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WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

**Written Testimony of Shabbir Imber Safdar**
**Executive Director, The Partnership for Safe Medicines**

**Hearing: "Restoring Trust in FDA: Rooting Out Illicit Products"**
**Committee on Oversight and Government Reform**
**United States House of Representatives**

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Chairman Comer, Ranking Member Connolly, and distinguished members of the House Oversight and Government Reform Committee, thank you for your leadership on this issue and for inviting me to testify.

My name is Shabbir Imber Safdar and I am the Executive Director of the Partnership for Safe Medicines (PSM), a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. I am honored to submit this testimony today about something I have spent nearly two decades working on — ensuring that Americans do not fall victim to counterfeit medicines. Here at PSM, we are dedicated to protecting consumers from the dangers of counterfeit medicines. We work with a coalition of healthcare professionals, patient advocacy groups, law enforcement, and industry stakeholders to promote policies that prioritize American patient safety, promote the integrity of our American pharmaceutical supply chains and **protect our pharmaceutical border security**.

Counterfeit medicines pose a significant threat to public health and safety, and to our national security. Unfortunately, counterfeit medicines have been around almost as long as medicine, but its growth has been dramatically rising over the past several years due to increased volumes of drugs, longer supply chains, drug shortages, technological developments making it easier to counterfeit drugs, and the involvement of international organized crime.[1] This growth is further exacerbated by relatively low criminal penalties for distributing adulterated, unapproved or misbranded drugs under the Federal Food, Drug, and Cosmetic (FD&C) Act.

Many counterfeit drugs are made abroad and arrive in the United States through the small package mail system or are smuggled in,[2] but bad actors within our borders also manufacture and distribute counterfeit medicines. These illicit products often contain incorrect or harmful ingredients or improper doses, and they are often falsely labeled. In the United States, counterfeit drugs have infiltrated our secure supply chain, endangering patients and undermining trust in the healthcare system. Mexican drug cartels smuggle millions of fake pills[3] over the border, while homegrown traffickers[4] import unsafe ingredients and illegal pill presses from China to manufacture their own deadly pills.

During the COVID-19 pandemic, Americans moved their purchasing power to e-commerce platforms at an accelerated rate, including buying unverified and counterfeit medicines from unlicensed sources. Since then, we have seen an explosion in rogue, illegal and fake online pharmacies selling counterfeit, substandard and harmful illicit substances branded as legitimate prescription medicines.

[1] Pharmaceutical Safety Institute, "Incident trends 2019 - 2023," https://bit.ly/4jDLn1N
[2] U.S. Food and Drug Administration, "Counterfeit medicine," https://bit.ly/4lg8GzZ
[3] U.S. Drug Enforcement Administration, 2020 National Drug Threat Assessment, https://bit.ly/4hYIFCr
[4] Deseret News, "Judge Orders Utahn Who Sold Fentanyl-laced Pills on Darknet to Spend Life Behind Bars," October 15, 2020, https://bit.ly/3XKJkjO; U.S. Department of Justice, "Vero Beach Orthopedic Surgeon Sentenced to Life in Prison Following Conviction for Fentanyl Analog Drug Conspiracy Resulting in Death," July 6, 2018, https://bit.ly/2JTWLI8.

The global anonymity of the Internet provides a safe haven for illicit prescription drug sales. According to the National Association of Boards of Pharmacy (NABP), nearly 95% of websites[5] offering prescription-only drugs online operate illegally as fake online pharmacies.[6] Many sites lead unsuspecting customers to believe the dispensing pharmacy is in the United States or Canada. In fact, over 40% of Americans purchasing medications online mistakenly believe all websites offering prescription medicines are approved by the Food and Drug Administration (FDA) or state regulators, despite FDA warnings against illegal online pharmacies.[7]

While Americans are unfortunately familiar with deaths related to counterfeit pills laced with fentanyl,[8] other counterfeit medicines – such as counterfeit oncology,[9] HIV,[10] blood thinners,[11] and diabetes and obesity medicines[12] – continue to pose significant threats to public health. These fake drugs often contain incorrect, insufficient, or no active ingredients, leading to ineffective treatments, dangerous side effects, or other serious health problems. Patient harm statistics are alarming, with at least 100,000 deaths[13] estimated annually due to counterfeit medicines.

## Counterfeit Diabetes & Weight Loss Medicines

Due to the explosion of blockbuster weight loss and diabetes medicines and injectables (GLP-1s) on the market, PSM recently investigated and analyzed, in partnership with former director of the FDA's Office of Criminal Investigations and federal prosecutor George Karavetsos, the current state of counterfeit Ozempic, Wegovy, Mounjaro, and Zepbound within the U.S. prescription drug supply chain and found that suspicious, unauthorized, and illegal ingredients for these increasingly popular medicines are flooding into the United States from foreign sources despite U.S. laws forbidding them from coming through the border. *See* Exhibit A.

Unfortunately, the state of affairs is exponentially worse than the general public is aware of. Because these medicines are so life changing, they have become popular, and with popularity comes criminal opportunism that endangers patients.

The global market is awash in unsafe GLP-1 injectables and criminals are trying to profit from sneaking them into the hands of American patients. Look-alike counterfeits like insulin pens relabeled as Ozempic, unregulated medicines from unlicensed online pharmacies, "research grade" GLP-1s that are not fit for human use, compounded products made with substandard ingredients or in facilities that aren't sterile, and mystery substances sold on social media are all being pushed at American patients.

The report uncovered several concerning facts:

- The FDA and U.S. Customs and Border Patrol (CBP) records show 239 shipments of semaglutide and tirzepatide (the active ingredients in popular GLP-1 medicines) from foreign manufacturers failed to register their facility with the FDA, an essential legal requirement to ensure the safety of the U.S. drug supply.
- The FDA stopped only 44 of these shipments, allowing 195 illegal shipments into the U.S. market, where they were likely used in knockoff products sold to unsuspecting Americans.

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[5] National Association of Boards of Pharmacy, "Buy Safely," https://bit.ly/4lmgArW.
[6] U.S. Food and Drug Administration, "Internet Pharmacy Warning Letters," https://bit.ly/4cfsnUu.
[7] National Association of Boards of Pharmacy, "Rogue Rx Report, https://bit.ly/3FV6j5G.
[8] U.S. Drug Enforcement Administration, "DEA Issues Warning About Illegal Online Pharmacies," October 4, 2024, https://bit.ly/4hYUsRm.
[9] U.S. Department of Justice, "Two Brothers from India Arraigned on Indictment for Selling Counterfeit Cancer Drugs and Adulterated Medications," February 28, 2025, https://bit.ly/4hYNQ5l.
[10] CNBC, "Gilead Sciences Alleges Dangerous Drug-counterfeiting Operation at Two NYC Pharmacies in Lawsuit," August 16, 2024, https://bit.ly/3E8OMqc.
[11] The Partnership for Safe Medicines, "Fake Medicine in Mexican Pharmacies, https://safedr.ug/rxinmexico.
[12] National Public Radio, "A Website Sold Patients Obesity Drugs at Affordable Rates. Now They're Paying the Price," February 8, 2025, https://bit.ly/4iViaiC.
[13] Organization for Economic Co-operation and Development, "Trade in Counterfeit Pharmaceutical Products," https://bit.ly/43Gurmu.

- Sixty shipments of unregistered semaglutide and tirzepatide originated from China or Hong Kong; 42 originated from India.
- Many of these shipments were identified as ingredients for use in drug compounding. Others used even more troubling descriptions, such as "non-sterile liquids." Semaglutide and tirzepatide are injectable products that must be sterile. The FDA has warned patients of serious and potentially life-threatening risks posed by compounders that use non-sterile ingredients to make knockoff weight loss injectables.

Simply by studying FDA's imports database, PSM found one shipment of semaglutide that claimed to be manufactured in a JW Marriott in Canada. After a thorough review of FDA's registered facilities in Canada, PSM discovered that this hotel was indeed not an FDA-registered or inspected facility and the products contained were highly likely to be counterfeit. Luckily, CBP inspectors refused that shipment.

*JW Marriott, 39 Smythe St, Vancouver Canada. Not an FDA-registered facility. (Photo credit: Google Maps)*

Unfortunately, border inspectors cannot catch them all. Over 175 similar shipments from unregistered facilities snuck their way into the country. One such shipment claimed to be manufactured in a fitness club in Canada. Obviously, a fitness club is highly unlikely to be an FDA-registered facility, but PSM did its due diligence and verified through FDA's imports database and confirmed that it, indeed, was not a registered facility.


*National Fitness Center, 220 Humberline Dr., Etobicoke, Canada. Not an FDA-registered facility.*

Under current law, the FDA is required to block shipments of pharmaceutical ingredients from unregistered manufacturing facilities at the border. Yet this report shows dangerous, unchecked drug ingredients are entering the United States in large numbers, bound for use in compounded and counterfeit products. In fact, PSM found the following recent examples that demonstrate the severity of this issue:

- In 2023, a man in Chicago purchased counterfeit Ozempic from an unverified, unlicensed source. Instead of containing Ozempic, the syringe was filled with insulin, which caused the man to suffer from hypoglycemia so severely that he lost consciousness and went into a coma.[14] Thankfully, paramedics saved his life.
- In November 2024, an Arkansas pharmacy received counterfeit Ozempic from a Florida distributor that raised some red flags. The pharmacy wisely quarantined the suspect product and alerted the local state investigator who came over and scanned the quarantined and suspect product, using a new tool from NABP, called Pulse.[15] The Arkansas State Board of Pharmacy then moved to suspend the Arkansas license of the Florida distributor that shipped it, protecting thousands of other patients in Arkansas and around the country from harm.
- In January 2025, the Ohio Board of Pharmacy suspended the licenses of two doctors for selling their clinics' patients GLP-1 drugs labeled as "For Research Purposes Only," with staff at one clinic admitting that the drugs lacked instructions on how to reconstitute them or list expiration dates. The doctor at the second clinic admitted that his source was an out-of-state unlicensed seller.[16]

[14] ABC7 Chicago, "Chicago man issues warning after taking fake Ozempic diabetes, weight loss drug," January 3, 2024, https://bit.ly/4cjKVmz.
[15] The Partnership for Safe Medicines, "PSM Applauds Arkansas Board of Pharmacy for Protecting Patients," February 14, 2025, https://safedr.ug/ARBOP-fakeOzempic.
[16] Ohio Capital Journal, "Two Ohio Doctors and Their Clinics Disciplined Over Weight Loss Drugs," January 28, 2025, https://bit.ly/43zMwm6.

The Arkansas example illustrates the success of the Drug Supply Chain Security Act (DSCSA), a law passed by Congress in 2013 aimed at enhancing patient safety across the U.S. prescription drug supply chain. Using the Pulse Verification Tool, the inspector confirmed the medicine to be counterfeit in under a second, whereas previously, such a determination by investigators would have taken weeks of investigative time and resources.

On the federal level, our first defense is U.S. enforcement regulators. The FDA and CBP are responsible for approving or denying medicine imports at the border, but agents are overwhelmed by the massive volume of incoming packages that these dangerous products still make it into the country and into the hands of unsuspecting patients. As part of PSM's investigation, we analyzed the FDA's import records and found that CBP failed to detect and interdict close to 80% of declared shipments of semaglutide and tirzepatide from unapproved manufacturers.[17] Almost certainly more packages of unapproved GLP-1s have entered the country through other illicit channels where the contents are not disclosed to CBP.

## Unapproved, unverified compounded medicines harm patient safety

The lack of track-and-trace data for compounded medications exacerbates this issue among legally compounded medications as well. Currently, weight loss injectables approved by the FDA lack a generic counterpart. But patients still need to know where the ingredients for compounded versions come from, and whether the source is an FDA-registered facility. FDA investigations into compounding have revealed:

- Medicine contaminated with dangerous bacteria in non-sterile working conditions;
- Unapproved ingredients not safety-tested for human use; and
- Cheaper, research-grade ingredients not pure enough for human consumption.

As of February 2025, FDA had received more than 775 reports of adverse events with compounded versions of semaglutide and tirzepatide. In March 2025, the FDA sent ProRx, LLC, a registered 503B outsourcing facility, a warning letter about its use of bulk ingredients from an unregistered source to compound medicine.[18] Coupled with PSM's recent report (discussed above) that found nearly 200 shipments of semaglutide and tirzepatide shipped into the country from non-FDA-registered facilities, the threats to patient safety are rising.[19]

## "For Research Only" ingredients sold on Etsy for Human Consumption

Unfortunately, e-commerce platforms, like Etsy and others, also appear to be selling counterfeit and knock off versions of GLP-1s. Etsy, an online marketplace founded in 2005 and known mostly for offering vintage or handcrafted items, has turned into a source for criminals to peddle research-grade chemicals, unsafe for human consumption, to Americans looking for cheap alternatives to brand name GLP-1s.

In 2023, PSM discovered a thriving trade in chemicals on the site, including those sold to individuals seeking homemade versions of highly regulated pharmaceuticals. *See* Exhibit B. While many questionable items found were generally not counterfeit prescription drugs, some of the listings could be used as a direct substitute for prescription medicines, illicit drugs or ingredients for such medicines. Etsy.com has no verification service for sellers of active pharmaceutical ingredients, meaning customers cannot verify whether they are buying real products manufactured under safe conditions. The potential danger these vendors pose to public health is significant.

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[17] George Karavetsos and the Partnership for Safe Medicines, "Knockoff Weight Loss Drugs From Illegal Foreign Sources," https://safedr.ug/knockoffGLP-1.
[18] U.S. Food and Drug Administration, "Warning Letter ProRx, LLC," March 4, 2025, https://bit.ly/3FWr7tt.
[19] George Karavetsos and the Partnership for Safe Medicines, "Knockoff Weight Loss Drugs From Illegal Foreign Sources," https://safedr.ug/knockoffGLP-1.

These dangerous, unverified products can be separated into a few buckets: Do-It-Yourself Injectables; Miscellaneous Supplies (not handcrafted); Unapproved Foreign Medicines; and, Raw Chemicals and Precursors. *See* Exhibit B for images of product lists.

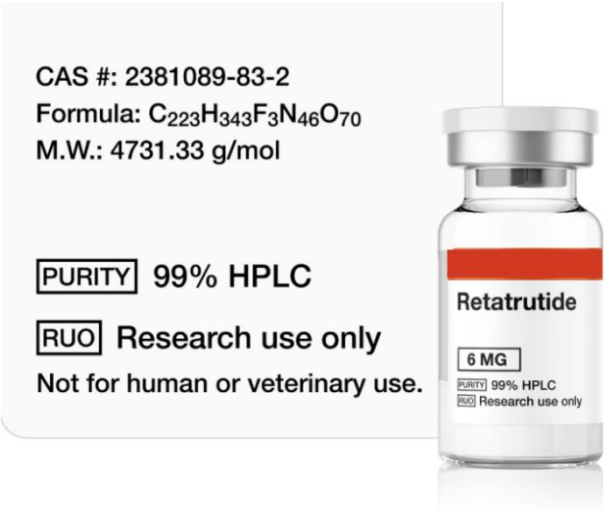



*Image of "retatrutide" for sale on peptide website. Seen April 2, 2025.*


*Image of "semaglutide for sale on Etsy. Seen June, 5 2023.*

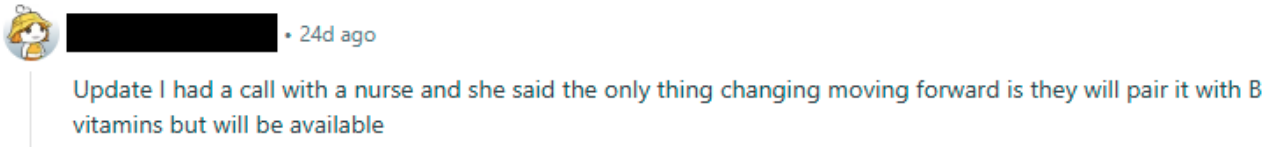
Because of the unknown and highly suspect contents contained within the vials (like those seen above), 38 state Attorneys General sent a letter[20] to Acting FDA Commissioner, Sara Brenner, M.D., M.P.H., in February 2025, urging FDA to take enforcement actions against bad actors "profiting off the high demand for FDA-approved weight loss and diabetes drugs." Unfortunately, patients have no way of verifying whether the advertised medicine is legitimate or where the active ingredients came from.

Additionally, the Federal Bureau of Investigation (FBI) issued a warning[21] in February 2025 warning the public about "noncompliant healthcare providers, to include pharmacies, weight loss clinics, and medical spas, engaging in fraudulent compounding practices by unlawfully misrepresenting compounded weight loss drugs." This warning covered concerns about fraudulently compounded semaglutide drugs, sub-therapeutic grade ingredients, and cited a specific pharmacy sanctioned for unsafe compounding.

## Concerns about compounding for telehealth profits, not patient appropriateness

As we have reached the end of the shortage of semaglutide and tirzepatide, we have seen a number of telehealth companies promoting "mass compounded personalization" of GLP-1 medicines. Compounding a medicine for a patient with unique needs is a valid right of a prescriber and a legitimate reason to compound. However, suddenly many telehealth patients have been switched to "personalized doses" of GLP-1s without requesting an alteration to their care or without any conversation with a physician about their needs, or without clear understanding about why they needed, mid-therapy, to suddenly change their prescription.

[20] https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/
[21] https://www.ic3.gov/PSA/2025/PSA250228




*Example user discovering their compounded product changed without knowing why. (Reddit, March 2025)*

## Counterfeit Medicines Sold on Online Marketplaces and Social Media Platforms

The problem of counterfeit medicines expands beyond just Etsy, however, and encompasses various other e-commerce marketplaces, fake online pharmacies, and social media platforms alike. The wide use of e-commerce marketplaces and social media platforms has made it easier for drug dealers to peddle counterfeit medicines, fake pills and other illicit drugs in unprecedented volume, targeting youths and increasingly reaching teenagers online. PSM tracked deaths related to fake pills marketed on social media for nearly five years and found connected deaths in twenty-nine states, with many more likely going undetected when considering the marketing of tainted controlled substances.[22]

These fake pills are widely accessible via social media platforms. The problem is so severe that the DEA even launched its own public awareness campaign, "One Pill Can Kill Campaign," to educate the public on this dangerous and growing trend.

The prevalence of counterfeit medicines on e-commerce marketplaces and social media platforms is not limited to just fake pills laced with fentanyl. Criminals peddle counterfeit therapeutics as well. In May 2024, the United States Department of Justice (DOJ) charged a Long Island, NY woman who allegedly was selling misbranded and adulterated weight loss drugs, including Ozempic, in videos posted to TikTok.[23]

Criminal enterprises and bad actors, such as the Long Island woman, advertise counterfeit medicines directly to patients on these platforms without the necessity for a medical consultation or prescription. Thus, social media advertisements pursuant to such activity are negligent and should not be permitted to exist. Again, these listings violate many of the platforms' own terms and service for use of the platforms, as well as community safety guidelines.

Social media platforms could act today to help prevent these activities and resulting deaths. But rather than take steps to reduce or eliminate illicit drug activity on their platforms, they continue to delay – and sometimes outright ignore – actions against these criminal users, even going so far as to claim these activities do not violate their terms of service. Law enforcement needs prompt access to information that these platforms have in order to facilitate investigations and legislation that would require platforms to share that information would help to protect other users, especially teens and young adults.

[22] https://www.safemedicines.org/2021/06/fentanyl-pill-victims-are-getting-younger-parents-blame-snapchat.html
[23] U.S. Department of Justice, "Long Island Woman Arrested for Selling Misbranded and Adulterated Weight Loss Drugs, Including Ozempic, on TikTok," May 1, 2024, https://bit.ly/4lhynAr.

## Illegal and unsafe international medicine trade

Fake Ozempic shipped de minimis and seized by CBP in Ohio, July 2024

Many counterfeit drugs come into the country via the U.S. Postal Service. In the past decade, de minimis shipments coming into the United States have increased from 139 million to nearly 1.3 billion parcels a year. Preventing counterfeit medicine and the equipment needed to illegally manufacture counterfeit medicines from entering the country is one of the strongest ways to protect Americans.

With three million de minimis packages entering the United States every day, it is impossible to find all the needles in the haystack. Requiring Advanced Electronic Data (AED) is a well-understood method that would allow CBP to narrow the size of that haystack and stretch precious resources to find harmful counterfeit medical products in the daily package stream. PSM recently submitted comments in support of CBP's proposed reforms to add AED to de minimis packages.[24] *See* Exhibit C.

## PBM Under-Reimbursement Practices Endanger Supply Chain and Patient Safety

For the past decade, the practice of pharmacy benefit managers (PBM) under-reimbursing pharmacies for medicines dispensed to insured patients have left pharmacies to dispense medications at a loss. This practice is not by accident; it is by design.[25] A pharmacist either accepts that loss or they could turn to an alternative source to get the medication the patient needs at a price that will not cause the pharmacy to go bankrupt. The criminals behind those illicit drugs are not trying to help patients – they are only trying to make money.

Criminals fabricate under-reimbursed medicines for their crime and have been caught selling diverted and counterfeit versions of various medicines, through criminal wholesalers, to unsuspecting pharmacies. In some cases, this unsafe medicine has landed in the hands of patients and caused patient harm.

## Instances of Counterfeit Therapeutics Beyond GLP-1s

Unfortunately, GLP-1 agonists are just the most recent therapeutic class that counterfeiters have gravitated towards. They will make fakes of anything, if they can make a profit doing so.

One of the most insidious counterfeiting drug crimes involves counterfeit cancer medications because, if the patient dies, no one ever questions whether the patient took fake medicines. In July 2024, the DOJ indicted an Indian national who allegedly sold counterfeit cancer drugs, including Keytruda, to patients in the United States beginning in August 2018.[26] It is unknown how many Americans battling cancer had their treatments compromised due to this bad actor and his co-conspirators, but without the knowledge, training, and resources of federal law enforcement, American cancer patients could still be taking fake oncology drugs and dying from failed treatments..

Counterfeiters have also targeted HIV medications. Gilead Sciences has been fighting a multiple-year battle against two different prescription drug trafficking networks that allegedly sold counterfeit and diverted HIV medication to pharmacies

[24] The Partnership for Safe Medicines, "Re: Docket Nos. USCBP-2025-0002 & USCBP-2025-0003," March 14, 2025 https://safedr.ug/CBPcomment.
[25] The Partnership for Safe Medicines, "Are Pharmacy Benefit Managers' Below-cost Reimbursement Practices Creating Opportunities for Criminals to Enter the Legitimate Supply Chain?" https://safedr.ug/PBM-Below-cost.
[26] U.S. Department of Justice, "Foreign National Charged for Selling Counterfeit Cancer Drugs," July 25, 2024, https://bit.ly/42h4hUN.

across the country.[27] After issuing a public warning in August 2021 about counterfeit versions of Biktarvy and Descovy circulating in the United States, Gilead Sciences filed a civil lawsuit against over 150 individuals and companies for their roles in the first of these prescription drug trafficking schemes.[28] The DOJ charged Lazaro Hernandez and Armando Herrera, alleged kingpins of the first drug trafficking network, with conspiracy to defraud the United States, to introduce into interstate commerce adulterated and misbranded drugs, and to commit money laundering, with both men receiving 15-year and four-year sentences, respectively.[29] Then, in June 2024, Gilead Sciences filed a second civil lawsuit against 33 individuals, companies, and pharmacies in New York City that were allegedly trafficking in counterfeit Gilead HIV drugs.[30] This case is still pending.

Furthermore, Americans engaging in medical tourism, especially with Mexican border pharmacies, put themselves at heightened risk of exposure to counterfeit medicines. Two years ago, American patients received counterfeit versions of Xarelto and Eliquis, two popular blood thinners, at legitimate Mexican pharmacies only to discover the pills contained no active pharmaceutical ingredients at all.[31] Counterfeits specifically targeted American patients by printing packaging labels in English, not Spanish as one would expect in Mexico. Patients who ingested these fake pills faced an increased risk of suffering from blood clots, or developing serious conditions, such as strokes or heart attacks, from failed treatments caused by counterfeit blood thinners.

And, in April 2024, the DOJ launched a federal investigation after multiple patients suffered from botulism-like illnesses from counterfeit Botox injections.[32] Botulism is a rare and potentially fatal illness that attacks the body's central nervous system. In Tennessee, four individuals suffered harm from these counterfeit injections, with two requiring hospitalizations. Similarly in Illinois, health officials reported that victims developed double vision, fatigue, facial drooping, and difficulty breathing.[33] In the end, 17 cases were reported across 9 states, with 13 people hospitalized.

## Ensuring safety for the supply chain

Because of the hard work of Congress, the United States has a traceable drug supply chain by law. Signed into law in 2013, the DSCSA created an electronic, interoperable system that allows anyone operating within the prescription drug supply chain to confirm that the medicine they received is legitimate and provides a reporting framework for medicines they suspect may be counterfeit.

The DSCSA has already played a key role in detecting counterfeit and diverted HIV medicines, helping to unravel a $240mm crime, currently being prosecuted by the DOJ. In November 2024, the DSCSA also played a key role in facilitating the detection of the unit of fake Ozempic found in the Arkansas pharmacy mentioned previously. The product was a "lookalike counterfeit," delivered in a fake box printed specially for it. NABP's Pulse Verification Tool, created in response to DSCSA implementation, immediately detected the drug's counterfeit nature.[34]

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[27] The Partnership for Safe Medicines, "Fake HIV Medication Reached U.S. Pharmacies - and Patients," https://safedr.ug/Fake-HIV-Meds.
[28] Reuters, "Gilead Widens Battle Against Alleged Counterfeit HIV Drug Ring," September 28, 2022, https://bit.ly/41ZdAdf.
[29] Fierce Pharma, "In Fraud Case Targeting HIV Meds, Florida Man Gets 15 Years in Prison," June 21, 2023, https://bit.ly/4iXmDBx; U.S. Department of Justice, "Man Sentenced for Illegally Distributing Over $16M of Adulterated HIV Medication," December 21, 2023, https://bit.ly/42tzupb.
[30] CNBC, "Gilead Sciences Alleges Dangerous Drug-counterfeiting Operation at Two NYC Pharmacies in Lawsuit," August 16, 2024, https://bit.ly/3E8OMqc.
[31] The Partnership for Safe Medicines, "Fake Medicine in Mexican Pharmacies," https://safedr.ug/rxinmexico.
[32] U.S. Centers for Disease Control and Protection, "Harmful Reactions Linked to Counterfeit 'Botox' or Mishandled Botulinum Toxin Injections," December 17, 2024, https://bit.ly/44a1CyU.
[33] The New York Times, "Health Officials Investigating Illnesses from Possible Counterfeit Botox," April 11, 2024, https://bit.ly/3EcqBqJ.
[34] National Association of Boards of Pharmacy, "Pulse," https://bit.ly/4cji169.



*Images of counterfeit Ozempic box, pen, and DSCSA information provided by Arkansas State Board of Pharmacy*

While Congress can be pleased with these early successes, the DSCSA is still in the final stages of its rollout, which is tricky. The FDA has the challenging job of encouraging all supply chain members to comply, without causing artificial drug shortages when technology data transfer doesn't succeed.

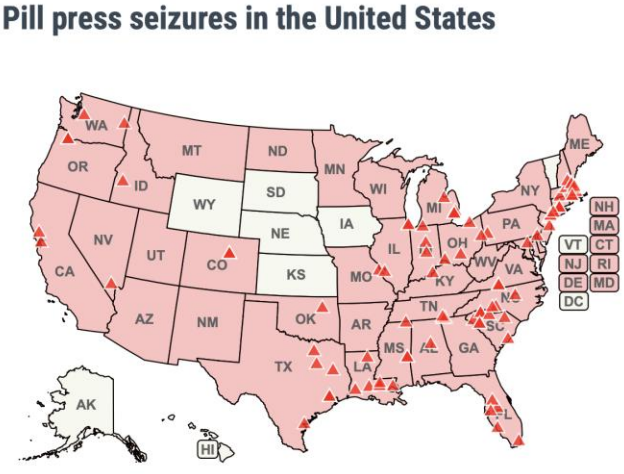
Several counterfeiters have allegedly violated the DSCSA, and the DOJ brought charges against several offenders specifically for these violations. The cases are currently pending, and the industry is awaiting how it will impact the broader community. Congress must continue to support DOJ's efforts to bring criminal counterfeiters to justice when they violate the DSCSA and break the supply chain.

## Ending the fake pill / fentanyl trade

The United States has been fighting the counterfeit fentanyl pill crisis for over a decade. While many counterfeit pills containing fentanyl are produced in Mexico, a significant volume of fake pills are made inside the United States using illegally obtained pill presses. Pill presses have been seized in 42 states since 2016.[35]

Legislation that would help to keep pill presses, an essential tool in the manufacturing of counterfeit pills, out of the hands of criminals could be helpful to deterring criminals from using them. The policy solution is tricky though, as serializing pill presses is a measure that would only be obeyed by law-abiding users, not the criminals themselves.

Resourcing CBP inspectors who can detect these deadly machines as they enter the U.S., and DOJ prosecutors who go after foreign nationals who sell them into the U.S., would be more effective in reducing this illegal trade.




States in pink indicate that law enforcement has found a least one pill press making illicit pills. Click the red triangles for specific seizure incidents, January 2023 through mid-March 2025.

While prosecutions in this area are rare, a long-running operation has resulted in the detention and prosecution (in process today) of a Chinese national for illegal pill press sales into the United States. *See* United States v. Xiaofei Chen.[36]

[35] The Partnership for Safe Medicines, "Illegal pill presses 2021 update," https://www.safemedicines.org/importation-page/illegal-pill-presses-2021-update

[36] The Partnership for Safe Medicines, "Case overview: US v Xiaofei Chen," https://www.safemedicines.org/2025/01/usa-v-chen-pill-press.html

## PSM Policy Recommendations

As the Committee works to secure America from foreign dependence and criminal adversaries and to reinforce **America First** policies that heighten our **pharmaceutical border security**, PSM urges you to keep in mind the following policy recommendations:

- **Ensuring U.S. pharmaceutical border security by continuing to support the Drug Supply Chain Security Act (DSCSA) by:**
  - Supporting FDA in its DSCSA implementation efforts;
  - Supporting enforcement efforts, such as the FDA's Office of Criminal Investigations and Homeland Security Investigations, to develop cases to prosecute those breaking the supply chain and endangering Americans with misbranded and counterfeit medicines; and,
  - Ensuring the DOJ brings supply-chain-specific criminal charges to deter violations of the DSCSA.

- **Enhancing U.S. pharmaceutical border security through customs reform, including:**
  - Mandating Advanced Electronic Data (AED) for de minimis packages and providing CBP with the upgraded technology resources to effectively use AED to better identify dangerous fake medical products before they enter our borders; and
  - Ensuring that FDA and CBP have sufficient resources and coordination to stop larger freight shipments that fail basic safety checks.

- **Reauthorizing the Office of National Drug Control Policy (ONDCP) and the High Intensity Drug Trafficking Area (HIDTA) Programs** to combat the growing threats posed by drug trafficking.

- **Increasing law enforcement funding** to combat counterfeit medicines by hiring and training more specialized personnel, investing in advanced investigative technologies, and conducting more comprehensive operations to dismantle counterfeit drug networks.

- **Imposing harsher penalties for counterfeit drug offenses** on individuals and organizations involved in the manufacture, distribution, and sale of counterfeit medicines.

- **Encouraging prosecution of unlicensed online pharmacies** that sell non-FDA-approved medication to Americans.
  - Prioritizing the prosecution of individuals selling "research grade" GLP-1s and other unapproved medicines to Americans a priority, as 38 state and territorial Attorneys General recommended to the FDA.
  - Encouraging DOJ to prioritize prosecution of criminals who break the safe and secure prescription drug supply chain.

- **Encouraging the FDA to supervise the conclusion of the GLP-1 shortage** and sanctioning entities that compound without legal authority. This is key to restoring safety in the GLP-1 drug supply.

- **Passing comprehensive PBM Reform** to restore security to the U.S. prescription drug supply chain.

- **Holding e-commerce marketplaces, fake online pharmacies, and social media platforms accountable** for failing to prevent criminals from using their platforms to sell illegal and illicit substances and counterfeit medicines.
  - Requiring platforms to obey a minimum standard of compliance and to work with brand protection teams, or to properly enforce their own terms of services, which prohibit sales of pharmaceuticals - legitimate and counterfeit alike - on their platforms.

  - Swiftly passing the Cooper Davis Devin Norring Act, which would provide a safe harbor for social media platforms when they report drug dealers using their platforms to peddle fake pills to our communities.

- **Take steps to address illegal sale of therapeutic counterfeits on social media**
  - Amending 18 U.S. Code § 2320 to include offers for sale on social media sites as criminal aiding and abetting the trafficking in counterfeits.
  - Waiving Section 230 protections for social media platforms that fail to adhere to reasonable standards to prevent the sale and offer of counterfeit prescription drugs, thereby exposing those platforms to trademark liability in cases brought by brand owners.
  - Requiring social media platforms - especially those with online marketplaces - to search for and act on their own against offerors/sellers of illicit, misbranded, adulterated, counterfeit or otherwise unsafe medicines.
  - Requiring social media platforms to disclose traceable and verifiable information on an offeror/seller of counterfeit medicines to brand protection teams, law enforcement agencies, and other platforms.
  - Instituting an escalating penalty regime based on the number of violations by a platform.