COUNTERFEIT MEDICAL PRODUCTS: WHAT PHARMACY PROFESSIONALS SHOULD KNOW ABOUT DETECTION, HARM AND REPORTING

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Kansas Pharmacists Association // 2026 Annual Meeting & Trade Show August 26-30 // Wichita, KS

Disclosures

Faculty

Kenneth McCall, faculty for this activity, has no relevant financial relationship(s) with ineligible companies to disclose.

Planners

None of the planners for this activity have any relevant financial relationships with ineligible companies to disclose.

Pre-Test Question #1

What is the most commonly reported reaction associated with counterfeit medical products in the FDA Adverse Event Reporting System?

A. Anaphylaxis
B. Drug ineffective
C. Nausea
D. Rash

Pre-Test Question #2

Which of the following statements is true regarding the temporal patterns of reported counterfeit products?

A. Reports involving PDE5 inhibitors were highest in 2022, while cardiovascular drug reports have increased steadily since 2010.
B. HIV drug counterfeit reports peaked in 2015, and there has been little recent reporting involving opioids or GLP-1 agonists.
C. PDE5 inhibitor counterfeit reports peaked in 2015, and more recent reporting has surged for counterfeits involving opioids, GLP-1 agonists, and cosmetic drugs.
D. Counterfeit product reports have remained evenly distributed over time without notable peaks by drug class.

Pre-Test Question #3

A pharmacist receives complaints from patients about product quality issues related to an injectable diabetes medication. Upon closer examination, the pharmacist notices that several packages have irregular labeling and packaging differences compared to previous shipments. The pharmacist determines the product is suspect.

What is the most appropriate next step in managing this situation under DSCSA requirements?

A. Continue dispensing product while monitoring for additional concerns
B. Quarantine all suspect product and begin an investigation
C. Notify the FDA using Form 3911 and destroy the product
D. Return the product to the wholesaler and document the concern

Objectives

At the completion of this program, pharmacy professionals will be able to:

- Describe the demographic, reporting, and temporal patterns of counterfeit medical product cases reported to the FDA Adverse Event Reporting System.
- Identify the medication classes and common indications most frequently associated with counterfeit product reports.
- Recognize features that may suggest counterfeit product exposure, including unexpected therapeutic failure, unusual adverse events, and product-class-specific reaction patterns.
- Review cases of suspected counterfeit medical products and apply lessons learned to meet Drug Supply Chain Security Act obligations for quarantining, investigating, documenting, and responding to products that may place patients at risk.

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

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

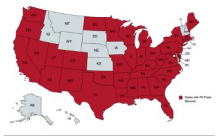
The Partnership for SAFEMEDICINES®

20⁺ Years Studying Drug Safety

Fake Adderall incidents

https://safedr.ug/socialmediafakepills

States with pill press seizures



https://safedr.ug/IllegalPillPresses

Fake Pill Deaths Linked To Snapchat

https://safedr.ug/socialmediafakepills

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

The Partnership for SAFEMEDICINES®

Outline

- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids/Benzos
  - GLP-1 Agonists
  - Cosmetic Drugs
- What if I have a suspect product?
- Assessment Questions

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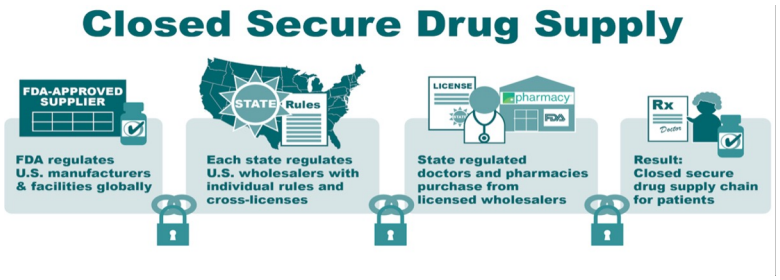
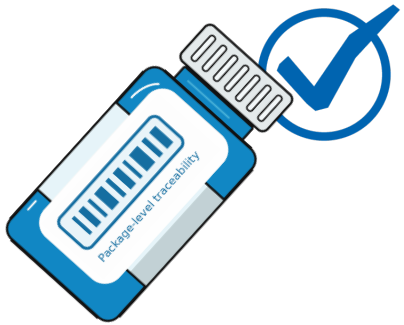
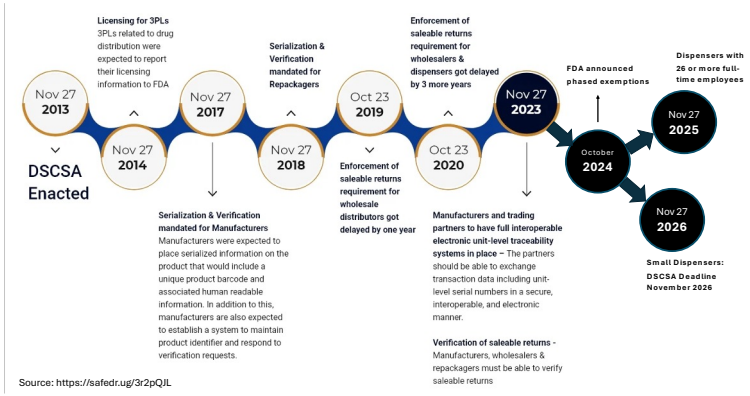


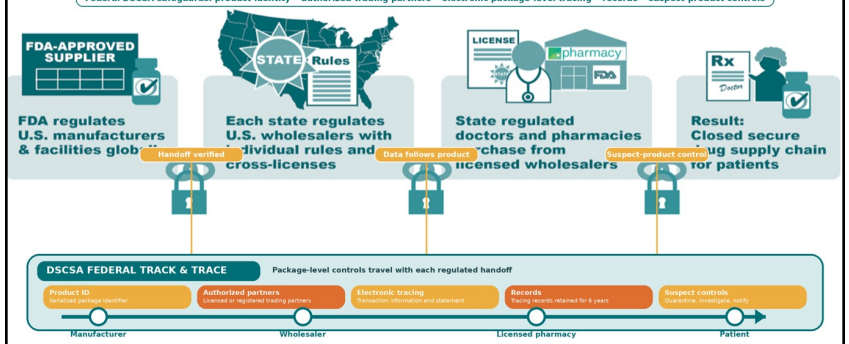
Drug
Supply
Chain
Security
Act





Source: https://safedr.ug/3r2pQJL

Implementation Timeline for DSCSA



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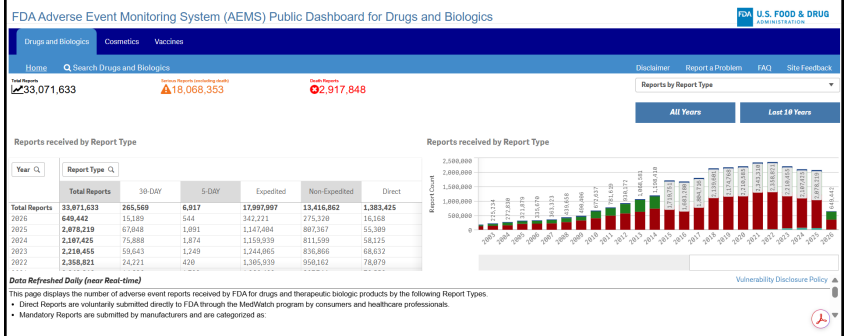
FDA Adverse Event Monitoring System

AEMS supports safety by collecting adverse event and medication error reports.



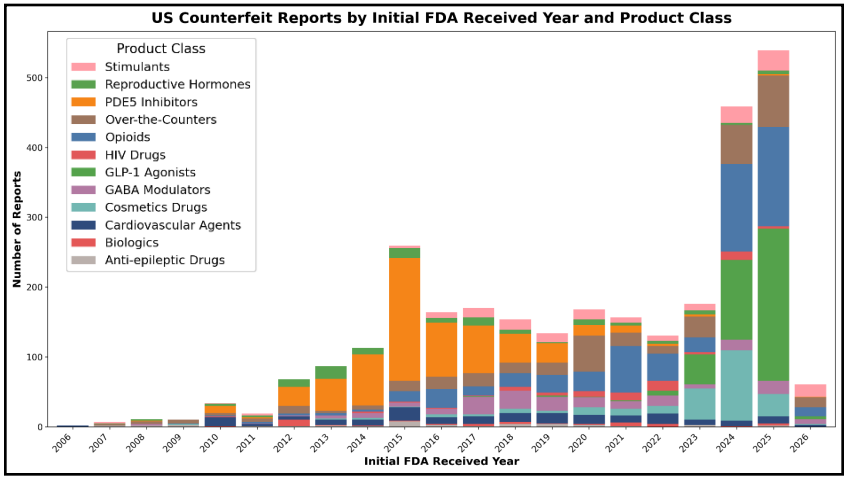
Characterize the Counterfeit Medical Product Reports in the FDA Adverse Event Monitoring System

- An analysis of counterfeit-product reports identified in the FDA AEMS from **2001 to 2025**.
- A total of **6,732 reports** were included.
- Mean age was **49.7 years**
- Reports involved:

males	43.6%
females	39.3%
unspecified sex	17.1%

How many counterfeit reports were submitted to the FDA AEMS in 2025?

652



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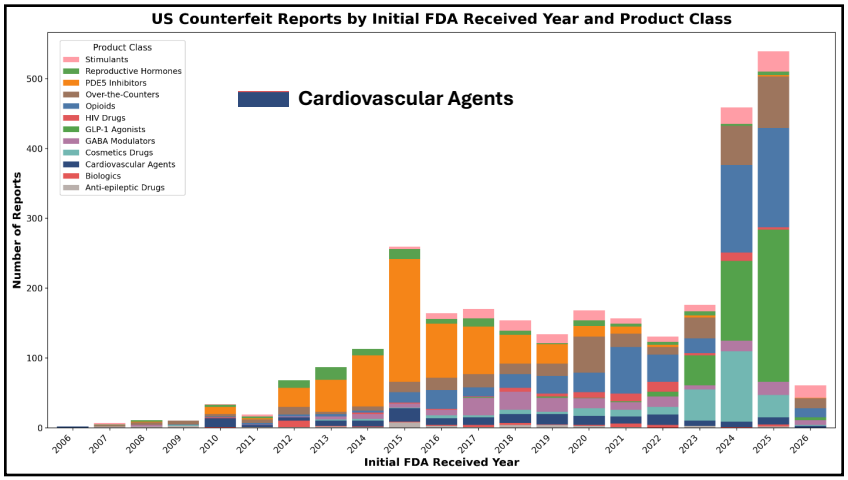
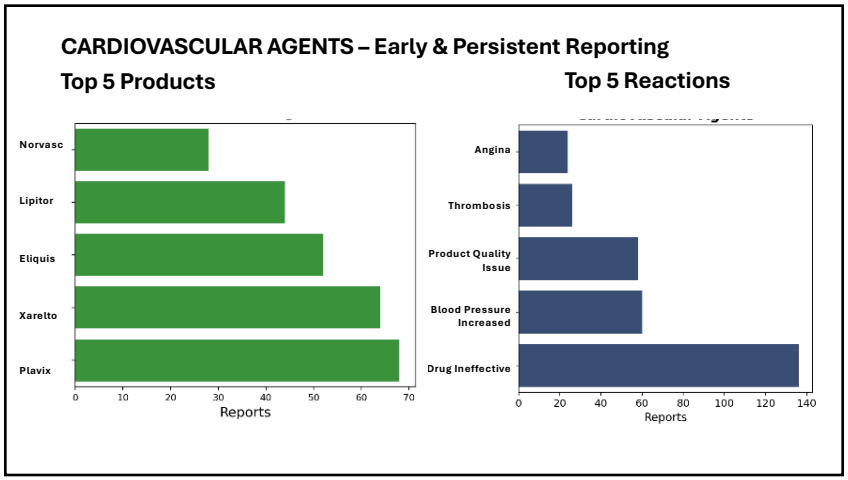
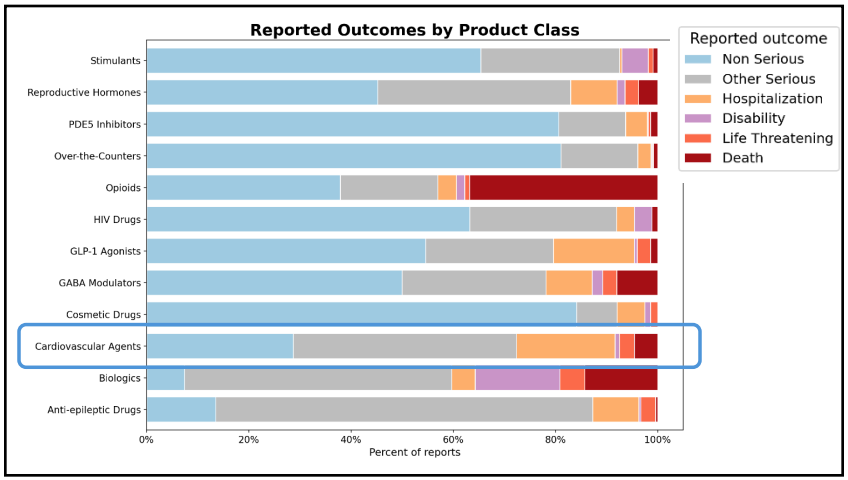
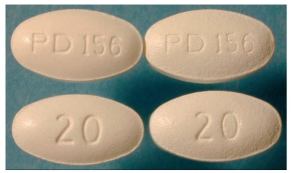






Largest Counterfeit Recall in US History

- 18 million fake Lipitor tablets across 15 states and affecting more than 600,000 US residents.
- The counterfeits first came to light in 2003 as a result of a patient complaining that the tablets had a bitter taste and dissolved quickly in the mouth before swallowing.
- These fakes were traced to a Missouri-based wholesaler and a Nebraska repackager named Med-Pro Inc.



Aside from a difference in their thickness, the counterfeit Lipitor® (left) is virtually indistinguishable from the authentic tablets.

Cardiovascular Drugs - Summary

Timeframe: Early & Persistent Reporting
Products: 2000s – Lipitor/Plavix, 2010s – Eliquis/Xarelto
Reactions: Drug Ineffective, Blood Pressure, Thrombosis, Angina
Outcomes: High proportion serious with hospitalizations
Case Example: Counterfeit Lipitor
Supply Chain Breach: Fraudulent Wholesaler/Repackager

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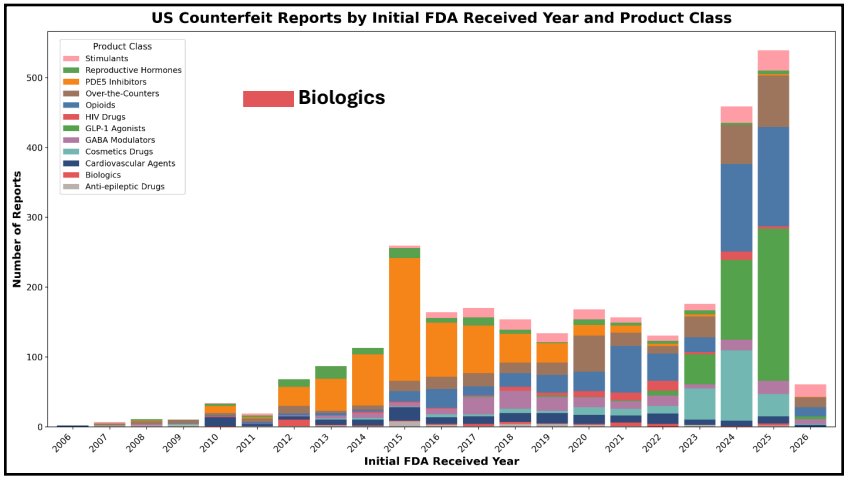
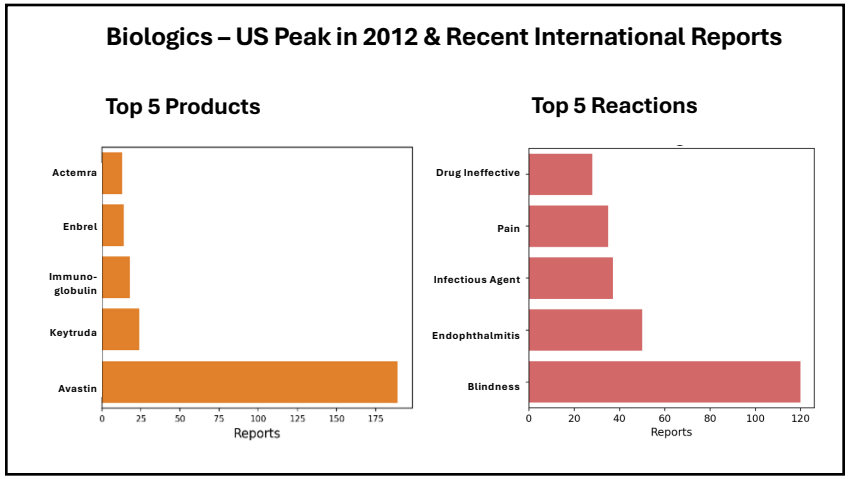
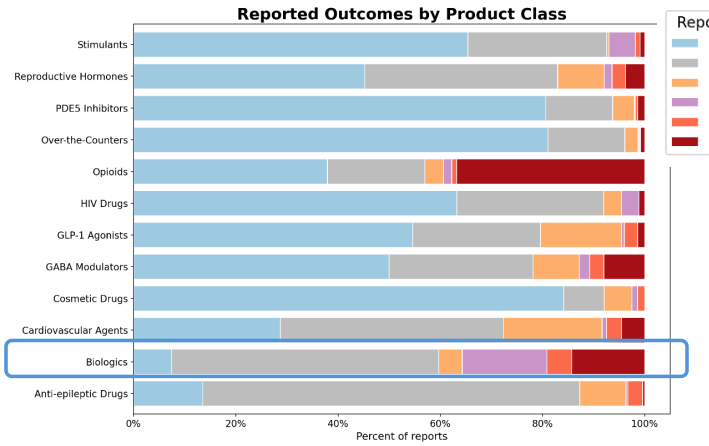




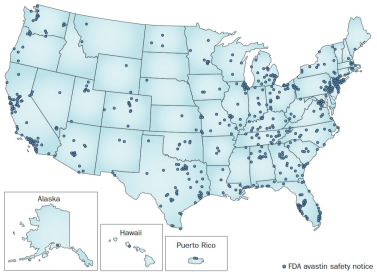


Counterfeit Avastin

- In 2012, the United States faced a significant public health crisis when counterfeit versions of the cancer drug **Avastin (bevacizumab)** were discovered in the domestic supply chain affecting **1,000 medical practices** across 48 states
- The fraudulent medication contained no active cancer-fighting ingredients and was instead found to consist of substances such as salt, starch, and acetone.
- **Source of the Fake Drugs:** The counterfeit trail was traced back through a complex international network involving wholesalers in **Turkey, Egypt, and the United Kingdom**.
- **Gallant Pharma International Inc.** (Gallant Pharma), an unlicensed wholesale drug distributor headquartered in Arlington, Va., that distributed more than 17,000 units of non-FDA-approved cancer and cosmetic drugs to doctors across the United States, was sentenced today to pay $3.4 million in forfeiture and restitution. On Dec. 2, 2013, Gallant Pharma pleaded guilty to two counts of illegal importation, five counts of introducing misbranded drugs and five counts of unlicensed prescription drug wholesaling.

Mackey TK, Cuomo R, Guerra C, Liang BA. After counterfeit Avastin®--what have we learned and what can be done? Nat Rev Clin Oncol. 2015 May;12(5):302-8.
https://www.fda.gov/drugs/drug-supply-chain-integrity/fda-issues-letters-doctors-who-may-have-purchased-counterfeit-or-unapproved-prescription-drugs

Patients receiving care at medical facilities across 48 states were at risk of harm from counterfeit Avastin

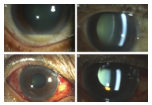


The death of Betty Hunter, a 76-year-old Arizona woman with lung cancer, is a prominent case of a patient dying after receiving counterfeit Avastin in the United States.

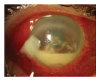
US Food and Drug Administration. Letters to Doctors about Risks of Purchasing Medications from Foreign or Unlicensed Suppliers [online], http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm (2012).
https://www.wral.com/cancer-patient-received-counterfeit-drug-prior-to-death/17643955/

Counterfeit Avastin-associated Blindness

- **International (2023)** dozens of patients in Pakistan and China experienced vision loss, with at least 12 people reporting complete blindness after receiving injections for diabetic eye conditions (macular degeneration).
  - Authorities identified the incident as contamination by third-party distributors selling fake, illegally repackaged versions of the drug.
- **Miami, Florida (2011/2012):** 12 patients in the Miami area suffered Streptococcus endophthalmitis—a severe eye infection—after receiving repackaged Avastin from a single Florida pharmacy.



Acute intraocular inflammation



Endophthalmitis

Wang F, Yu S, Liu K, Chen FE, Song Z, Zhang X, Xu X, Sun X. Acute intraocular inflammation caused by endotoxin after intravitreal injection of counterfeit bevacizumab in Shanghai, China. Ophthalmology. 2013 Feb;120(2):355-61.
Sachdeva MM, Moshiri A, Leder HA, Scott AW. Endophthalmitis following intravitreal injection of anti-VEGF agents: long-term outcomes and the identification of unusual micro-organisms. J Ophthalmic Inflamm Infect. 2016 Dec;6(1):2.

Biologics- Summary

Timeframe: US peak in 2012 and recent international reports

Products: Avastin by far the most reported agent

Reactions: Blindness, endophthalmitis, infectious agent

Outcomes: High proportion serious with disability and death

Case Example: Counterfeit Avastin

Supply Chain Breach: US distributors illegally sourcing product from international entities

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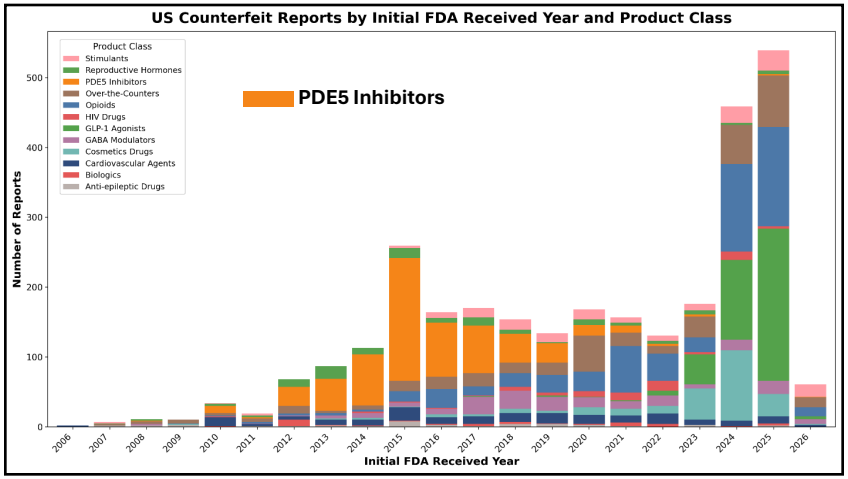
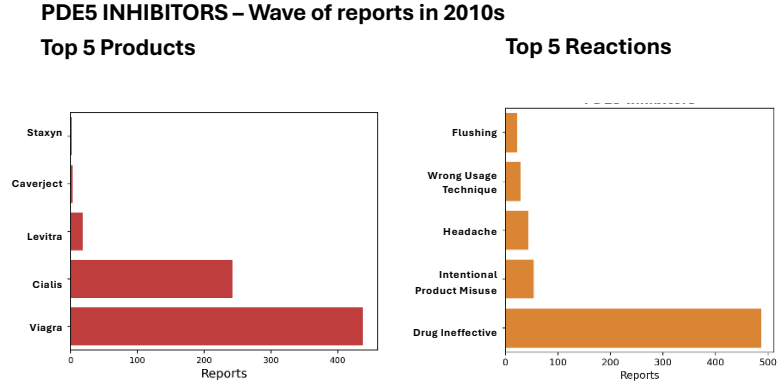
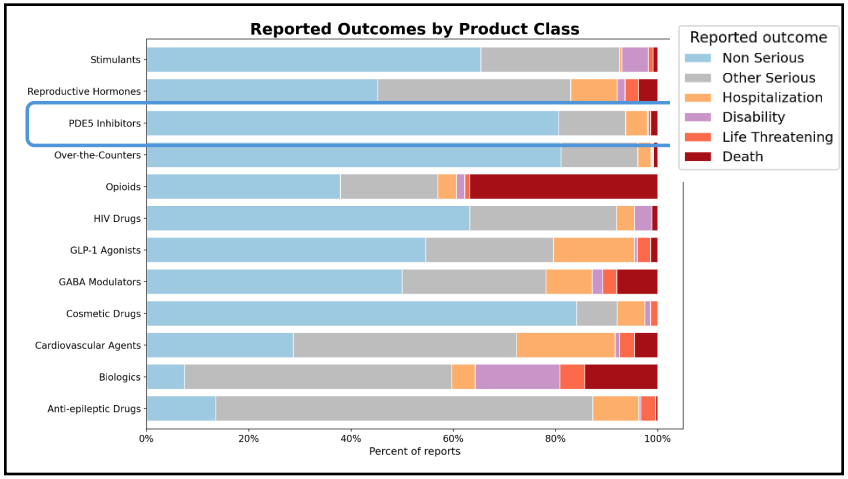






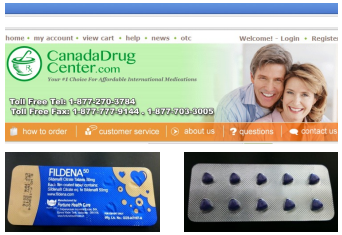
Counterfeit Viagra/Cialis Incidents

- **Chicago Pharmacist Conviction:** In April 2015, a Chicago pharmacist pleaded guilty to trafficking counterfeit Viagra and Cialis purchased from China. He smuggled approximately 1,600 tablets by declaring them as "gift pens" on customs forms and sold them without prescriptions at his pharmacy.
- **Multi-State Conspiracy:** A Los Angeles man was sentenced in December 2015 to over six years in prison for leading a "California Confidence Company" ring. The group obtained counterfeit Viagra, Cialis, and Levitra from China and sold them across California and Nevada, with seized inventory valued at over $1.2 million.
- **Southern District of Texas Prosecutions:** In June 2015, a major trafficker was found guilty of distributing dangerous counterfeit Viagra that contained 2-MBT, a chemical compound used in rubber manufacturing, rather than the labeled active ingredient.

https://www.nbcchicago.com/news/local/pharmacist-sentenced-for-selling-fake-viagra-cialis-on-northwest-side/107813/
https://www.fbi.gov/contact-us/field-offices/sacramento/news/press-releases/los-angeles-man-sentenced-in-multi-state-conspiracy-to-sell-more-than-1-million-in-counterfeit-erectile-dysfunction-drugs
https://www.justice.gov/usao-sdtx/pr/trafficker-pleads-distributing-dangerous-counterfeit-viagra-and-cialis

Maine's Experience with Drug Importation from Foreign Entities

- In 2013, the Maine Legislature passed LD 171, the "Act to Facilitate Personal Importation of Prescription Medication from International Mail Order Prescription Pharmacies."
- In partnership with an investigative journalist from WGME news, CBS 13, Portland, Maine, I ordered Viagra 50mg.
- The product contained 13% of the labeled strength of sildenafil.



PDE5 Inhibitors- Summary

Timeframe: Wave of reports in 2010s, peaking in 2015

Products: Viagra and Cialis most reported agents

Reactions: Drug Ineffective most common reaction

Outcomes: High proportion nonserious

Case Example: Counterfeit Viagra

Supply Chain Breach: Online entities claiming to be "Canadian Pharmacies"

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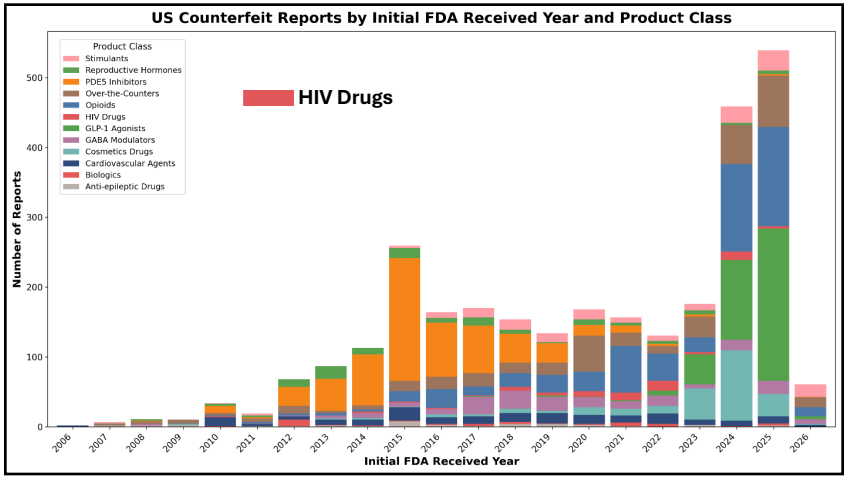
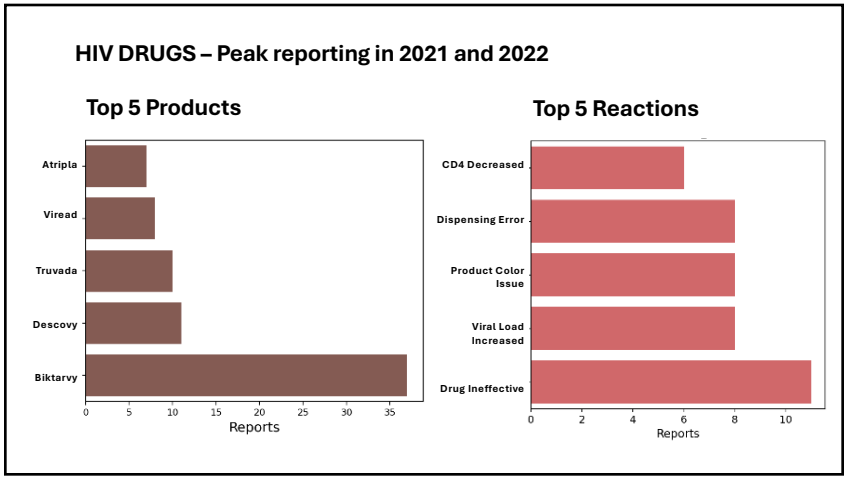
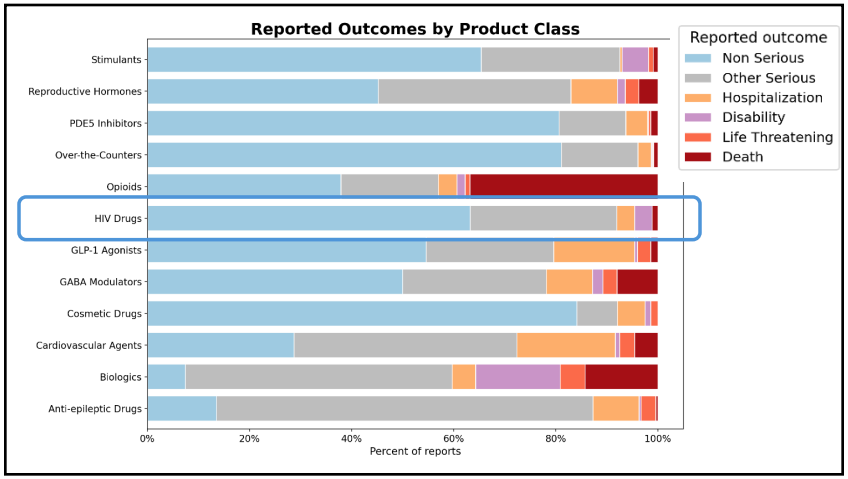




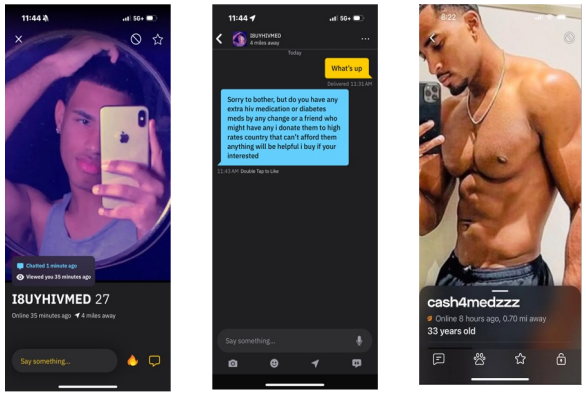


PATIENT BUYBACKS

- In June 2022, the Justice Department unsealed another HIV medicine trafficking case, alleging that a Miami man distributed $230 million in illegally acquired HIV medicines, as well as cancer and psychiatric drugs. In September 2022, Gilead Sciences' identified this man as a major organizer of the counterfeiting ring that is at the center of their lawsuit.
- In these diversion schemes, the criminals acquire medicine illegally through Medicaid fraud or street collection operations and then take that already-dispensed medicine and sell it back into the supply chain.

https://www.justice.gov/opa/pr/man-arrested-allegedly-distributing-over-230-million-adulterated-hiv-medication
www.justice.gov/opa

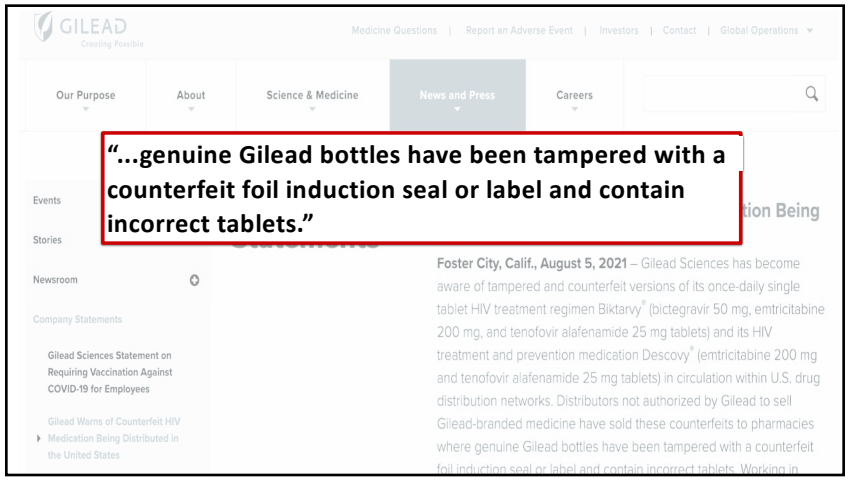
Suspect dating app users breaking the supply chain



Screenshots of intercepted illegal medicine buyers on dating apps. (Credit: Brandon Macsata, Director HealthHIV)

CRIMINAL WHOLESALERS

- **Fake sale logs:** The criminal wholesalers were required to provide sale transaction documentation as required by the Drug Supply Chain Security Act. The transaction logs given to the pharmacies were faked to show the medicine passed through well known major wholesalers. (It did not.) Gilead's Brand Protection / Product Quality department has stated that they will check a transaction log on any purchase for a pharmacy. Check with them before you purchase.
- **Real bottles, fake medicine:** The criminal wholesalers used real bottles purchased illegally from patients in order to get real serialization numbers, filled them with counterfeits, and sealed them incorrectly with their own foil. Alert pharmacists might have been able to spot these fakes.
- **85,247 of bottles of counterfeit Gilead product worth $250mm**



Have I got a deal for you….

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

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 Clare, MI)

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

Simplified example of a transaction log

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

Major counterfeit ring uncovered

Buy medicine or empty bottle from Medicaid 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!

…to licensed pharmacies and then to patients.

Case facts: (early stages in court)
- 85,000+ bottles seized / Value of $250mm
- Some fake product reached patients
- 140+ defendants

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?

Many HIV, HepC and PREP products were counterfeited. We are not allowed to name them in this presentation. Generic names available below.

Source: https://www.safemedicines.org/wp-content/uploads/2019/09/Gilead-v-SafeChain-et-al-Fourth-Amended-Complaint.pdf

Generic names: bictegravir, emtricitabine and tenofovir alafenamide, emtricitabine and tenofovir alafenamide tablets, emtricitabine-tenofovir, elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide, efavirenz / emtricitabine / tenofovir disoproxil fumarate, sofosbuvir, elvitegravir/cobicistat/emtricitabine/tenofovir DF, sofosbuvir, velpatasvir, and voxilaprevir, ranolazine, darunavir, cobicistat, emtricitabine, and tenofovir alafenamide.

Are pharmacies also targets of lawsuits? Yes.

Pharmacies have an obligation today, under the DSCSA, to investigate suspicious product. Many pharmacies were informed that there was diverted or counterfeit product being sold by wholesalers with fraudulent paperwork, but continued buying and dispensing anyway.

Many did not investigate suspect product.

Lanham Act civil actions are so expensive that these are likely **bankruptcy triggering events** for most independent pharmacies.

Who tipped off the crime?

Patients likely noticed changes in taste and color of tablets. One experienced side effects from one fake pill. It is unknown how many discovered it through re-diagnosis of uncontrolled HIV or recurrence of Hepatitis C symptoms.

A **pharmacist** in at least one case challenged the transaction logs. But many more pharmacists did not.

HIV Drugs - Summary

Timeframe: Peak reporting in 2021 and 2022

Products: Biktarvy, Descovy and Truvada

Reactions: Drug Ineffective and viral load increased

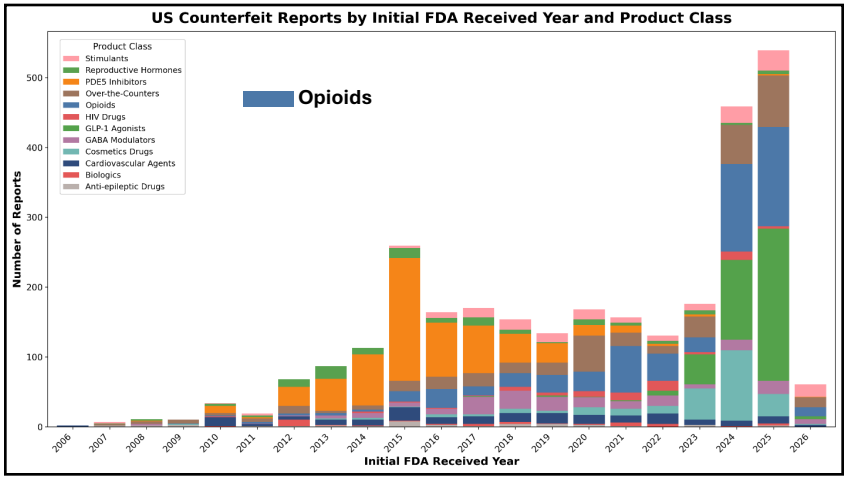
Outcomes: Both serious and nonserious

Case Examples: Counterfeit Biktarvy and Descovy

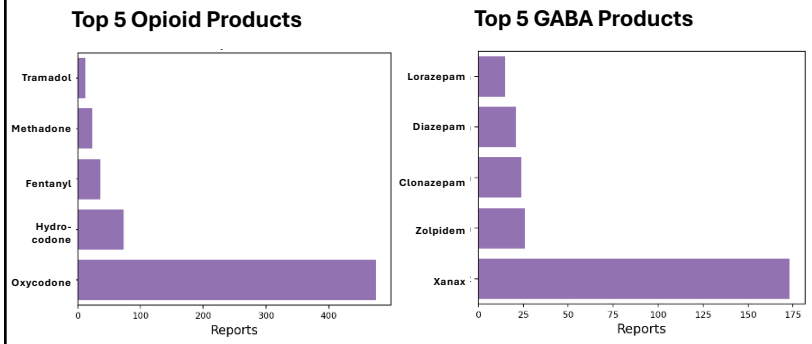
Supply Chain Breach: Patient "buybacks", Medicaid fraud, criminal wholesalers

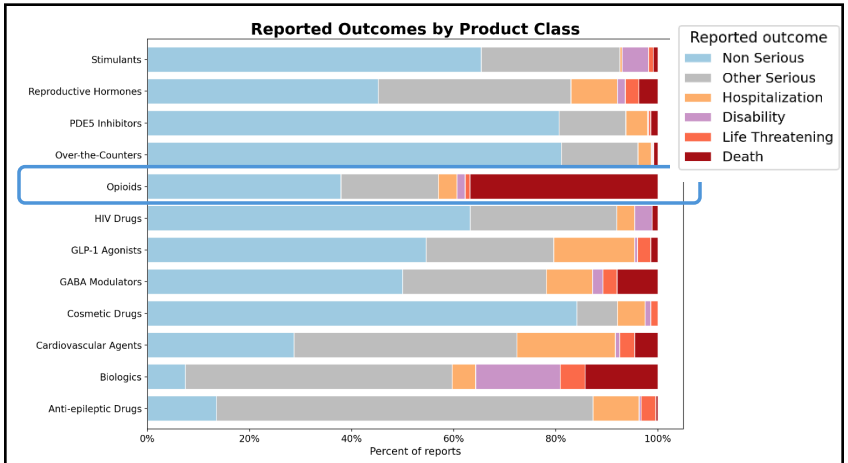
Outline

- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids
  - GLP-1 Agonists
  - Cosmetic Drugs
- What if I have a suspect product?
- Assessment Questions



OPIOIDS & GABA MODULATORS – Recent surge in reporting.





Counterfeit Opioids and Xanax

- On January 18, 2024, DEA along with federal, state, and local law enforcement partners in Mississippi arrested two individuals and seized over 80,000 fake fentanyl pills, designed to look like Xanax and oxycodone. They also seized significant quantities of fentanyl powder, cocaine, crack cocaine, methamphetamine, two pill presses, 13 firearms, a suppressor, and body armor.

- On April 15, 2026, Two men were arrested in New York for allegedly operating a large-scale fentanyl manufacturing and packaging operation inside a Brooklyn apartment. The Drug Enforcement Agency (DEA) called the apartment a "pill mill" and said the industrial pill press found in the apartment was capable of producing 4,800 pills per hour.

https://www.wral.com/raleigh-man-pleads-guilty-to-making-selling-anxiety-drugs-on-dark-web-/17336262/
https://www.dea.gov/pill-press-photo-gallery
https://www.dea.gov/press-releases/2026/04/15/two-men-charged-narcotics-and-firearms-offenses-for-running-fentanyl

Opioids/Benzos - Summary

Timeframe: 2020s – recent surge in reporting

Products: Oxycodone and Xanax among others

Reactions: Overdose, toxicity

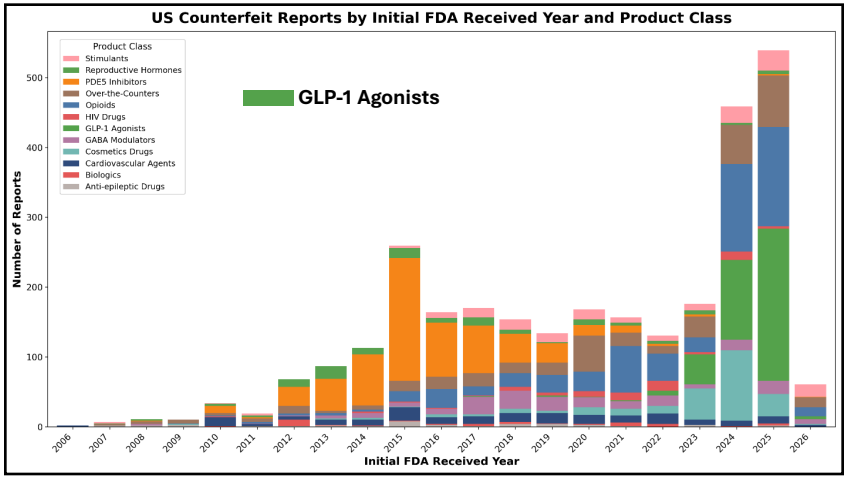
Outcomes: Serious including a high proportion of deaths

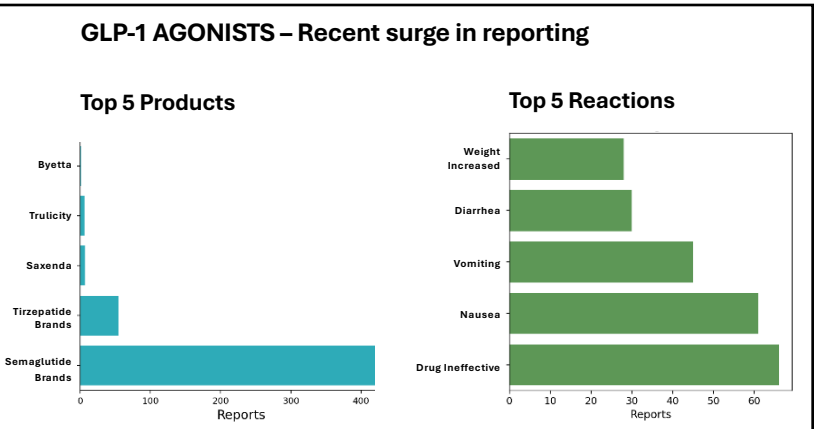
Case Example: Counterfeit Oxycodone and Xanax

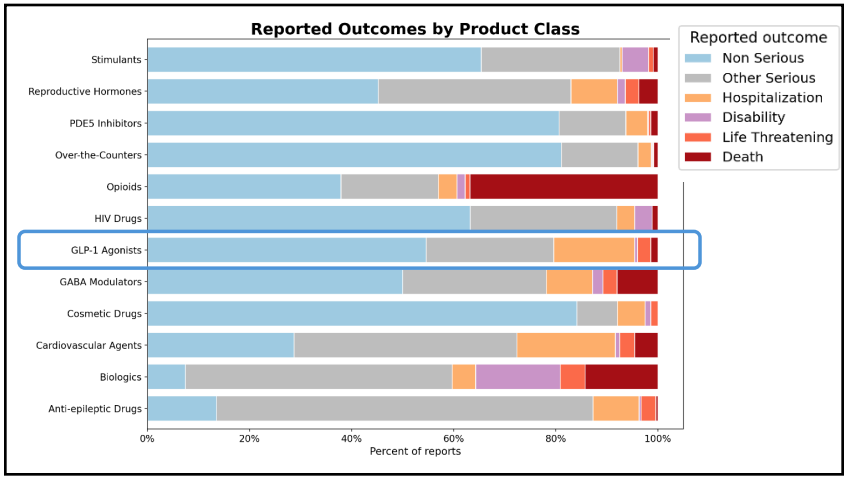
Supply Chain Breach: Clandestine pill press/pill mills creating fentanyl-laced counterfeits

Outline

- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids
  - GLP-1 Agonists
  - Cosmetic Drugs
- What if I have a suspect product?
- Assessment Questions







A Chicago man suffered a medical emergency

- **Mike Benson**, suffered a life-threatening medical emergency in late 2023 after injecting himself with what he believed was **Ozempic**, but was actually a counterfeit pen filled with **insulin**.
- **Reaction**: Moments after injecting the pen, Benson's blood sugar dropped to dangerously low levels (hypoglycemia). He described the room spinning and feeling "helplessly incapable of doing anything" before losing consciousness. **Coma and Seizure**: He suffered a seizure and fell into a **diabetic coma**.
- **Recovery**: Paramedics saved his life by administering carbohydrates while rushing him to Northwestern Memorial Hospital's emergency room. He spent a weekend in intensive care before recovering.
- **Source**: Benson obtained the drug from an unregulated, unlicensed source rather than a reputable pharmacy.
- **Product Swapping**: The counterfeit was likely an **Apidra SoloStar insulin pen** that had been relabeled as Ozempic. This specific insulin pen is a dark gray-blue, which is similar enough to the authentic Ozempic pen's blue color to fool many users.
- **FDA Action**: Following this and similar incidents, the U.S. Food and Drug Administration (FDA) seized thousands of units of counterfeit Ozempic from the U.S. supply chain, specifically warning about products with **lot number NAR0074** and **serial number 430834149057**.

https://abc7chicago.com/post/ozempic-weight-loss-diabetes-chicago-news-insulin/14268598/#:~:text=Chicago%20man%20issues%20warning%20after%20taking%20fake%20Ozempic%20diabetes%2C%20weight,medicine%20specialist%20with%20Northwestern%20Health.

Counterfeit Ozempic infiltrated the pharmacy supply chain

Email from Florida distributor to Arkansas Pharmacy

Good morning, [redacted]

Here is what we have now on injectable insulins:

OZEMPIC.25	285	$900	0169-4181-13
OZEMPIC1	323	$900	0169-4130-13
OZEMPIC2	24	$900	0169-4772-12
TRULIC.75	209	$900	0002-1433-80
TRULIC1.5	134	$900	0002-1434-80
TRULIC3	83	$900	0002-2236-80
TRULIC4.5	80	$900	0002-3182-80
WEGOVY.50	0	$1,125	0169-4505-14
WEGOVY1	0	$1,125	0169-4501-14
WEGOVY1.7	0	$1,125	0169-4517-14
WEGOVY2.4	0	$1,125	0169-4524-14
WEGOVY.25	0	$1,125	0169-4525-14
ZEPBOUND2.5	4	$1,125	0002-2506-80
ZEPBOUND5	7	$1,125	0002-2495-80
ZEPBOUND10	0	$1,125	0002-2471-80
ZEPBOUND7.5	20	$1,000	0002-2484-80
WEGOVY.25-SAMP	11	$700	0169-4525-94

Please let me know if I can be of any assistance.

Here is what we have today:

MOUNJARO12.5	7	$1,020
MOUNJARO5	12	$1,020
MOUNJARO7.5	9	$1,020
OZEMPIC.25	168	$900
OZEMPIC1	163	$900
OZEMPIC2	106	$900
TRULIC.75	74	$900
TRULIC1.5	59	$900
TRULIC3	42	$900
TRULIC4.5	23	$900

Arkansas BOP DSCSA / NABP Pulse success story

Images of counterfeit product

FDA Warning Letter to Sterling Distributors – June, 2025

The FDA warned Florida-based wholesaler Sterling Distributors over significant violations of the Drug Supply Chain Security Act, including selling prescription medicines without the appropriate license, buying products from unauthorized trading partners, and failing to identify or investigate suspect products in its possession. The distributor sold counterfeit Ozempic pens to pharmacies in Arkansas and Mississippi in late 2024.

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sterling-distributors-706508-06052025

GLP1 Agonists - Summary

Timeframe: 2020s – recent surge in reporting

Products: Semaglutide and tirzepatide brands

Reactions: Drug Ineffective, nausea, vomiting, diarrhea

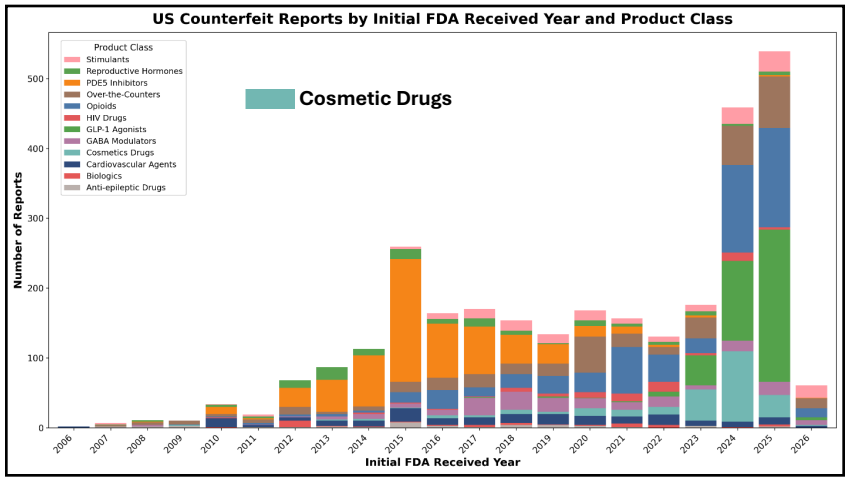
Outcomes: Some serious with hospitalizations

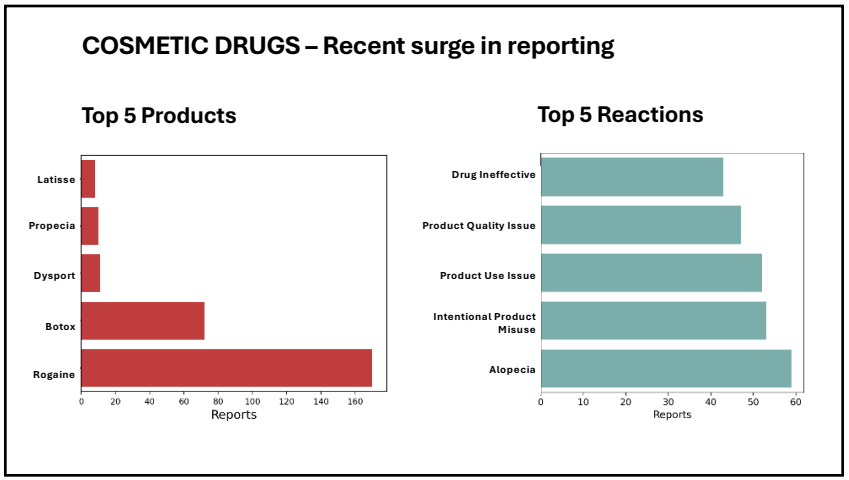
Case Example: Counterfeit Ozempic

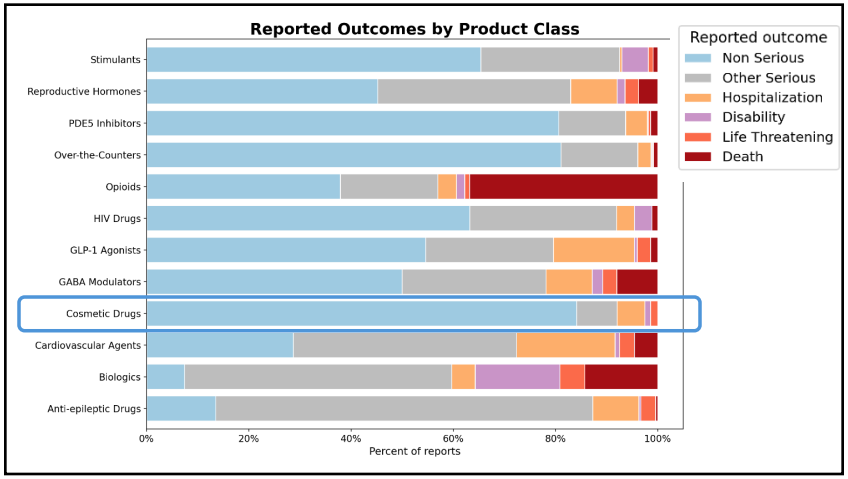
Supply Chain Breach: Wholesaler selling prescription medicines without the appropriate license, buying products from unauthorized trading partners.

Outline

- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event Monitoring System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids
  - GLP-1 Agonists
  - Cosmetic Drugs
- What if I have a suspect product?
- Assessment Questions







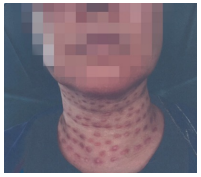
FDA Alert: Counterfeit Botox

- **[4-16-2024]** FDA is alerting health care professionals and consumers that unsafe counterfeit versions of Botox (botulinum toxin) have been found in multiple states and administered to consumers for cosmetic purposes.
- FDA is aware of adverse events, including hospitalizations, linked to the counterfeit Botox. Symptoms included blurred or double vision, difficulty swallowing, dry mouth, constipation, incontinence, shortness of breath, weakness and difficulty lifting one's head following injection of these products.

https://www.fda.gov/drugs/drug-alerts-and-statements/counterfeit-version-botox-found-multiple-states#:~:text=%5B4%2D16%2D2024%5D,been%20purchased%20from%20unlicensed%20sources.

Counterfeit Botox Incidents

- Criminal compliant filed against 'Princess Beauty, LLC', and the Cosmetology license under the name Fei Min in Flushing, Queens.
- The complaint: Fei Min "injected unknown substances into her face, neck, and breasts" and told her that the injections were "Botox and other treatments".
- The complainant received "128–140" neck injections of unknown substances, resulting in "redness, bleeding, swelling and substantial pain".
- The injection sites then blistered and became inflamed and "reddish," and the complainant experienced pain, itching, trouble sleeping, and a slight fever. Marks from the blisters and some scars still remain on the complainant.

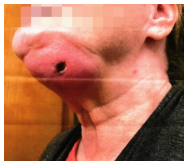


Injection site swelling

https://dos.ny.gov/med-spa-investigations-0

Counterfeit Botox Incidents Cont.

- In the matter of the complaint of Department of State, Division of Licensing Services against Patricia Rivas, the Department alleged that Rivas, a licensed esthetician, was operating an unlicensed salon in Warwick, NY
- Providing cosmetic injections, cryotherapy, and laser services ultimately resulting in a MRSA infection, sepsis, and hospitalization to a consumer. Following investigation, the Secretary of State issued an emergency suspension order and negotiated the revocation of Rivas's license.



MRSA Infection

https://dos.ny.gov/med-spa-investigations-0

Cosmetic Drugs - Summary

Timeframe: Recent surge with peak in 2024

Products: Botox and Rogaine

Reactions: Product quality, drug ineffective

Outcomes: Most nonserious with some reports of MRSA infections, burns, poisonings, allergic reactions

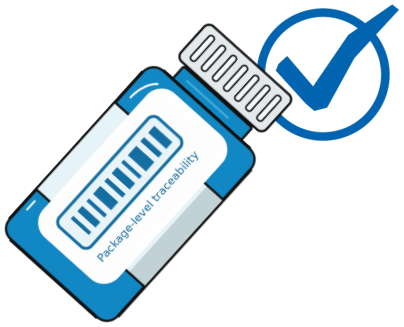
Case Example: Counterfeit Botox

Supply Chain Breach: Med Spa customers receiving injections of counterfeit drugs by unlicensed individuals

Outline

- Partnership for Safe Medicines
- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids
  - GLP-1 Agonists
  - Cosmetic Drugs
- What if I have a suspect product?
- Assessment Questions

Drug Supply Chain Security Act



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?

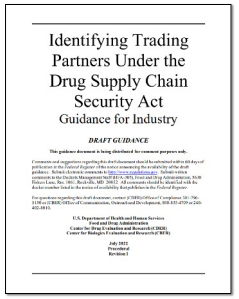
- Only purchase from **authorized trading partners** that have valid licensure and keep records of that. (everyone)
- Only trade products that have **identifiers** unless exempt or grandfathered (everyone)

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)

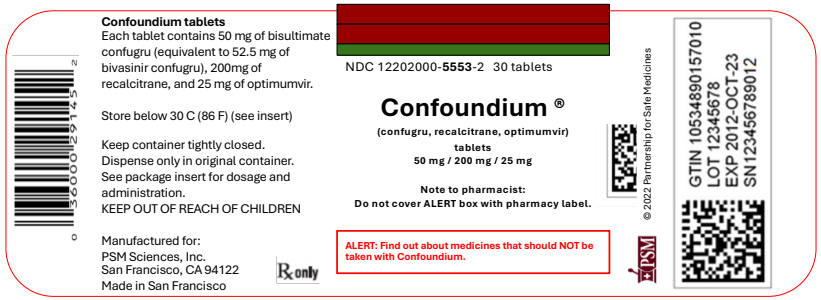
- Manufacturers
- Third party logistics providers (3PL)
- Wholesalers
- Repackagers
- Dispensers


Identifying Trading Partners Under the Drug Supply Chain Security Act
Guidance for Industry
DRAFT GUIDANCE

https://safedr.ug/dscsa_identify

Only trade serialized product (effective now)

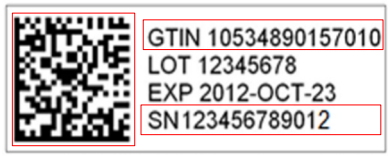
- Only trade products that have a Product identifier unless it has an exception (all dispensers)



What is on a serialized label?

- GTIN: Global Trade Item Number - 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.

Respond to requests for information (effective now)

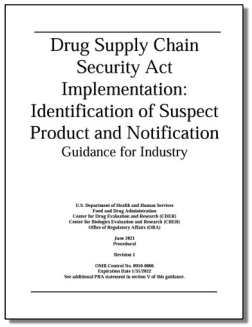
"Hey, this is the FDA Office of Criminal Investigation investigator, what HIV medicines have you received from SAFEMEDS LLC in the last 90 days and what are the serial numbers?"

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

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**.


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

The FDA has outlined all the reasons you should be suspicious.

91

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.**

*****NABP has authorized more than 15 providers to connect your pharmacy system with a **Pulse Interoperable Partner**.

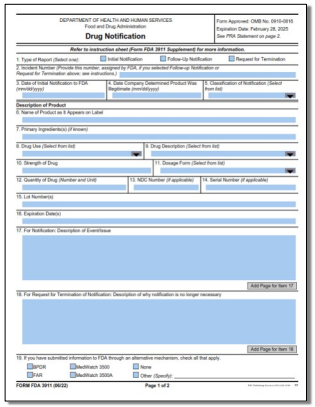
It's now either considered **cleared product** or **illegitimate product**. Update trading partners

…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

Drug Notification

Form Approved: OMB No. 0910-0916
Expiration Date: February 28, 2025
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report (Select one) ☐ Initial Notification ☐ Follow-Up Notification ☐ 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)

Description of Product

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

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None

☐ FAIR ☐ MedWatch 3500A ☐ Other (Specify): _____

FORM FDA 3911 (06/22) Page 1 of 2

Outline

- Drug Supply Chain Security Act
- Study of Counterfeit reports in the FDA Adverse Event Monitoring System
  - Cardiovascular Agents
  - Biologics
  - PDE5 Inhibitors
  - HIV Drugs
  - Opioids
  - GLP-1 Agonists
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Post-Test Question #1

What is the most commonly reported reaction associated with counterfeit medical products in the FDA Adverse Event Reporting System?

A. Anaphylaxis
B. Drug ineffective
C. Nausea
D. Rash

Post-Test Question #2

Which of the following statements is true regarding the temporal patterns of reported counterfeit products?

A. Reports involving PDE5 inhibitors were highest in 2022, while cardiovascular drug reports have increased steadily since 2010.
B. HIV drug counterfeit reports peaked in 2015, and there has been little recent reporting involving opioids or GLP-1 agonists.
C. PDE5 inhibitor counterfeit reports peaked in 2015, and more recent reporting has surged for counterfeits involving opioids, GLP-1 agonists, and cosmetic drugs.
D. Counterfeit product reports have remained evenly distributed over time without notable peaks by drug class.

Post-Test Question #3

A pharmacist receives complaints from patients about product quality issues related to an injectable diabetes medication. Upon closer examination, the pharmacist notices that several packages have irregular labeling and packaging differences compared to previous shipments. The pharmacist determines the product is suspect.

What is the most appropriate next step in managing this situation under DSCSA requirements?

A. Continue dispensing product while monitoring for additional concerns
B. Quarantine all suspect product and begin an investigation
C. Notify the FDA using Form 3911 and destroy the product
D. Return the product to the wholesaler and document the concern

Post-Test Question #4

Which serious outcome was notably associated with bevacizumab (Avastin) in reports of counterfeit drugs?

A. Blindness
B. Kidney failure
C. Hearing loss
D. Liver injury

Post-Test Question #5

You need to purchase a medication that costs $1,000 for a 2 oz vial. The manufacturer confirms they distribute exclusively through three authorized national wholesalers, all of whom quote you the same price.

Shortly after, you receive an unsolicited email from a wholesaler you've never heard of offering the product for $900 per vial. The email includes no verifiable contact information, requires prepayment by wire transfer, and lists a different lot number format than what you typically receive from authorized distributors.

Which of the following best describes this situation under DSCSA?

A. This is a normal pricing scenario and the product can be safely purchased
B. This is acceptable as long as the product appears intact upon arrival
C. This is only concerning if patients report adverse effects after dispensing
D. This is a warning sign of suspect product and the wholesaler should be treated as an unauthorized trading partner

THANK YOU!

Questions?
You can reach me at:

Kenneth McCall, PharmD, FAPhA
mac@safemedicines.org
kmccall@binghamton.edu

Collect Your CE
The Lecture Panda code for this session is:
`{code here}`

All course credits from this conference must be submitted by Oct 28, 2026