Three family members were found dead in the morning of <u>fatal fentanyl</u> overdoses from recently filled prescriptions for pain medication taken at bedtime (March 2016).

Texas ➤ Federal agents seized 10 kilos of oxycodone pills laced with fentanyl and arrested 14 people involved in manufacturing and distributing them (August 2017). Counterfeit pills first reported in August 2016.

Utah ➤ The DEA shut down a counterfeiting operation (headed by Aaron Shamo) that distributed <u>untold quantities of counterfeit, fentanyl-laced oxycodone and alprazolam tablets</u> throughout the United States (November 2016). Counterfeit pills <u>first reported</u> in June 2016. *Confirmed fatality*.



Incidents of note in the Western region



Alaska ➤ Alaska's state crime lab <u>confirmed</u> that a pill confiscated during a DUI arrest was fentanyl disguised as oxycodone (January 2017). Counterfeit pills <u>first reported</u> in December 2016.

California ➤ 14 people in the Sacramento area, three in San Francisco, and two in Santa Cruz County died overdosing on counterfeit prescription pills that contained fentanyl (October 2015–April 2016).

Montana ➤ Utah-based drug trafficker Aaron Shamo shipped counterfeit oxycodone pills made with fentanyl to Montana (November 2016).

Nevada ➤ Police reported a spike in overdoses from <u>counterfeit oxycodone</u> in the Reno area (May 2016).

Oregon ➤ A Portland man <u>died after taking fake oxycodone</u> laced with fentanyl (August 2016). Police seized approximately 2,000 counterfeit oxycodone pills in the course of the investigation.

Washington ➤ Toxicology tests confirmed that a Yakima-area resident overdosed after taking a fentanyl pill masquerading as Percocet (May 2016). Police suspect two additional overdoses and two deaths were the result of fentanyl-laced pills.



Resources

Use these resources to keep up-to-date and learn more information about counterfeits made with fentanyl.

- Find out on what's happening nationally and on a state level at <u>The Partnership for Safe Medicines Fentanyl Pill Crisis Tracker</u>
- Sign up for law enforcement fentanyl training from the <u>National Association of Drug</u> <u>Diversion Investigators</u>
- Watch the <u>U.S. Drug Enforcement Administration training video</u> on handling fentanyl in a law enforcement environment.

Methodology

The Partnership for Safe Medicines has compiled this report based on a extensive survey of public sources beginning in April 2015. We focused exclusively on the United States, only including a state when we found explicit reports of counterfeit pills laced with fentanyl or fentanyl analogs in news coverage, statements by law enforcement or public health agencies, or in court records. Because public sources are not focused on reporting about counterfeit prescription pills, we encountered some limitations:

- Authorities did not always test confiscated pills or run toxicology reports to identify a victim's cause of death. When they did run tests, they did not always report their findings.
- ▶ Public sources do not always report the form of fentanyl seized in raids, or disclose the form of fentanyl that killed a victim.
- Authorities and journalists do not always offer clear lists of victims, distinguish fatal overdoses from those in which patients survived, or confirm the cause of death months later when toxicology tests come in.
- Authorities may not report counterfeit pill incidents at all, especially if they are in the middle of an investigation.

Throughout this process, if a news report or police account didn't explicitly cite a counterfeit pill made with fentanyl, we did not count it. This means that we have certainly underestimated the size of the epidemic and its impact.

We also did not include any incident of a person dying from fentanyl that wasn't a counterfeit pill. Addicts sometimes take fentanyl directly, as well as mix it with heroin. This is a dangerous practice and often fatal, but it is outside the scope of our study.

Because of the limitations we've encountered relying on public sources, we have not offered an overall accounting of victims. We are not a government agency, and medical privacy laws limit our ability to investigate the cause of death. We have, however, noted every state in which a death was reported.

Photo Credits

Jessie Hyde, "From Mormon Kid to Alleged Drug Kingpin: Inside the Rise and Fall of Aaron Shamo," *Deseretnews.com*, June 22, 2017, www.deseretnews.com.

Scott Gottlieb, M.D. (@SGottliebFDA) [Commissioner of the FDA], "Toured operations at #FDA JFK Airport mail facility. Just some of thousands of seized fake, controlled drug packages https://t.co/RLXA81Iktt", Aug 25 2017, 16:33 UTC. [Tweet]



Become A Member

The Partnership for Safe Medicines is a group of organizations and individuals that have policies, procedures, or programs to protect consumers from counterfeit or contraband medicines. Contact Executive Director Shabbir Safdar at shabbir@safemedicines.org to learn more about membership.

International Health Facility Diversion



Comprised of 69 non-profit organizations, the Partnership for Safe Medicines (PSM) works with patient advocacy groups, consumer groups, pharmacy and law enforcement groups to teach them how to buy medication safely and affordably without risking their lives by dealing with unlicensed, dangerous counterfeit medication sellers.

PSM MEMBERS Academy of Managed Care Pharmacy Alaska Pharmacists Association American Association for Homecare American College Health Association American Pharmacists Association American Society of Health System **Pharmacists** Arizona Pharmacy Alliance (AzPA) Association for Accessible Medicines Association of Nurses in AIDS Care BioForward Biotechnology Innovation Organization California Life Sciences Association California Pharmacists Association California Society of Health-System Pharmacists (CSHP) Colorado BioScience Association Community Access National Network European Federation of Pharmaceutical Industries and Associations (EFPIA) Healthcare Distribution Association HealthCare Institute of New Jersey Healthcare Leadership Council The Hispanic Institute Illinois Pharmacists Association

Institute for Safe Medication Practices

Manufacturers and Associations

International AntiCounterfeiting Coalition

International Federation of Pharmaceutical

Association Kidney Cancer Association The Latino Coalition The Life Raft Group Maryland Pharmacists Association Maine Pharmacy Association Maine Society of Health-System Pharmacists (MSHP) Men's Health Network Minnesota Pharmacists Association Missouri Pharmacy Association National Alliance for Hispanic Health National Alliance On Mental Illness National Association of Chain Drug Stores National Association of Boards of Pharmacy United States Chamber of Commerce National Association of Drug Diversion Investigators National Association of Manufacturers National Alliance of State Pharmacy Associations National Biopharmaceutical Security Council National Community Pharmacists Association National Grange of the Order of Patrons of Husbandry NeedyMeds New York State Council of Health-system Pharmacists (NYSCHP) North Carolina Association of Pharmacists

Oklahoma Pharmacists Association Parenteral Drug Association PDMA Alliance Pennsylvania Pharmacists Association Pennsylvania Society of Health-system **Pharmacists** Pharmaceutical Industry Labor-Management Association (PILMA) Pharmaceutical Security Institute Pharmacist Planning Services Institute PhRMA RetireSafe Spina Bifida Association of America Texas Pharmacy Association Texas Society of Health-System Pharmacists University of New England College of Pharmacy University of Texas at Austin College of Pharmacy Vietnam Veterans of America Virginia Pharmacists Association Vermont Pharmacists Association West Virginia Rx WomenHeart GOVERNMENT PARTNERS Orange County Health Care Agency INTERNATIONAL MEMBERS

Centre for Mental Health

