

# How Criminals Sneak Counterfeit Drugs into the US Supply Chain



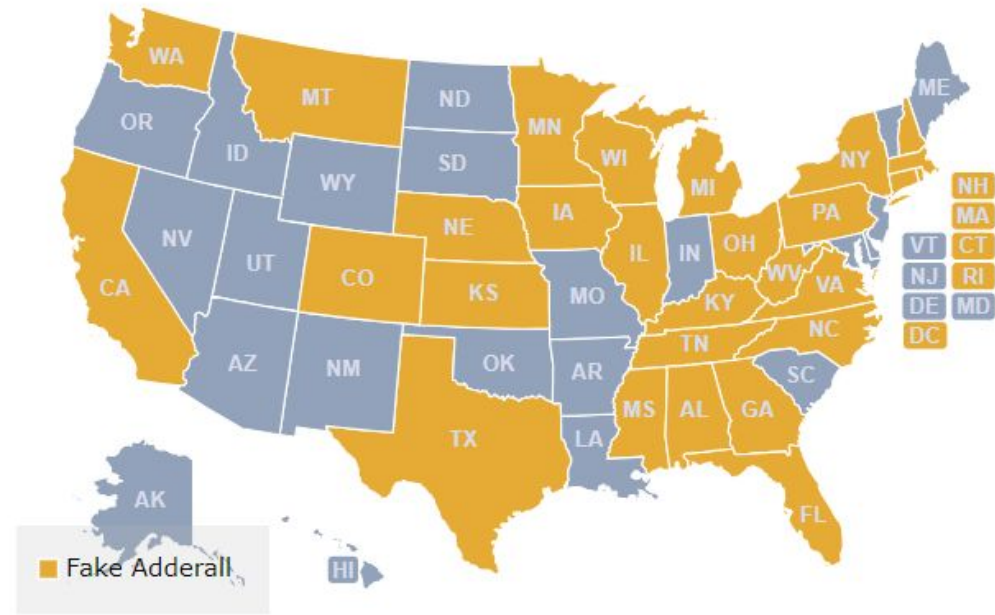
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415 630 3736

ADAP Advocacy Association	Iowa Pharmacy Association	New Hampshire Pharmacists Association
Alabama Pharmacists Association	Kansas Pharmacists Association	New Jersey Pharmacists Association
Alaska Pharmacists Association	Maine Pharmacy Association	New Mexico Pharmacists Association
American Pharmacists Association	Maryland Pharmacists Association	North Carolina Association of Pharmacists
Arizona Pharmacy Alliance (AzPA)	Minnesota Pharmacists Association	Ohio Pharmacists Association
Arkansas Pharmacists Association	Mississippi Pharmacists Association	Oklahoma Pharmacists Association
Biotechnology Innovation Organization	Missouri Pharmacy Association	Oregon State Pharmacy Association
California Pharmacists Association	National Alliance of State Pharmacy Associations	Pennsylvania Pharmacists Association
Colorado Pharmacists Society	National Association of Boards of Pharmacy	Pharmaceutical Industry Labor- Management Association (PILMA)
Community Access National Network	National Association of Chain Drug Stores	Pharmaceutical Researchers and Manufacturers of America
Connecticut Pharmacists Association	National Association of Drug Diversion Investigators	Pharmaceutical Security Institute
Delaware Pharmacists Society	National Association of Manufacturers	Pharmacist Society of Wisconsin
Florida Pharmacy Association	National Association of State Controlled Substances Authorities	RetireSafe
Healthcare Distribution Association	National Coalition for LGBT Health	Rx Outreach
HealthCare Institute of New Jersey	National Consumers League	Rx Partnership
HealthHIV	National Grange of the Order of Patrons of Husbandry	Tennessee Pharmacists Association
Illinois Pharmacists Association	Nebraska Pharmacists Association	Texas Pharmacy Association
Indiana Pharmacists Association	NeedyMeds	Virginia Pharmacists Association
Institute for Safe Medication Practices		Washington State Pharmacists Association
International AntiCounterfeiting Coalition		West Virginia Pharmacists Association
International Health Facility Diversion Association		

PSM's membership is the entire supply chain: manufacturers, distributors/wholesalers, pharmacists, and patient advocates.

# 20 Years Studying Drug Safety

## Fake Adderall incidents since 2015

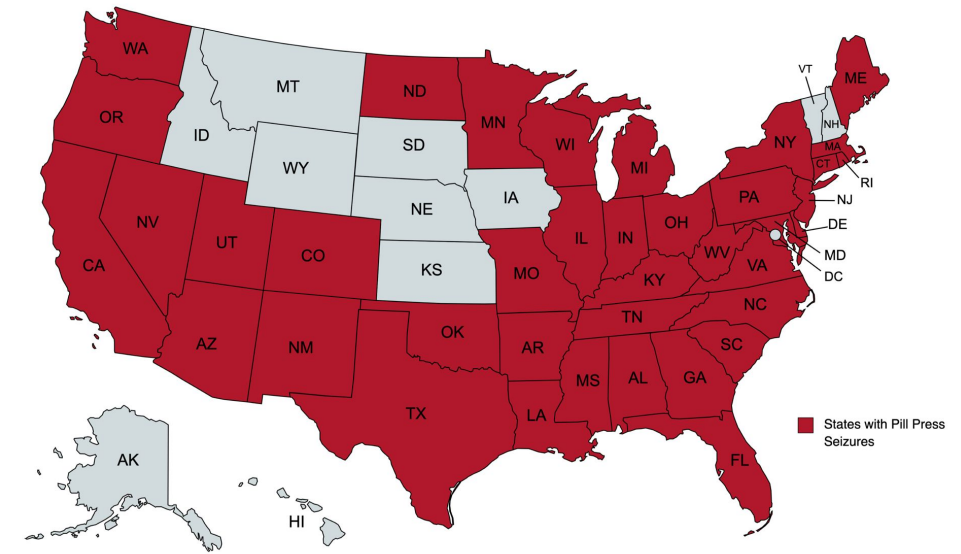


<https://safedr.org/socialmediafakepills>

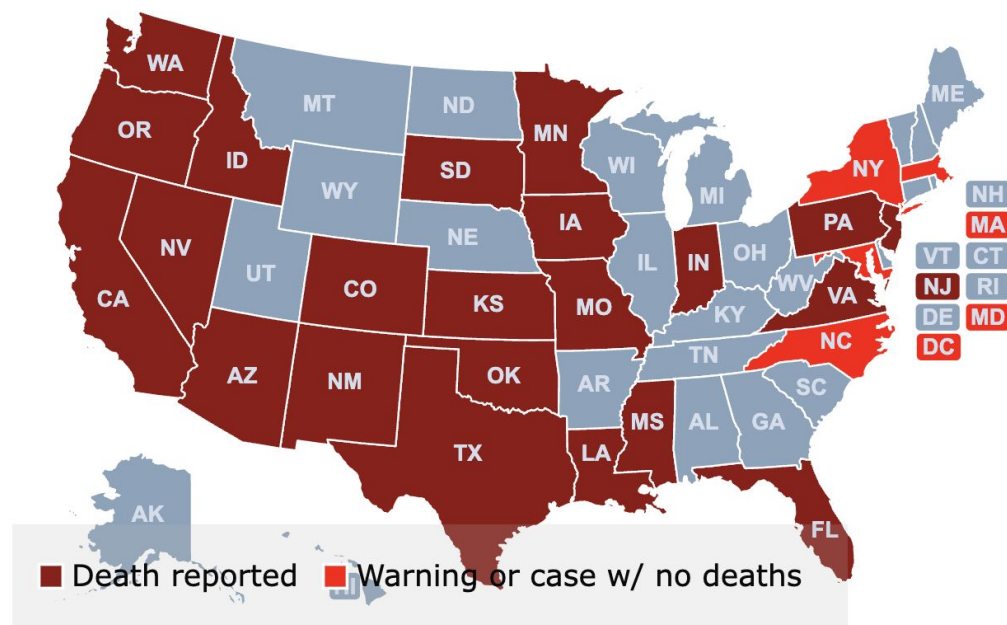


<https://safedr.org/IllegalPillPresses>

## States with pill press seizures



## Fake Pill Deaths Linked To Snapchat



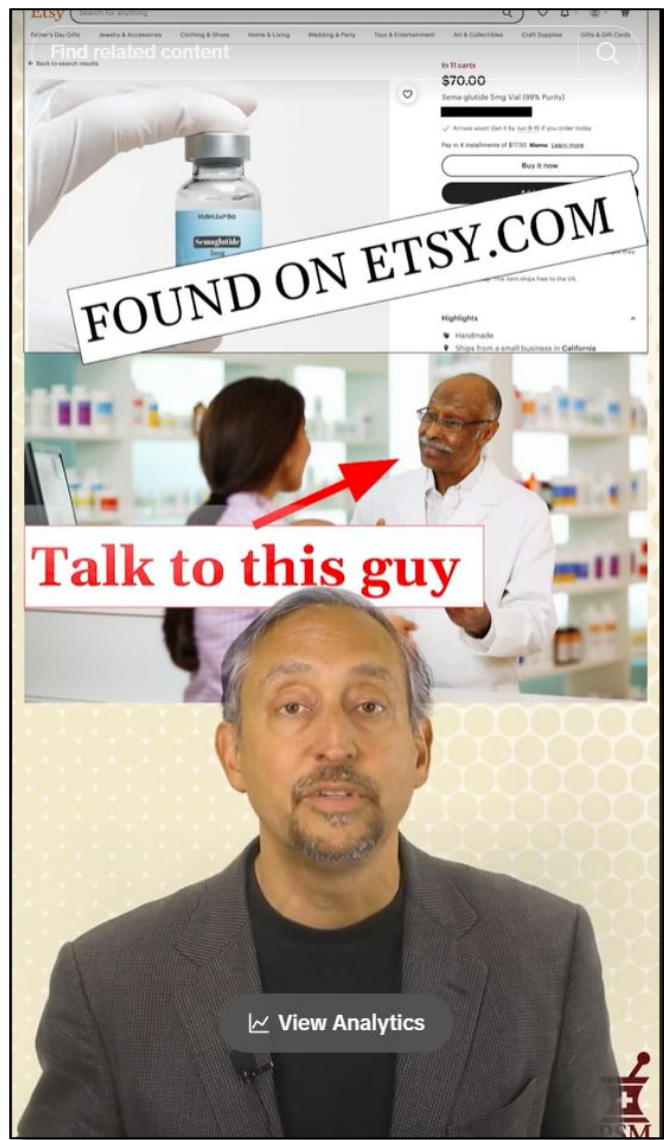
<https://safedr.org/socialmediafakepills>




You can find our videos and blanket coverage of counterfeit medicines in America on every major social network.

We make anticounterfeiting content for your LinkedIn or other social media


Our counterfeit medicine safety videos posted everywhere (and TikTok!)



Recent incidents of counterfeit medicine in the supply chain and DSCSA training for pharmacy professionals



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Training materials for what every pharmacy should know about DSCSA

# Fake Ozempic found in retail pharmacy in the United States (and in 13 other countries - still growing)

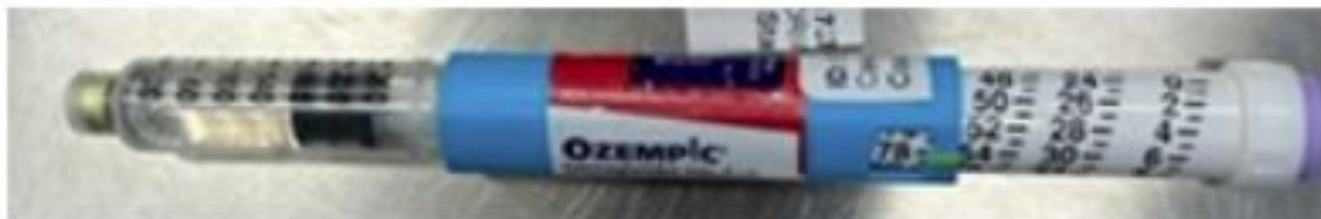
## Authentic Ozempic® pen



## Authentic Ozempic® Carton



## Counterfeit pen



## Counterfeit Carton



Images from Novo Nordisk's press release.

← Back to search results



In 11 carts

\$70.00

Sema-glutide 5mg Vial (99% Purity)

HushHerbals ★★★★★

✓ Arrives soon! Get it by Jun 8-15 if you order today

Pay in 4 installments of \$17.50. **Klarna.** [Learn more](#)

Buy it now

Add to cart

♥ Add to collection

**Star Seller.** This seller consistently earned 5-star reviews, shipped on time, and replied quickly to any messages they received.

**Hooray!** This item ships free to the US.

Highlights

Handmade

Ships from a small business in **California**

# Alternative Funding Vehicles

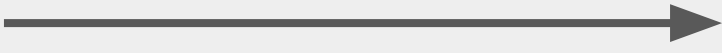
The town of Needham, MA provides health insurance for its employees and retirees. The healthcare costs of a few patients are driving premium increases for the whole group.



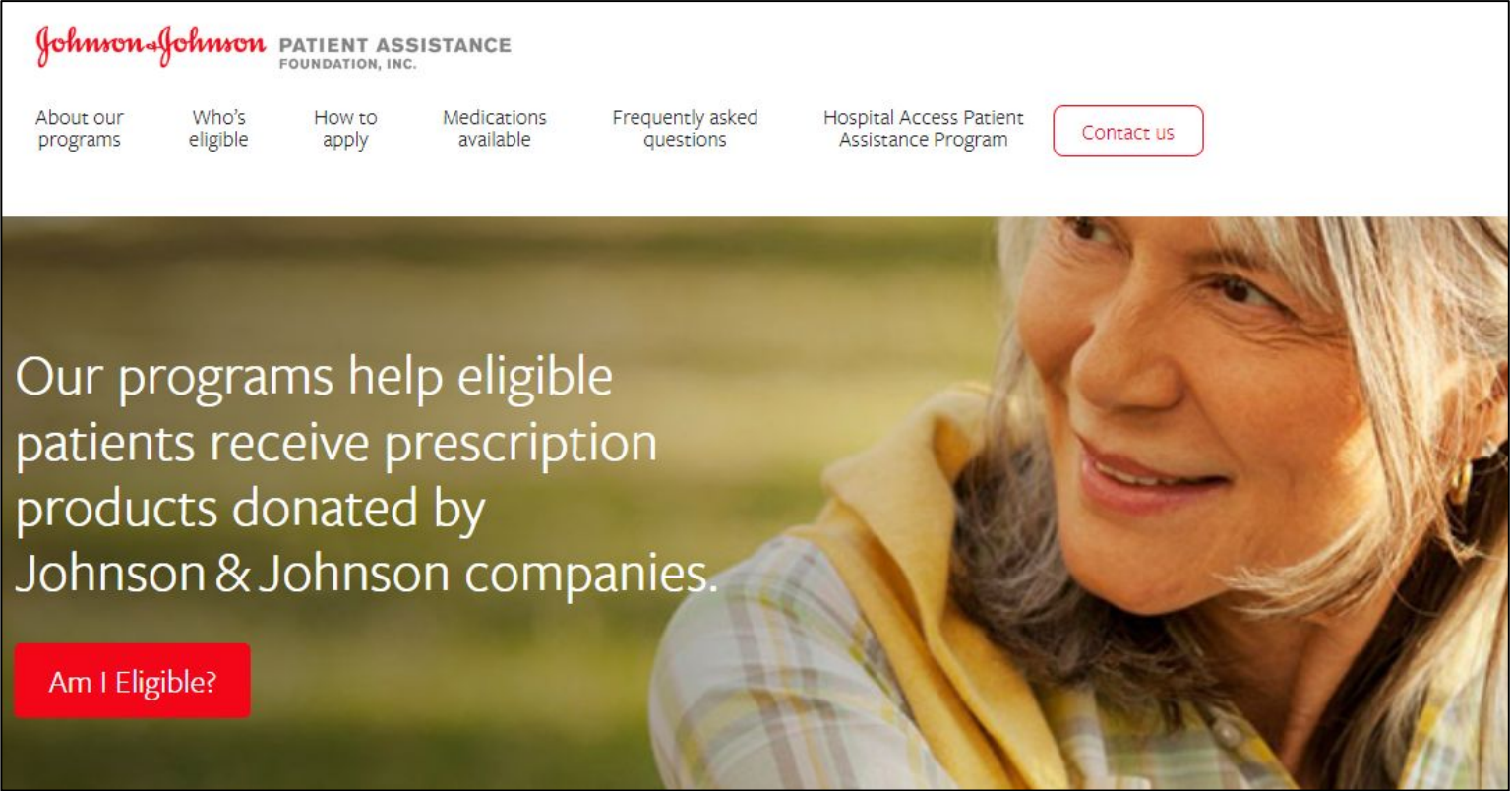
“If we could find a way to take them out of the insurance pool, would our costs go down?”

# Alternate Funding Technique #1: Withdraw coverage

**\*POOF\*** Your blood thinner is no longer covered by our insurance, and therefore you are technically uninsured.




Apply to the manufacturer's indigent patient assistance program for free medication as if you were uninsured.





# Alternate Funding Technique #2: Send patient overseas

 **MY MEDICATION**  
A D V I S O R

**WEST SUBURBAN HEALTH GROUP**  
ORDERING FROM CANARX

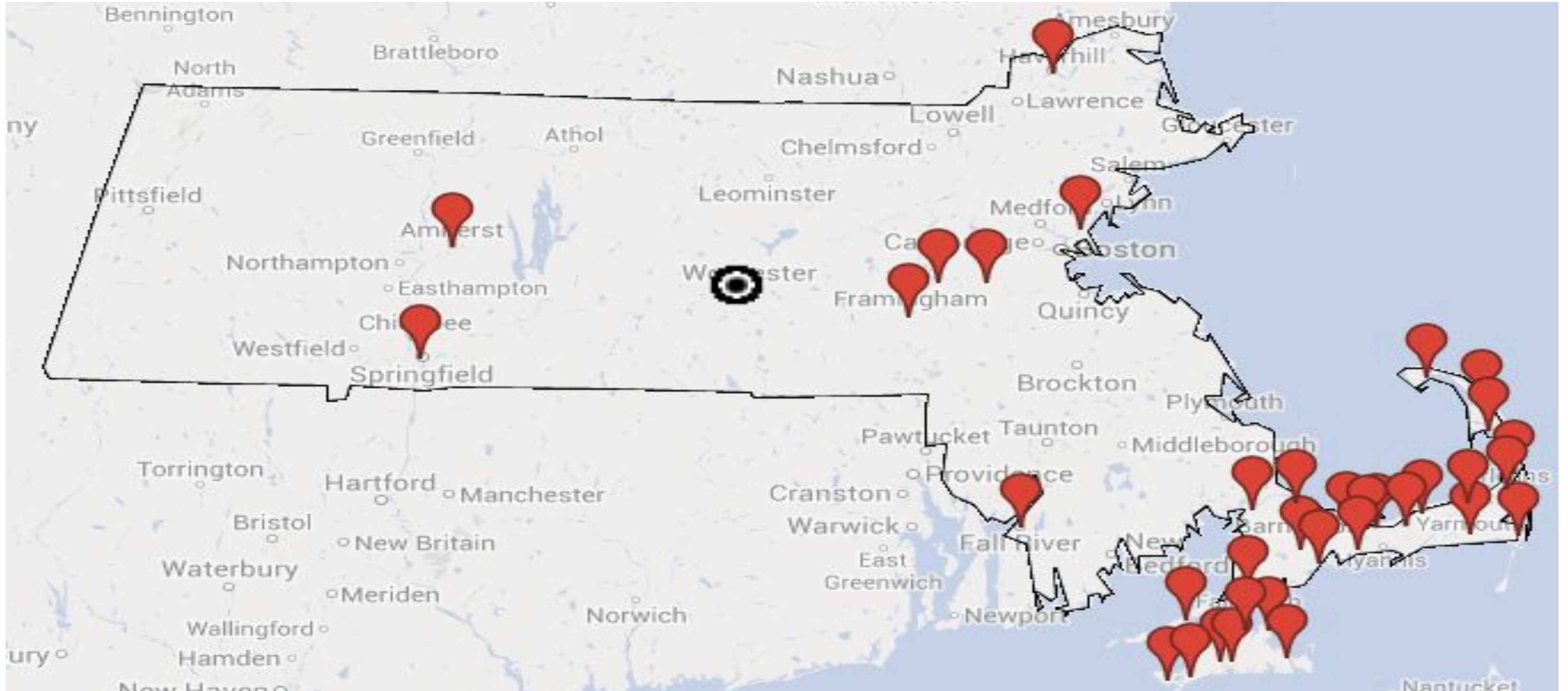
## Steps for Ordering Your Medications from CanaRx Through the *myMedicationAdvisor*® Program

- 1. Review the *myMedicationAdvisor* Medication List.**  
See which of the maintenance medications you and your covered dependents currently use may be available through CanaRx. CanaRx offers medications from Canada, the United Kingdom (England), Australia, and New Zealand. These medications will be **FREE** to you through this program.
- 2. Complete the *Medication Record/CanaRx Order Form*.**  
Each person covered by your health plan will need their own *Medication Record/CanaRx Order Form* to purchase medications from CanaRx. You can make copies of the form, or request additional copies from your employer or from the *myMedicationAdvisor* HelpLine at (877) 467-3113. You can also download the Medication Record from the web site, [www.myMedicationAdvisor.com](http://www.myMedicationAdvisor.com).
- 3. Read the *CanaRx Terms of Agreement*.**
- 4. Sign the *Medication Record/CanaRx Order Form* where indicated.**
- 5. Call your doctor's office and request standard mail order prescriptions for each medication you will be ordering (this means the prescription specifies a 3-month supply with 3 refills.)**  
Because these are prescriptions for medications you have already been taking, you do not need to wait for an appointment; your doctor's office will be able to do this for you without your seeing the doctor.
- 6. Send your prescriptions and *Medication Record/CanaRx Order Form* to CanaRx to complete your order.**  
There are two ways to do this:
  - a) Your **doctor** can **fax** your *Medication Record/CanaRx Order Form* along with your prescription(s) to CanaRx at 1-866-715-6337, or

Free medication, no copay from Canada, UK, Australia, and New Zealand.

Waiving all rights

# How big is the problem?



Data from 2015

# Does the problem exist elsewhere?



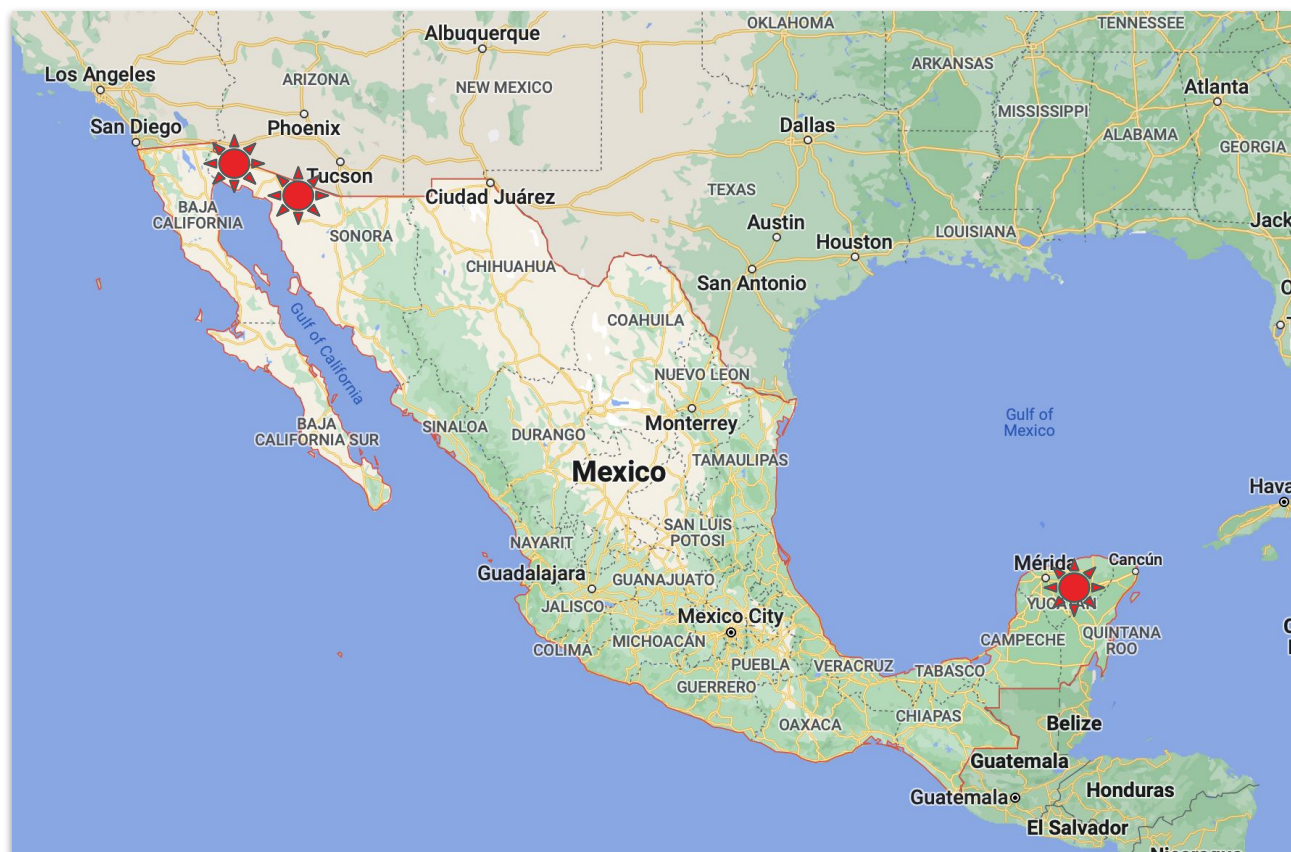
Former iSaveRX states are highlighted in blue. Inactive or "on hold" programs are in blue and purple.

Programs we believe are currently active are in red.

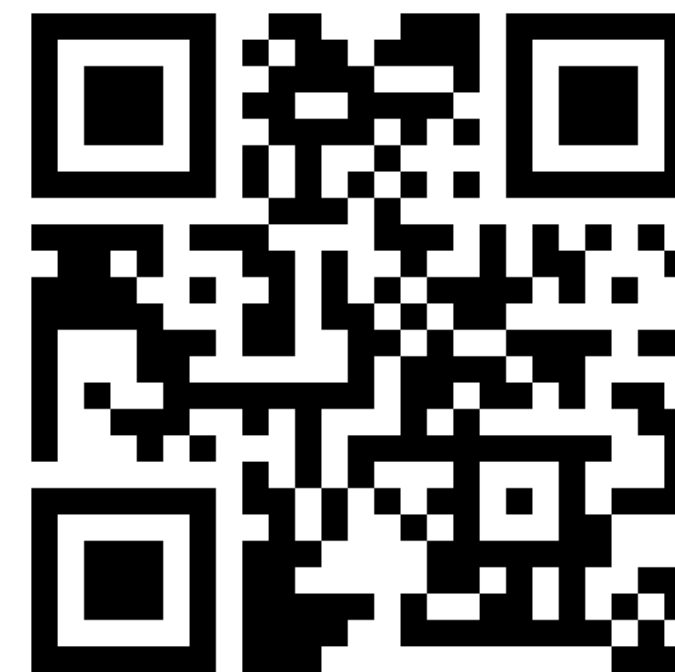
The Partnership for Safe Medicines has studied the problem throughout the US, and found that there are 49 active programs throughout the United States connected with a single rogue online pharmacy, CanaRX.



Images of fake product courtesy PSI



UC purchases of fake blood thinner



See our PSA

# Mexican border pharmacies caught selling fake medicine



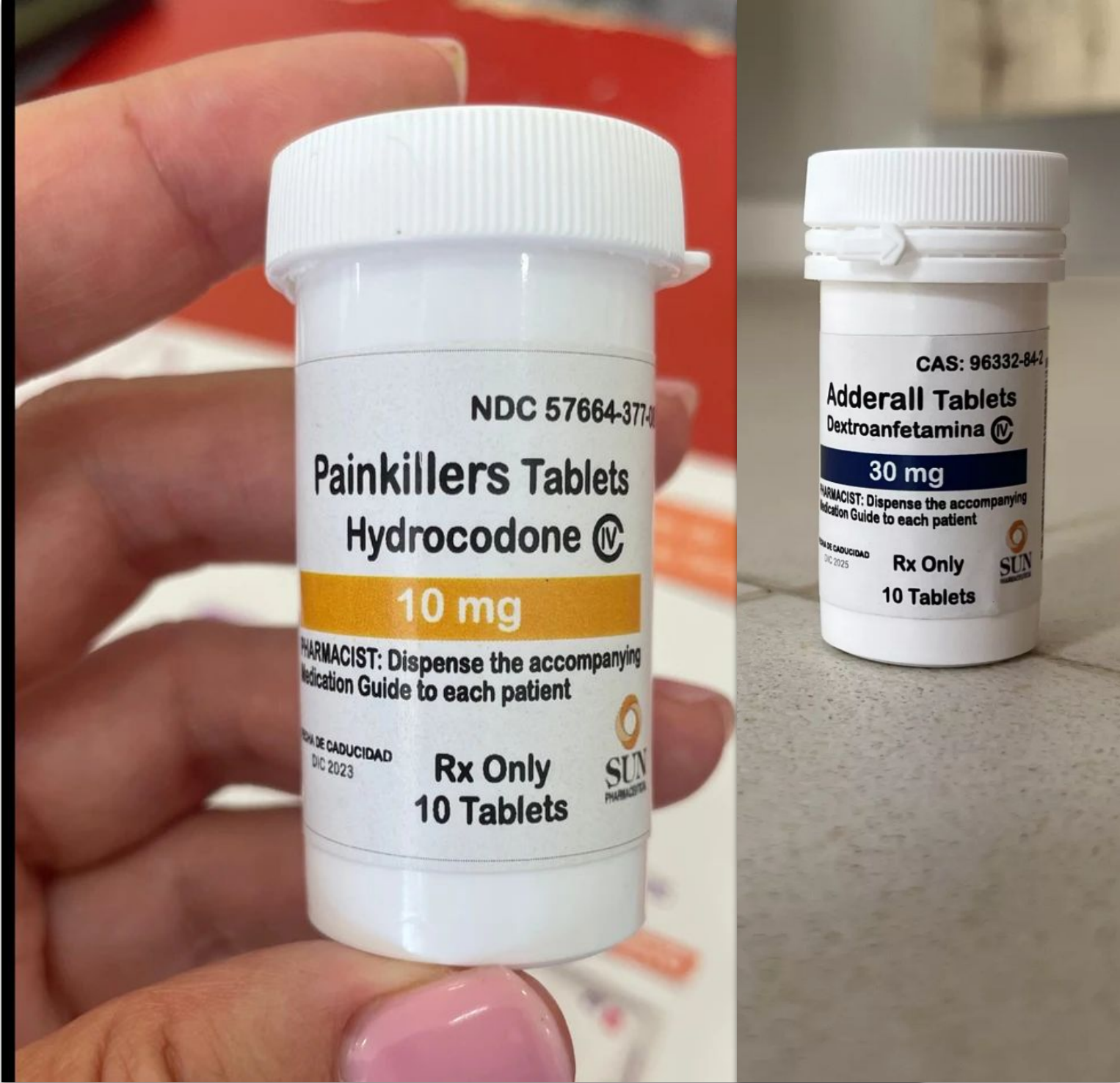
Recently falsified blood thinners have been found in multiple different Mexico border pharmacies.

Product has US packaging and placebo product.

Recently, a PBM took a popular blood thinner off their formulary, causing patients and doctors to scramble.

A pharmacy in Los Algodones, Mexico

# Licensed Mexican pharmacies target Americans



Source: Vice News



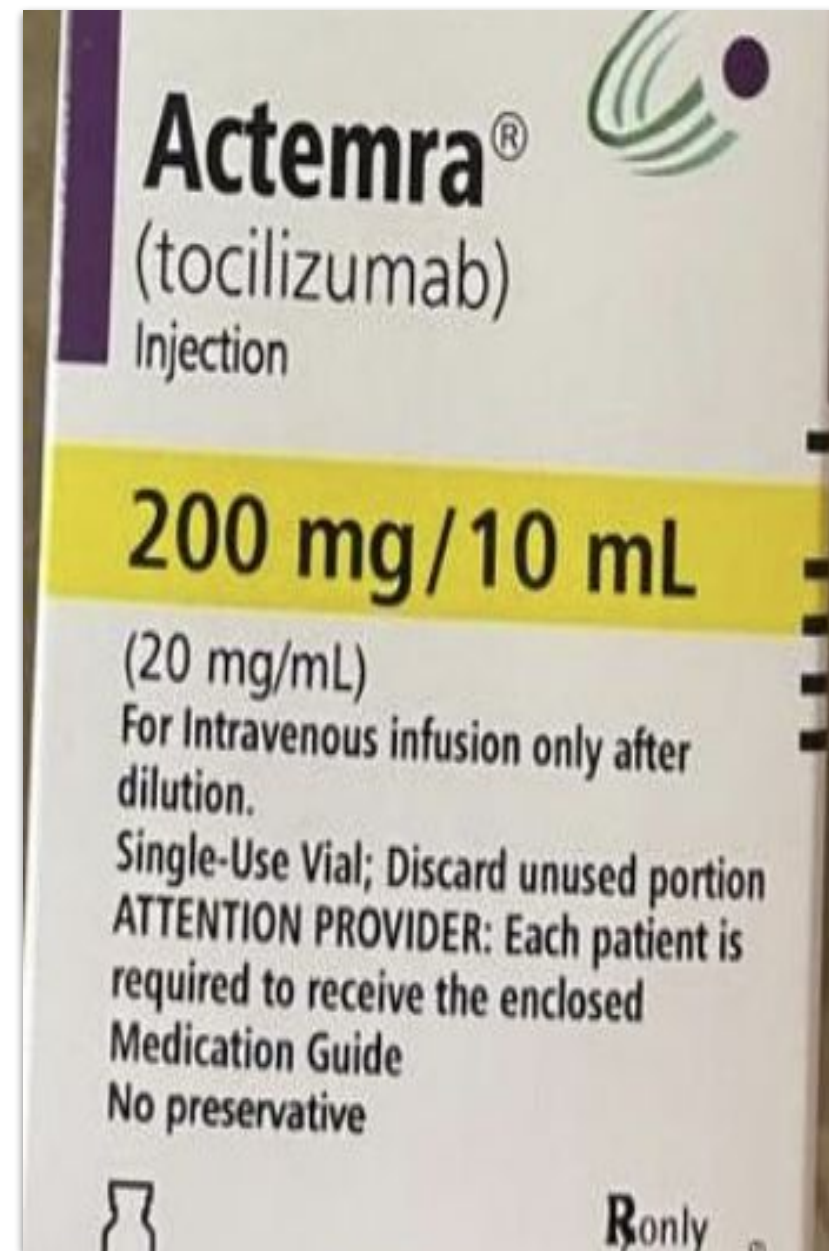
Some pharmacies in Mexico passing off fentanyl, meth as legitimate pharmaceuticals

# Los Angeles Times

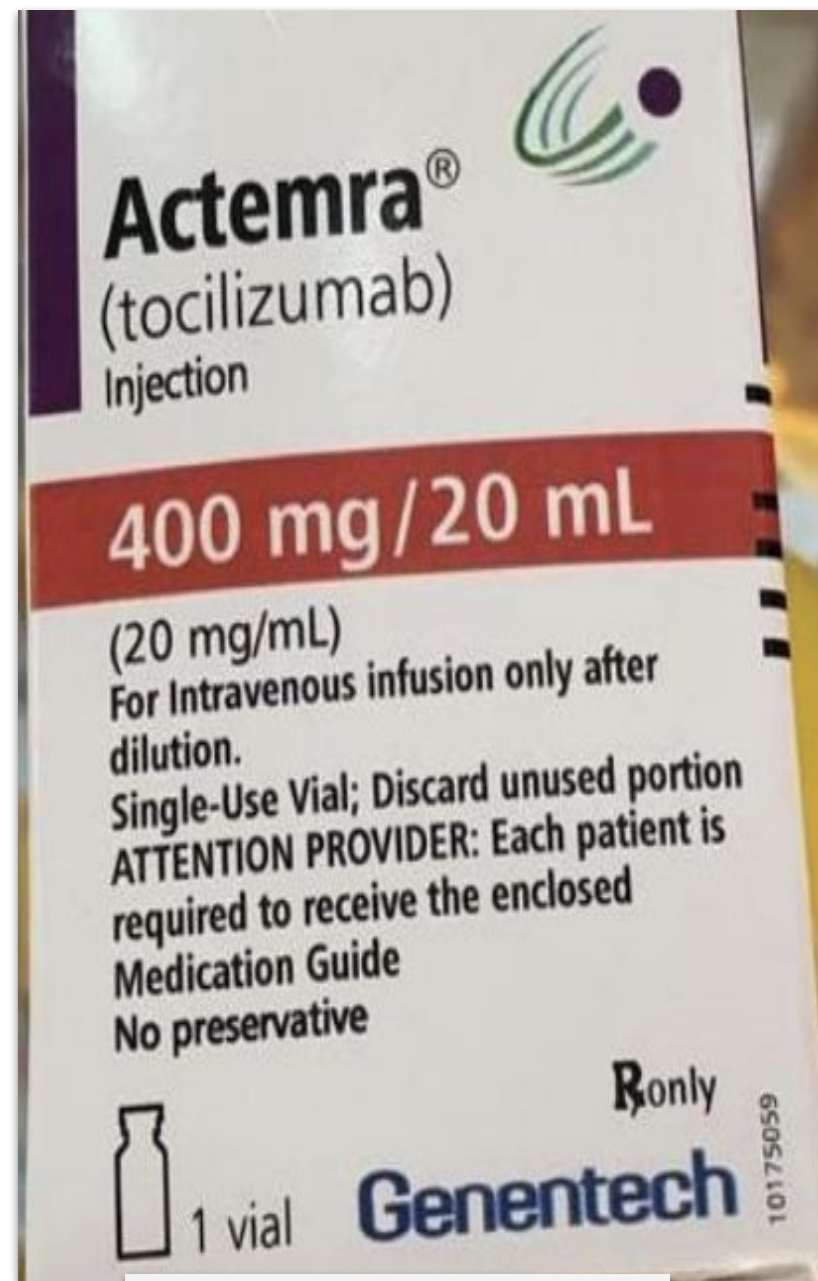
BY KERI BLAKINGER, CONNOR SHEETS  
Photography by WALLY SKALIJ  
FEB. 2, 2023 5 AM PT

# Counterfeit arthritis medicine in Mexico labeled in English

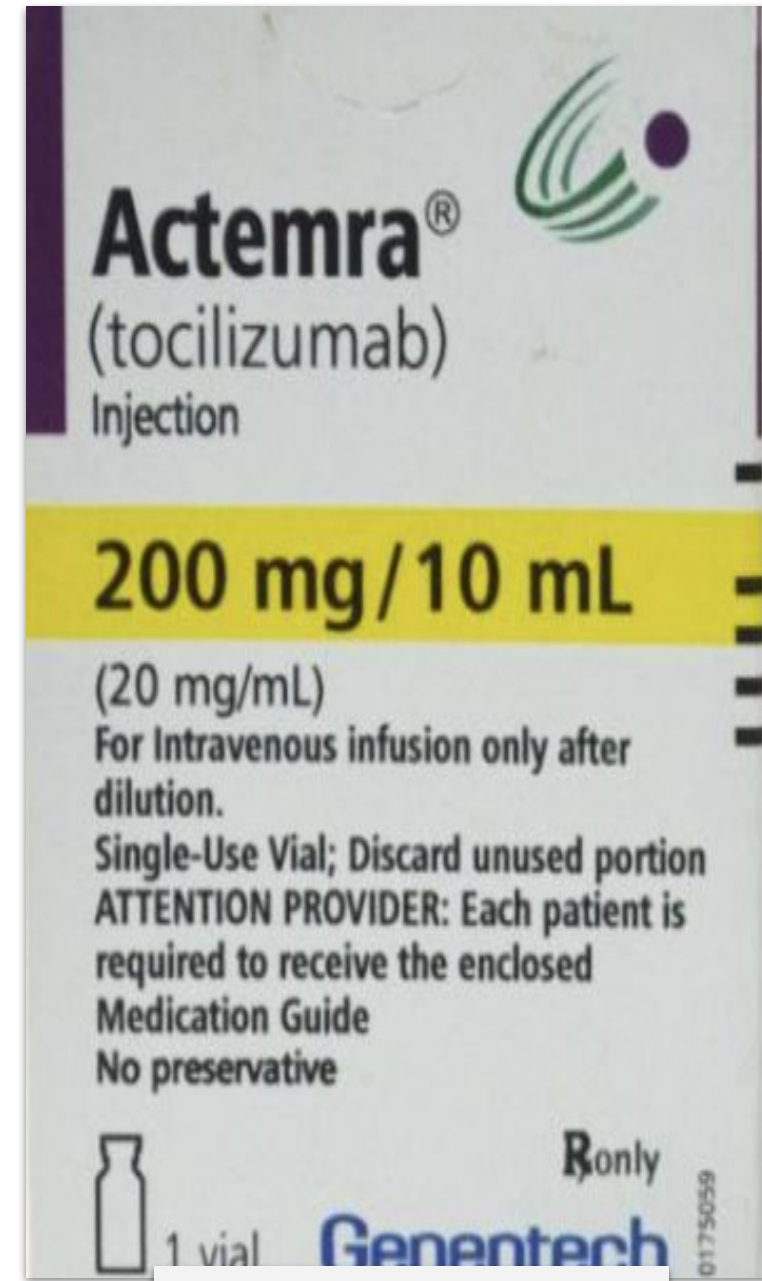
## COFEPRIS Counterfeit Arthritis Treatment Warnings



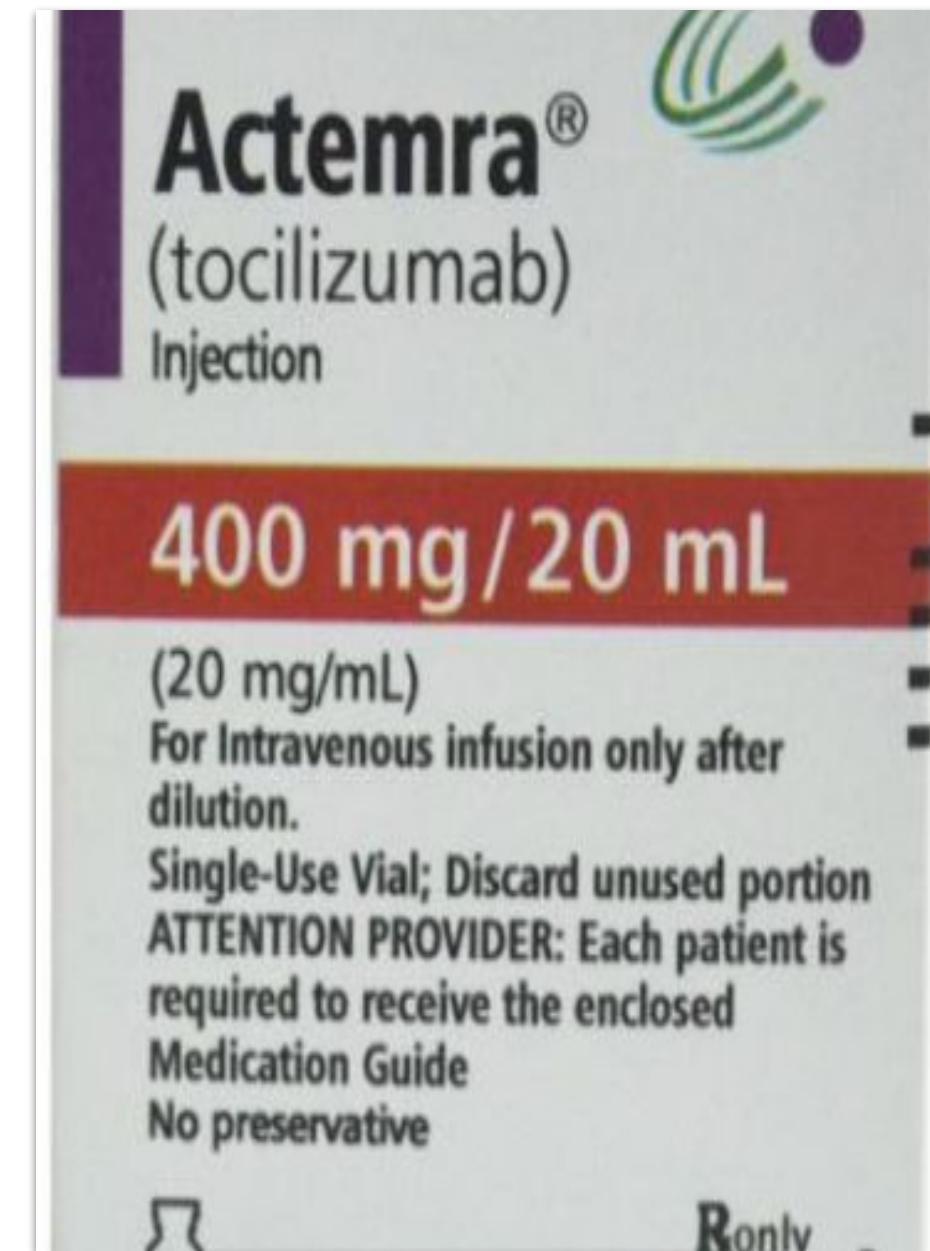
Actemra 200mg  
2021



Actemra 400mg  
2021



Actemra 200mg  
2022



Actemra 400mg  
2022

# The case that started the national conversation on safety.

**Maxine Blount**

Maxine Blount, 61, of St. Charles, died Thursday (Oct. 24, 2002) at Missouri Baptist Hospital in Town and Country.

Mrs. Blount was owner-operator of Mailboxes Etc. in O'Fallon for 11 years. She was a member of Order of the Eastern Star; Kiwanis Club in O'Fallon; and president-elect of O'Fallon Chamber of Commerce.



**Blount**  
*Business owner*

A funeral service was held Sunday at Baue Funeral and Memorial Center in St. Charles. Interment was at St. Charles Memorial Gardens.



Counterfeit Procrit:  
incorrect strike  
through in the "6"



This vial is real.

Photo: STL Post-Dispatch, National Institutes of Health

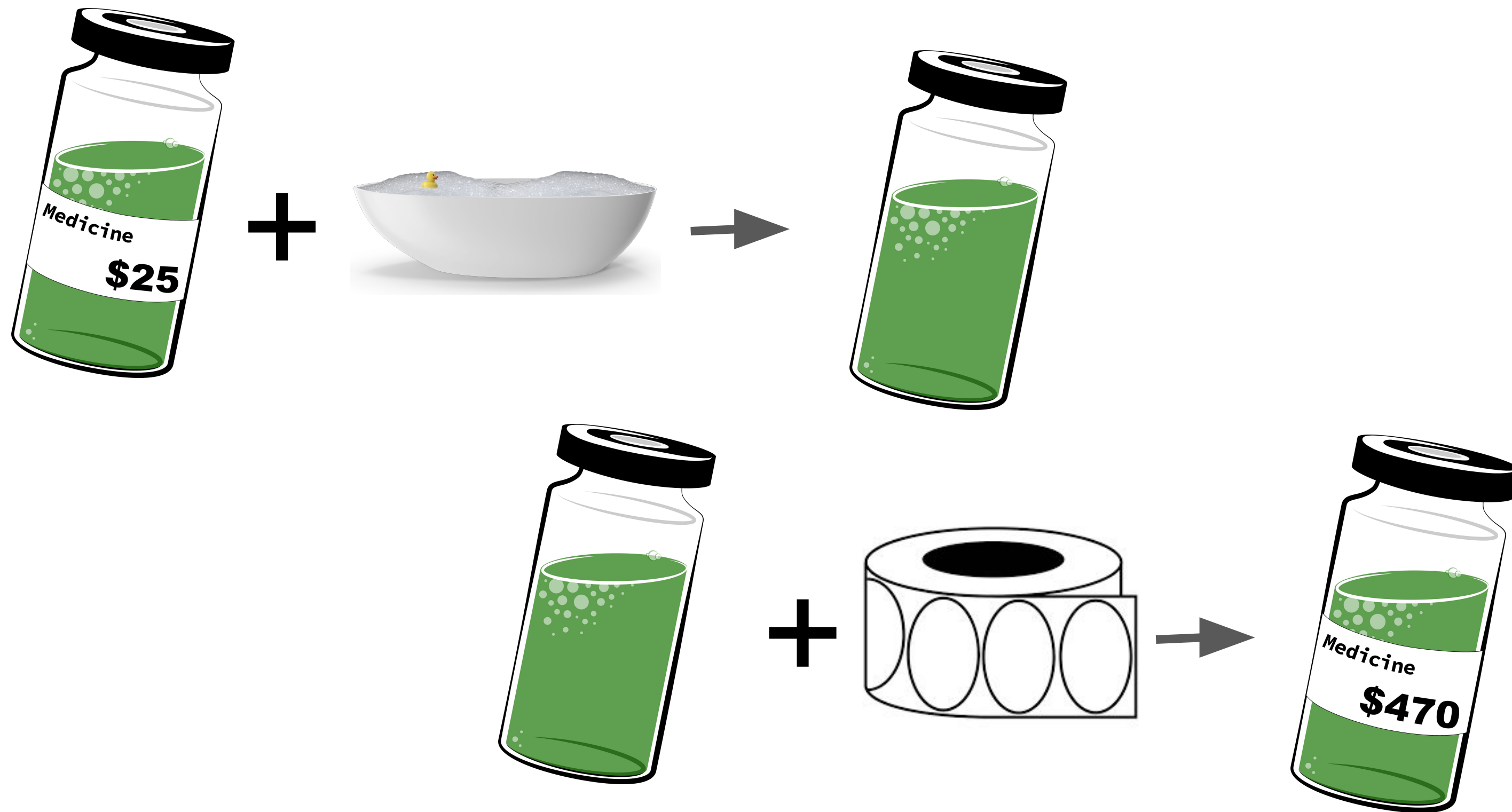


# Behind the scam

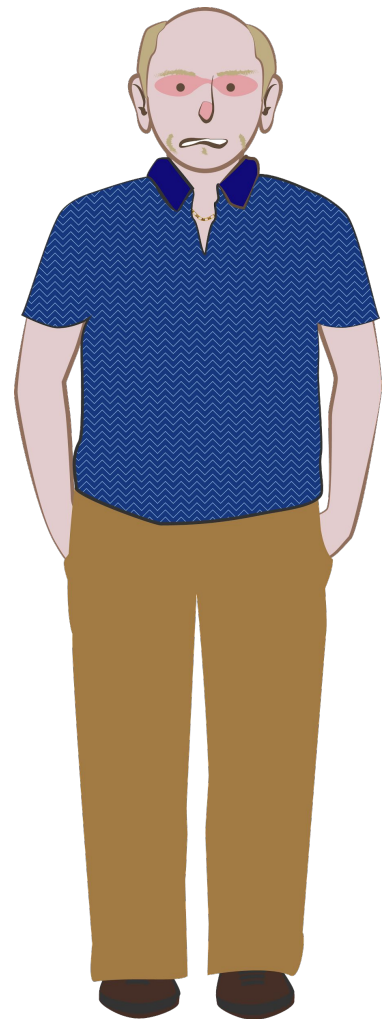


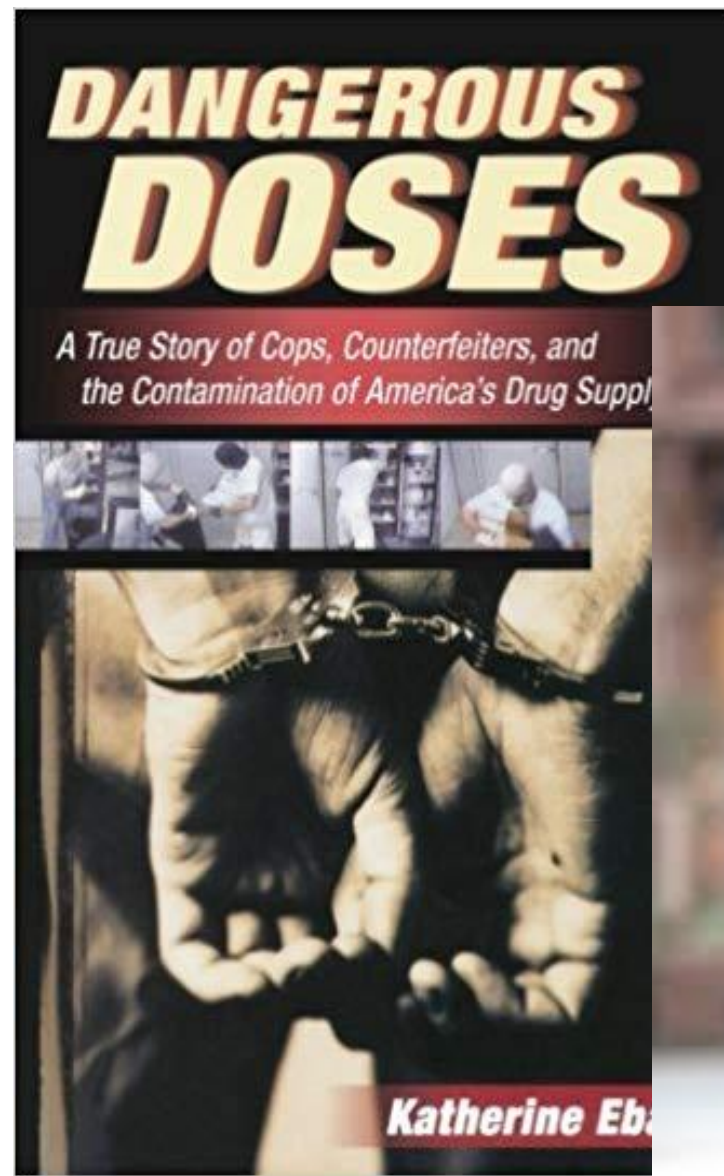
Photo: adam.com

# Behind the scam: How did they do it?

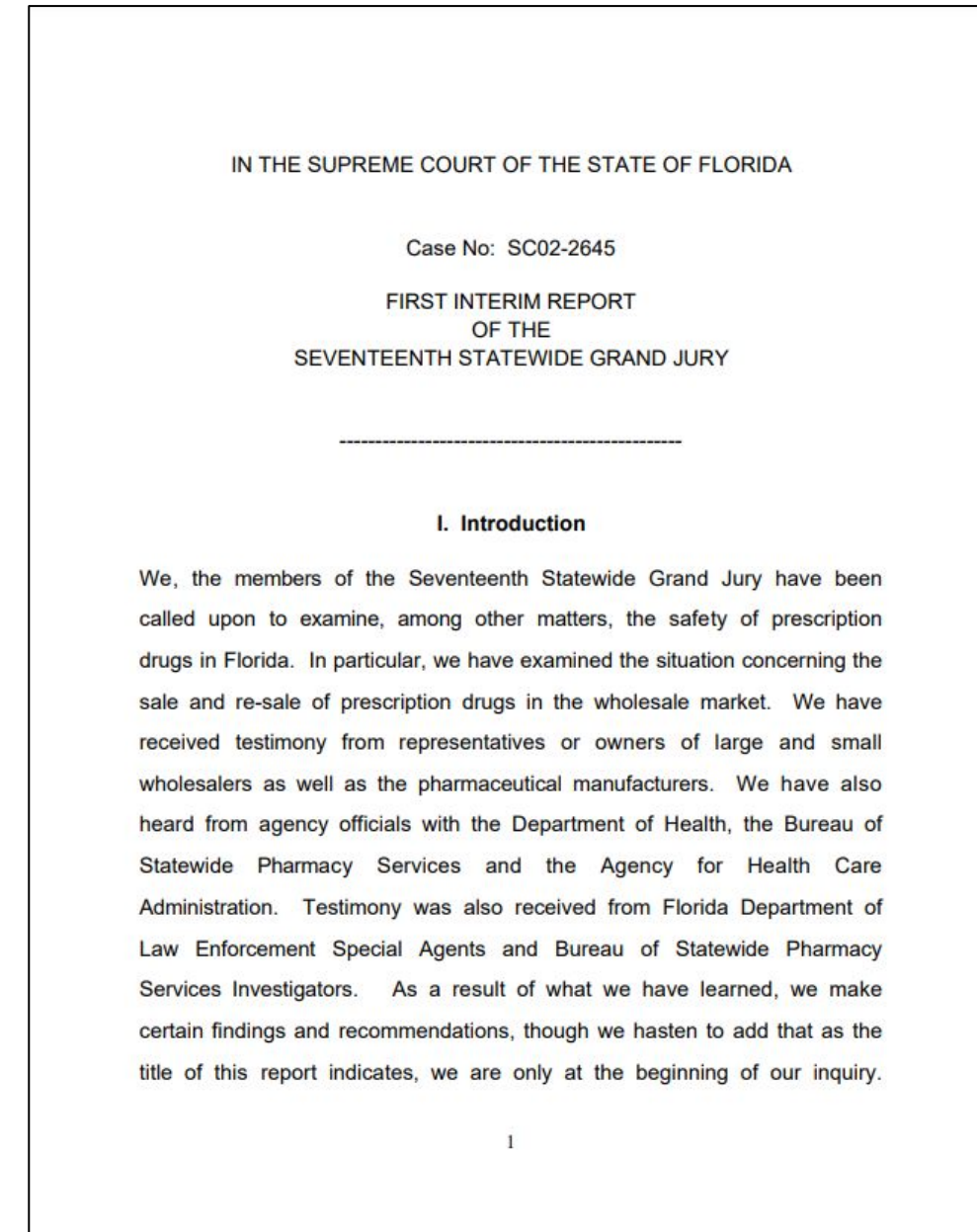


# Behind the scam: Obfuscating the source

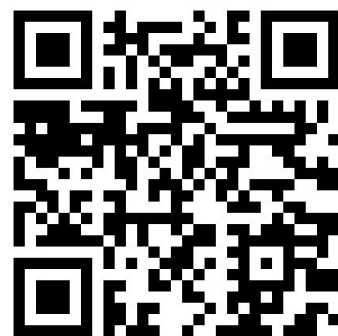




## “Dangerous Doses” by Katherine Eban



## Florida grand jury report with policy recommendations



Scan this QR code or go to this URL for the complete story on our website: [https://safedr ug/florida\\_uplabeling](https://safedr ug/florida_uplabeling)

# Counterfeit Avastin

**WARNING: COUNTERFEIT AVASTIN®**

Counterfeit Counterfeit Counterfeit Counterfeit Counterfeit Counterfeit Counterfeit Counterfeit

Avastin® Bevacizumab 400 mg/16 ml EXP 03 2013 MFD 08 2011

For i.v. use after 400 mg/16 ml For i.v. use after 400 mg/16 ml

Made in Switzerland F. Hoffmann-La Roche Made in Switzerland F. Hoffmann-La Roche

Flip off caps from vials

Printing defects found on counterfeit Avastin® vial labels

Printing defects found on counterfeit Avastin® vial labels

Poor quality double helix logo on vial flip off caps

Unique mould marks

Counterfeit crimp caps on vials are poor quality screen printing.

The printing and other defects on this flyer are unique to the counterfeit Avastin® vials depicted. These vials will be referred to as "Avastin\_Vial\_1". Known counterfeit vial labels have been observed with lot B86017 (exp. 03 2013) which did not match lot on cartons. For this or any other flyers please reference the flyer version indicated here.

Avastin\_Vial\_1\_03262012\_DCA

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.

This warning flyer is for internal FDA investigative use only. The information contained in this warning flyer is based upon information at the time of publication and is subject to change. For more information contact Duane Satzger, Ph.D., FCC Director at (513) 679-2700 or [rd.satzger@fda.hhs.gov](mailto:rd.satzger@fda.hhs.gov)

# Patients like Betty Hunter

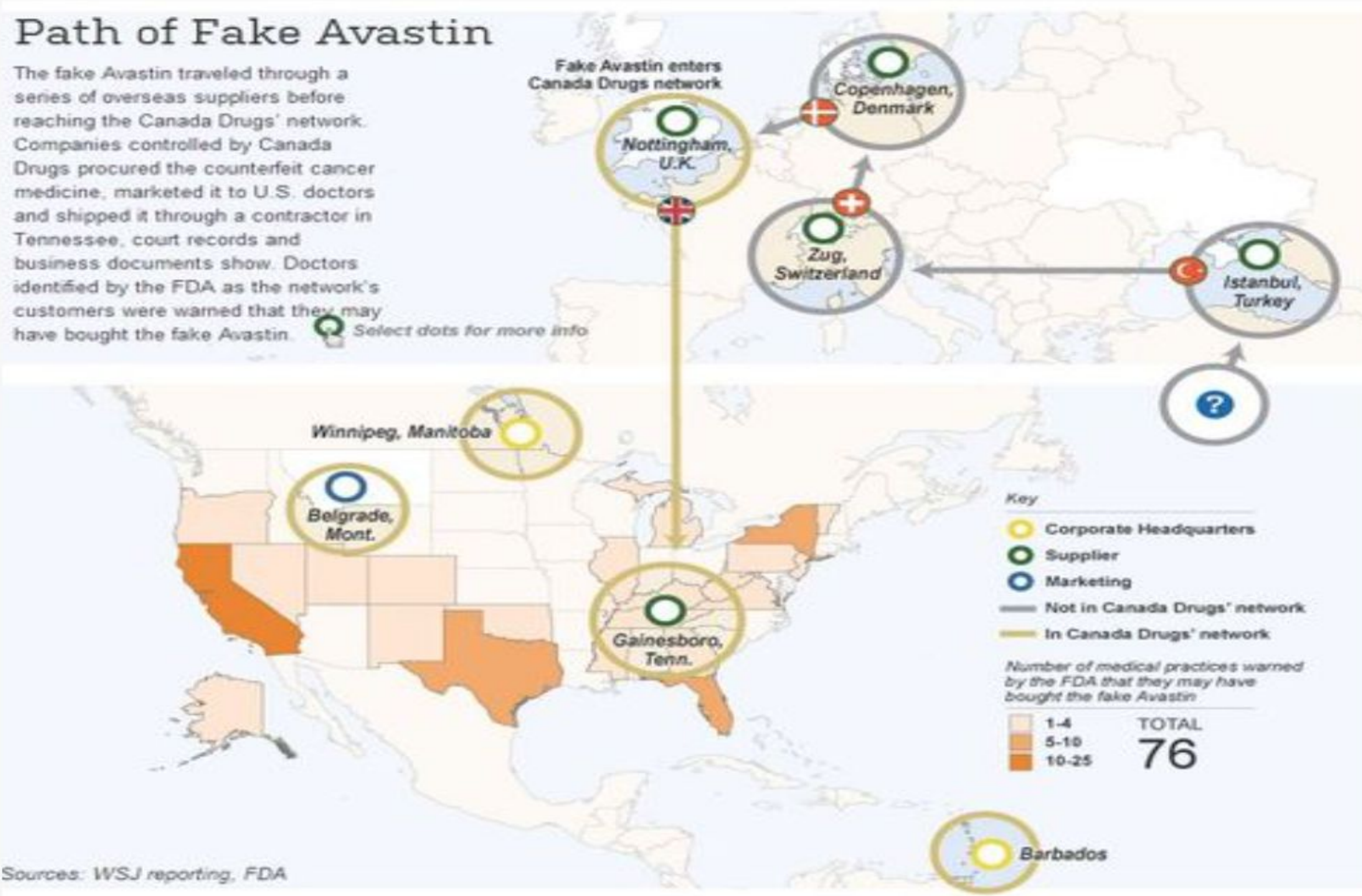


Photo: Bullitt Film

# Case Study: Path of Fake Avastin

## 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

# What did the counterfeit Avastin look like?



↑ Note the foreign language on the boxes ↑



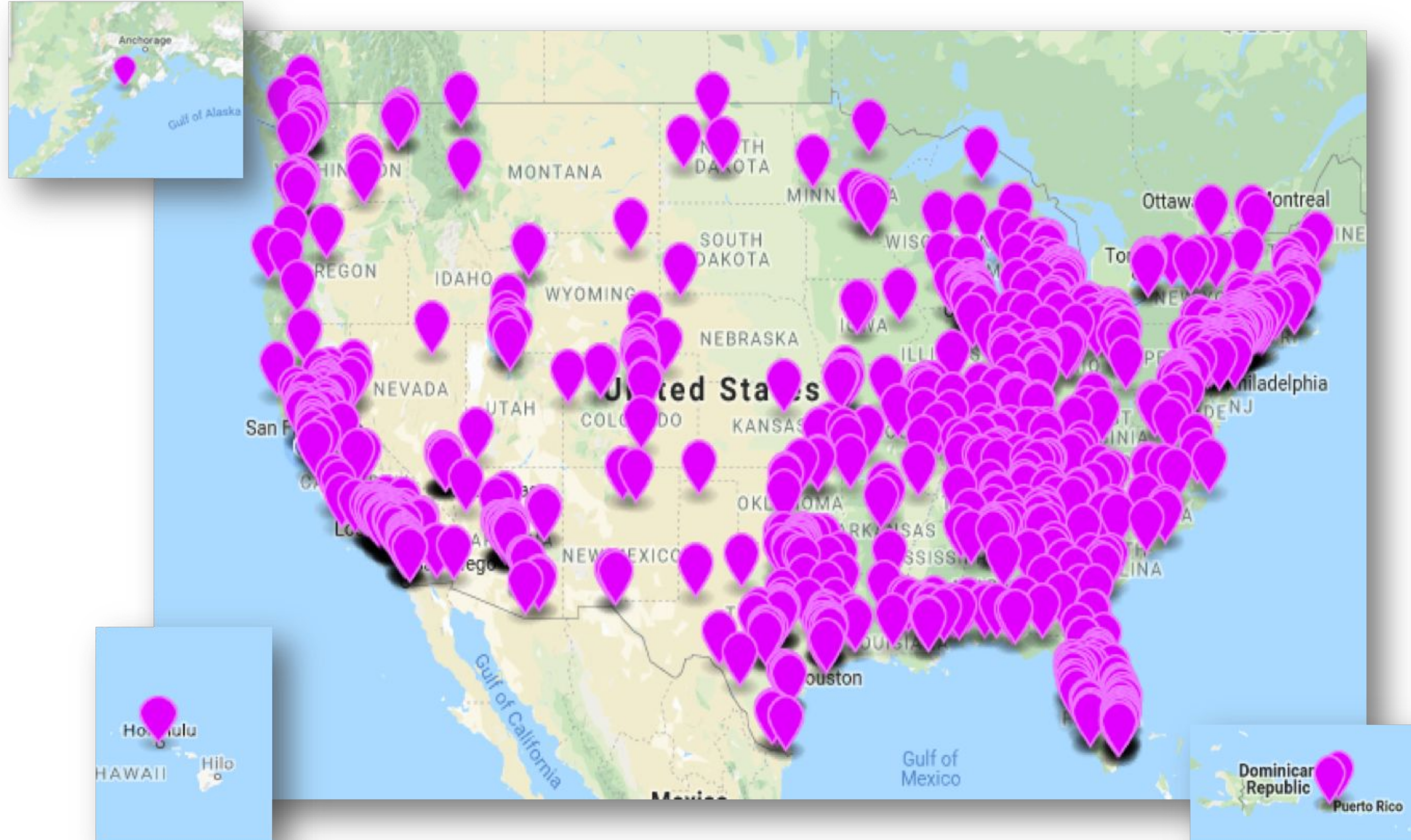
# CanadaDrug.com's disregard for patient safety

DRUGS had persistent temperature control problems, and cold-chain products were often delivered to customers warm, causing frequent returns.

41. Moreover, instead of automatically disposing of the drugs that had been returned by customers after they arrived warm, CANADA DRUGS often re-refrigerated the returned merchandise, so it could be sold to other customers.

42. The cold-chain delivery problems were brought to the attention of the executive management at CANADA DRUGS. Customer complaints were not only forwarded to Clinical Managers such as NAKAMURA and CHALUS, but also to SIGURDSON, the CFO of CANADA DRUGS. The cold-chain delivery problems

# Every physician the FDA warned for buying from unlicensed wholesalers



# Where to learn more



Scan this QR code to read our publication about this terrible era for patient safety.



It starts with a deal....

Dear XXXX Pharmacy,

I am a specialty wholesaler with access to slightly discounted HIV medicine due to it being close to expiration. I can provide it for a **5% discount off the normal WAC of \$3,200 / 30 tablets** instead for \$3,040.

A DSCSA-compliant transaction sales log will be supplied.

**Ever get these offers? Let us know at [editors@safemedicines.org](mailto:editors@safemedicines.org)**

## Sales history for serial # 123456789

1/24/2021 - Pharmaceutical Manufacturer  
(Foster City, CA)

2/13/2021 - Major Drug Wholesaler  
(Conshohocken, PA)

2/15/2021 - American Wholesale Drugmart  
(Eau Claire, MI)

3/14/2021 - JoesMeds LLC (Weehawken, NJ)

*Simplified example of a transaction log*

## Sales history for serial # 123456789

1/24/2021 - Pharmaceutical Manufacturer  
(Foster City, CA)

...and when he asked  
the wholesaler

2/13/2021 - Major Drug Wholesaler  
(Conshohocken, PA)

2/15/2021 - American Wholesale Drugmart  
(Eau Claire, MI)

3/14/2021 - JoesMeds LLC (Weehawken, NJ)

# The result

- The transaction log was fake.
- The medicine was therefore either counterfeit or diverted but certainly unsafe to give to patients.
- It was returned to the wholesaler.

It should have been:

- Quarantined.



Scan the QR code to get the report or go to <https://safedr.ug/Fake-HIV-Meds>

# Multi-year crime ring and investigation



**Janssen Alerts Counterfeit SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide) is Being Distributed in the United States** December 24, 2020



**Gilead Warns of Counterfeit HIV Medication Being Distributed in the United States**

Foster City, Calif., August 5, 2021



**Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs January 18, 2022**



# How criminals defraud pharmacies and HIV patients

Buy medicine or empty bottle from indigent population...



...and fill with placebo or any other handy medication you have.

Forge transaction log, claiming sales steps it never had.

## Sales history

1/24/2021 - Manufacturer sale  
(Muncie, IN)

2/13/2021 - Major wholesaler  
(Chicago, IL)

3/14/2021 - Trusty Guy  
Specialty wholesaler  
(Lawrence, KS)

Sell through little known paper wholesalers...

**Special this month!**  
**12% off HIV medicines due**  
**to near expiration product!**  
**Must move fast!**

...to licensed pharmacies who unknowingly dispense it to patients.

# Major counterfeit ring uncovered

Buy medicine or empty bottle from indigent population..



Forge transaction log, claiming sales steps it never had.



Sell through little known paper wholesalers...



..and fill with pressed pills of tylenol, placebo or any other handy medication you have.

## Sales history

1/24/2021 - Manufacturer sale (Muncie, IN)

2/13/2021 - Major wholesaler (Chicago, IL)

3/14/2021 - Trusty Guy Specialty wholesaler (Lawrence, KS)

Special this month!  
20% off due to near expiration product! Must move fast!

## Case facts: (early stages in court)

- 85,000+ bottles seized / Value of \$250mm
- Some fake product reached patients
- 140+ defendants

...to licensed pharmacies and then to patients.

# Who got sued?

**Ringleaders** who directed the whole scheme and their money launderers.

**Suppliers** who bought existing product and pressed and repackaged the counterfeit product.

**Distributors** who helped create the fake paper trail and sold the fake product.

**Pharmacies** who were egregious in purchasing counterfeit product even after being warned by Gilead.

**Marketers** who helped market these to pharmacies.

**Money launderers** who helped hide the cash!

## What brands were counterfeited?

Biktarvy

Descovy

Truvada

Genvoya

Atripla

Sovaldi

Stribild

Vosevi

Ranexa

Symtuza

# Much of the case is being built under the Lanham Act

- Allows trademark holders to work with law enforcement on searches, seizures, and discovery actions.
- **Civil damages (attorneys fees, profits, and actual loss) followed by criminal charges could make a powerful legal double punch.**



Photo: wikipedia

The Lanham Act is a strict liability statute. “I didn’t know” is not a defense.

**D**rug  
**S**upply  
**C**hain  
**S**ecurity  
**A**ct

in  
the

**D**rug  
**Q**uality  
**a**nd  
**S**ecurity  
**A**ct

# What is **not** part of the core DSCSA?

- Edible microtags
- Scratch off to verify
- Blockchain-based technologies
- RFID tags
- Infrared and ultraviolet pigments
- Digital watermarks



Scratch off tech Bloomberg.com



Edible microtag healthcarepackaging.com



RFID tag healthcarepackaging.com

Some of these technologies may be part of software solutions sold by vendors to help with DSCSA compliance.

# What is the DSCSA really?

- A combination of **technology standards** and **legal obligations**.
- Creates a nationwide system to track medication from factory floor to pharmacy receipt.
- Covers manufacturers, wholesalers, relabelers, repackagers, logistics providers, and dispensers.
- Relieves pharmacies of most of the burden of technology change.
- **Requires no behavior change from patients.**

# What specifically are the requirements for dispensers?

- Only purchase from **authorized trading partners** that have valid licensure and keep records of that. (everyone)
- Only trade products that have **identifiers** unless exempt or grandfathered (everyone)

And for pharmacist dispensers only:

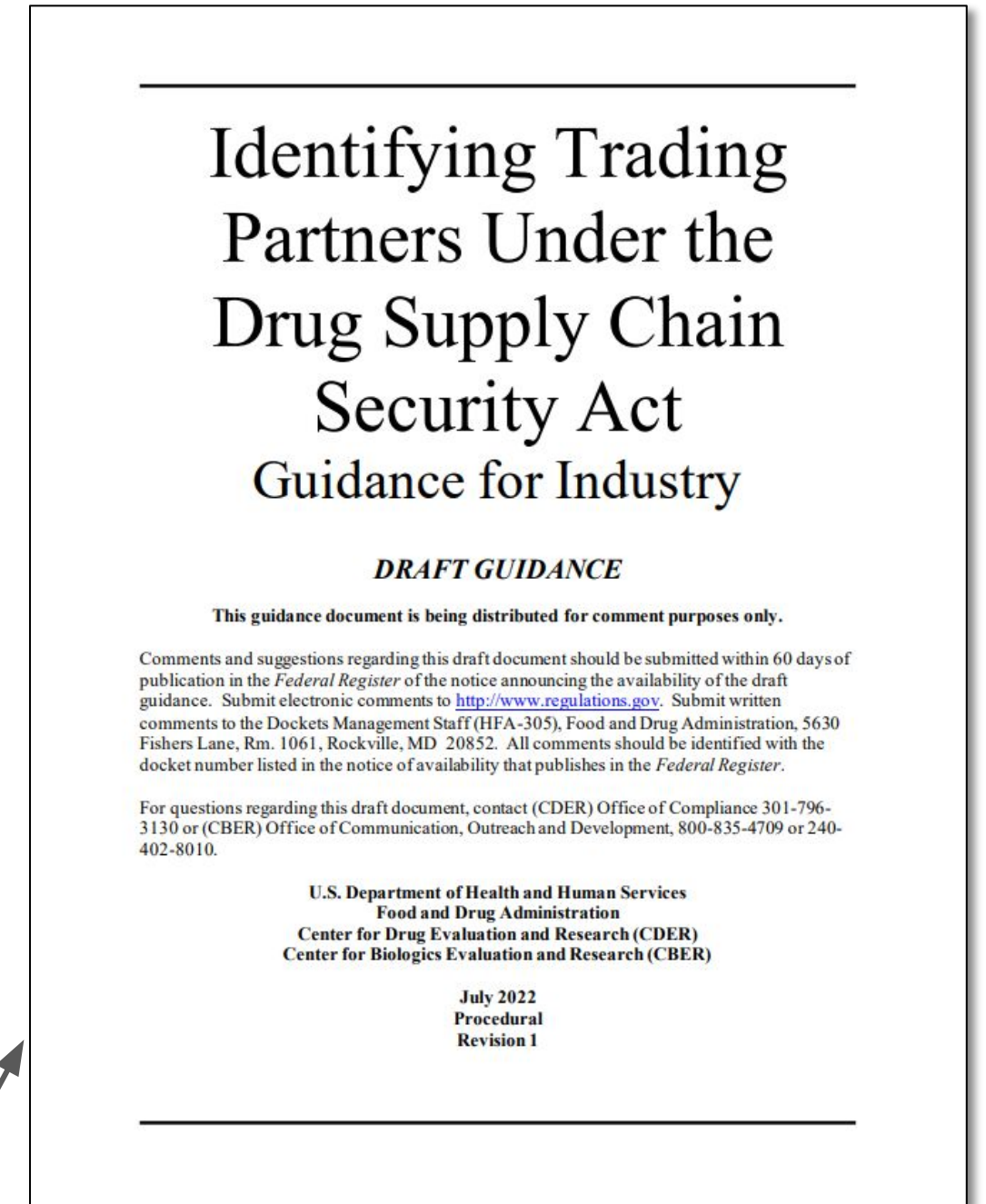
- Participate in **product tracing** for all transactions **when required**.
- **Respond to requests** for information.
- Verify, **investigate**, and quarantine suspect or illegitimate product.



# Trade only with licensed trading partners as defined by the DSCSA (effective now)

- Manufacturers
- Third party logistics providers (3PL)
- Wholesalers
- Repackagers
- Dispensers

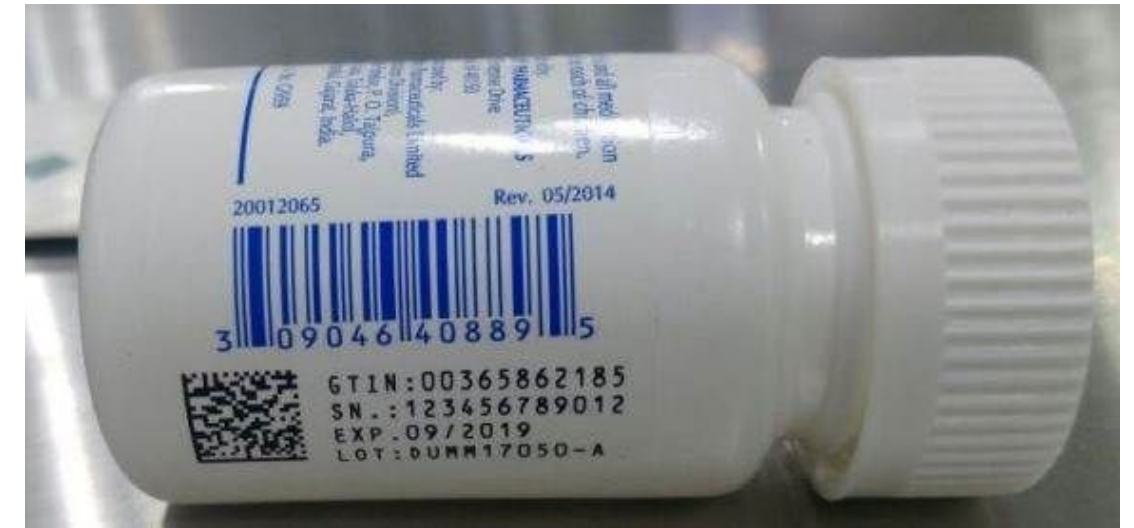
This is still a draft guidance document, but isn't expected to wildly change.



[https://safedr.ug/dscsa\\_identify](https://safedr.ug/dscsa_identify)

# Only trade serialized product (effective now)

- Only trade products that have a Product identifier unless it has an exception (all dispensers)
- **There is not a requirement that you pass along this data to the patient.**



Source: [printweek.com](http://printweek.com)

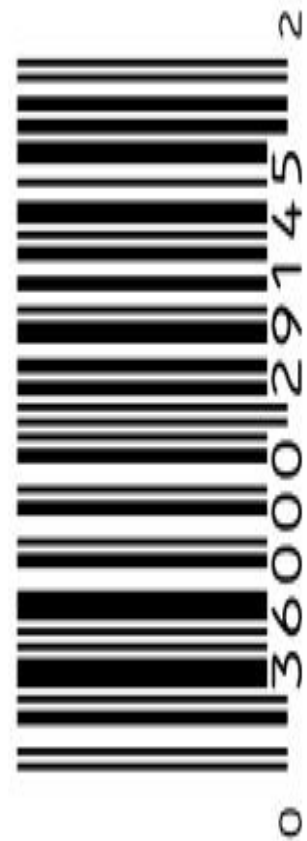


This vaccine vial is not serialized, though it does carry a bar code. The entire “aggregated” case itself is serialized.

This 2D barcode can be scanned with a cell phone.

Generic name: recombinant zoster vaccine

Photo: [Shabbir Safdar](#)



**Confoundium tablets**

Each tablet contains 50 mg of bisultimate confugru (equivalent to 52.5 mg of bivasinir confugru), 200mg of recalcitrane, and 25 mg of optimumvir.

Store below 30 C (86 F) (see insert)

Keep container tightly closed.  
Dispense only in original container.  
See package insert for dosage and administration.

**KEEP OUT OF REACH OF CHILDREN**

Manufactured for:  
PSM Sciences, Inc.  
San Francisco, CA 94122  
Made in San Francisco

**R<sub>x</sub>only**



NDC 12202000-5553-2 30 tablets

**Confoundium®**

(confugru, recalcitrane, optimumvir)  
tablets

50 mg / 200 mg / 25 mg

**Note to pharmacist:**  
**Do not cover ALERT box with pharmacy label.**

**ALERT: Find out about medicines that should NOT be taken with Confoundium.**

© 2022 Partnership for Safe Medicines



GTIN 10534890157010  
LOT 12345678  
EXP 2012-OCT-23  
SN123456789012

# What is on a serialized label?

- GTIN: Identifies company and product.
- SN: Unique serial number of that package.
- Lot: Manufacturing lot (as before)
- Exp: Expiration (as before)

**You are not required to pass along this data to the patient.**



## What is required to be labeled?

“The smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser”

USC: 21 USC 360eee

Title 21, Chapter 9, subchapter V, Part H, 360eee

# What is not serialized?

- **blood or blood components** intended for transfusion,
- **radioactive drugs or radioactive biological products**
- **imaging drugs,**
- **certain intravenous products described in clause (xiv), (xv), or (xvi)\*\* of paragraph (24)(B)**
- **any medical gas**
- **homeopathic drugs**
- **or a drug compounded** in compliance with section 503A or 503B.

\*\*e.g. dialysis solution, replenishment of fluids and electrolytes, sterile water.

# Participate in product tracing in all transactions (Nov. 2023)

- Since March 1, 2016, lot-level product tracking has been required for most change of ownership.
- In November 2023, this will mean receiving and storing serialized data with product you buy.
- If you **buy something today** from a lesser-known wholesaler (not your prime) you've probably received a transaction history along with the product, but that will sunset in November 2023 and you will no longer received a convenient full history.

## Exception

When transacting with another dispenser for a specific named patient need.

# Respond to requests for information (effective now)

“Hey, this is the FDA Office of Criminal Investigation investigator, what HIV medicines have you received from SAFEMEDS LLC in the last 90 days and what are the serial numbers?”

Manufacturers have 1 business day and not more than 48 hours to respond to requests.

“(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate **Federal or State official**, in the event of a recall or for the purpose of **investigating a suspect or an illegitimate product**, a dispenser shall, **not later than 2 business days after receiving the request** or in another such reasonable time [...] **provide the applicable transaction information, transaction statement, and transaction history** which the dispenser received from the previous owner” - Sec. 582(d) for Requirements for Dispensers

# Investigate, verify, and quarantine suspect and illegitimate product (effective now)

- This is, by far and away, the thing that could change your pharmacy operations the most.
- The obligations under these requirements are in effect now.



# What is suspect and illegitimate product?

- The definition of ILLEGITIMATE PRODUCT includes any product where there is credible evidence that it is: Counterfeit; Diverted; Stolen; Intentionally adulterated such that it would cause serious adverse health consequences or death to humans; **The subject of a fraudulent transaction;** Appears otherwise unfit for distribution.
- Suspect product is product you have reason to believe may be illegitimate.
- The only difference between a suspect product and an illegitimate one is the level of evidence

# What are likely reasons to suspect product is illegitimate?

- It's cheaper than your normal wholesaler's price.
- It's coming from a small, obscure, wholesaler.
- It has a weirdly long or obfuscated supply chain.
- It appears to be in poor condition, or looks different than product you are used to dispensing, or has erroneous inserts.
- You have reason to believe it was not handled properly.
- You suspect it might be diverted, stolen, or part of a fraudulent transaction.
- This is not an exhaustive list. **If a careful pharmacist would be wary of it, then it's suspect.**

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## Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Office of Regulatory Affairs (ORA)

June 2021  
Procedural

Revision 1

OMB Control No. 0910-0806  
Expiration Date 1/31/2022  
See additional PRA statement in section V of this guidance.

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[The FDA has outlined all the reasons you should be suspicious.](#)

# What if I have suspect product?

I have a suspicion....or....someone has notified me I have suspect product.

1. Identify everything suspect in your possession and quarantine it.
2. Notify trading partners and the manufacturer to **promptly** conduct an investigation into the product.
3. You must verify serial numbers, lot numbers, and product identifiers for at least **3 packages or 10%** of suspect product, whichever is greater.
4. You must validate transaction history, transaction information in your possession.
5. Anything else necessary to investigate it.
6. Keep records of this for **six years**.

It's now either considered **cleared product** or **illegitimate product**. Update trading partners

# ...and if it's cleared?

1. Remove it from quarantine.
2. If you notified trading partners that it was suspect, notify them it's cleared with a termination of notification.
3. Keep records of this for **six years**.

# ...and if it's illegitimate?

1. Disposition it. (Ensure it will never re-enter the supply chain.)
2. Don't return it to the wholesaler!
3. Notify your trading partners.
4. Notify the FDA with a form 3911.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved: OMB No. 0910-0816 Expiration Date: February 28, 2025 See PRA Statement on page 2.
<b>Drug Notification</b>		
<i>Refer to instruction sheet (Form FDA 3911 Supplement) for more information.</i>		
1. Type of Report (Select one): <input type="checkbox"/> Initial Notification <input type="checkbox"/> Follow-Up Notification <input type="checkbox"/> Request for Termination		
2. Incident Number (Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)		
3. Date of Initial Notification to FDA (mm/dd/yyyy)	4. Date Company Determined Product Was Illegitimate (mm/dd/yyyy)	5. Classification of Notification (Select from list)
<b>Description of Product</b>		
6. Name of Product as It Appears on Label		
7. Primary Ingredient(s) (if known)		
8. Drug Use (Select from list)	9. Drug Description (Select from list)	
10. Strength of Drug	11. Dosage Form (Select from list)	
12. Quantity of Drug (Number and Unit)	13. NDC Number (if applicable)	14. Serial Number (if applicable)
15. Lot Number(s)		
16. Expiration Date(s)		
17. For Notification: Description of Event/Issue		
<a href="#">Add Page for Item 17</a>		
18. For Request for Termination of Notification: Description of why notification is no longer necessary		
<a href="#">Add Page for Item 18</a>		
19. If you have submitted information to FDA through an alternative mechanism, check all that apply.		
<input type="checkbox"/> BPDR	<input type="checkbox"/> MedWatch 3500	<input type="checkbox"/> None
<input type="checkbox"/> FAR	<input type="checkbox"/> MedWatch 3500A	<input type="checkbox"/> Other (Specify): _____
FORM FDA 3911 (06/22)	Page 1 of 2	FDC Publishing Services (888) 445-4781

# How do I.... verify serial numbers?

Every manufacturer has a brand protection team that can be reached quickly. Look for language in the inserts or on the website for “concerns about product integrity”.

Some companies have a standing offer to both validate transaction history and serial numbers for any pharmacy that calls.

They must answer in 24 hours (or longer if the FDA allows).

*You must verify serial numbers for at least 3 packages or 10% of suspect product, whichever is greater.*

There is an FDA guidance document on how to verify products under the DSCSA available here: <https://www.fda.gov/media/117950/download>

However the requirement to verify at least three packages or ten percent is written into the law:  
<https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

# How do I.... validate transaction history?

1. New systems are supposed to allow tracing without having to make phone calls, but until those systems are developed...

Call each entity on the transaction history and verify the record you're holding matches what actually happened.

2. If it has eight steps in the supply chain before you, you're making eight phone calls (at least).
3. Validate where they bought it from, where they sold it to, the date, and the serial number.

*You are responsible for “validating any applicable transaction history and transaction information in the possession of the dispenser;”*

USC: Title 21, Chapter 9, Subchapter V, Part H, 360eee-1

# Examples!

# How do I.... validate transaction history?

## Sales history

1/24/2021 - Pharmaceutical Manufacturer  
(Foster City, CA)

2/13/2021 - Major Wholesaler  
(Conshohocken, PA)

2/15/2021 - American Wholesale Drugmart  
(Eau Claire, MI)

3/14/2021 - JoesMeds LLC (Weehawken, NJ)

*Simplified example of a  
transaction log*

*After November 2023,  
you will not get a  
transaction history  
this long.*

*You will only receive  
the information from  
the wholesaler about  
who s/he bought it  
from.*

*Weirdly, your  
workload to verify  
will decrease.*



# Counterfeiters and diverters hate this one weird trick....

## Sales history

1/24/2021 - Pharmaceutical Manufacturer  
(Foster City, CA)

2/13/2021 - Cheapo Wholesale Meds  
(Conshohocken, PA)

2/15/2021 - American Wholesale Drugmart  
(Eau Claire, MI)

3/14/2021 - JoesMeds LLC (Weehawken, NJ)

Is Cheapo Wholesale Meds an authorized “first sale” wholesaler for this medicine?

No? Then this entire report is a fraud.

*Simplified example of a transaction log*

# How do I find authorized “first sale” distributors?

There is no known central repository of authorized distributors, each manufacturer that has one will have it on their website.

If the first sale isn't to one of these, it's fraudulent.

The following wholesalers are **the only authorized “first sale” distributors** of PSM's pharmaceutical product Confoundium

®

- American Wholesale Drug-Mart
- Joe's Really Good Meds
- Safdar Drug Wholesalers

This is an example of what you will find on many manufacturers websites. (This drug is fictitious)

# How does this affect returns?

- For saleable product, you don't have to provide **transaction history, transaction information, or transaction statement** if you're returning to the same trading partner you bought it from.
- For nonsaleable product you can return it to any of the following without having to provide any of this transaction information:
  - the manufacturer or repackager,
  - the wholesale distributor from whom the product was purchased,
  - a returns processor, or
  - a person acting on behalf of one of the above.

# Questions!

Dear XXXX Pharmacy,

I am a specialty wholesaler with access to slightly discounted HIV medicine due to it being close to expiration. I can provide it for a **5% discount off the normal WAC of \$3,200 / 30 tablets** instead for \$3,040.

A DSCSA-compliant transaction sales log will be supplied.

The Partnership for  
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Howdy, Shabbir Safdar

**TAKE ACTION To Kick COVID-19 Scammers Off The Internet!**  
Learn more and write congress here.

BEHIND THE SCAM  
**UPLABELING**

**August 5, 2020 Video: Behind The Scam: Uplabeling**  
August 5, 2020  
This week's video goes "behind the scam" to show you "Uplabeling," which is a technique that counterfeit criminals have used in the past to make major profits. In uplabeling, counterfeiters took a low-dose medical product and made it look like a more expensive, high-dose version of the same drug simply by changing the label.

**Counterfeit Medicine News For The Week Of July 27, 2020**  
August 3, 2020  
In PSM's round-up this week: Continuing COVID-19 fraud, counterfeit Botox, and ongoing counterfeit pill news.

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EXPLAINER July 20, 2020 Video: Importation

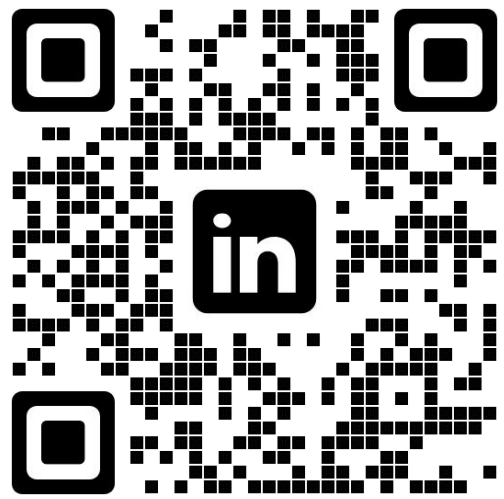
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[www.safemedicines.org](http://www.safemedicines.org)

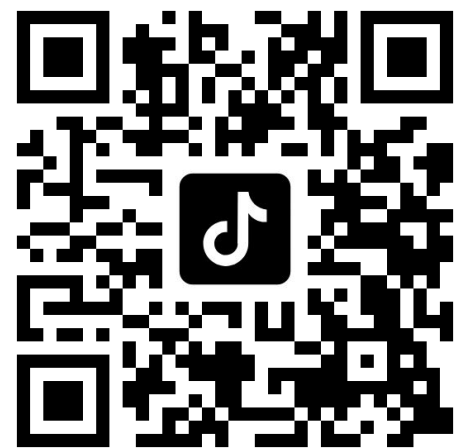
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