



Anti-Counterfeiting & Patient Safety

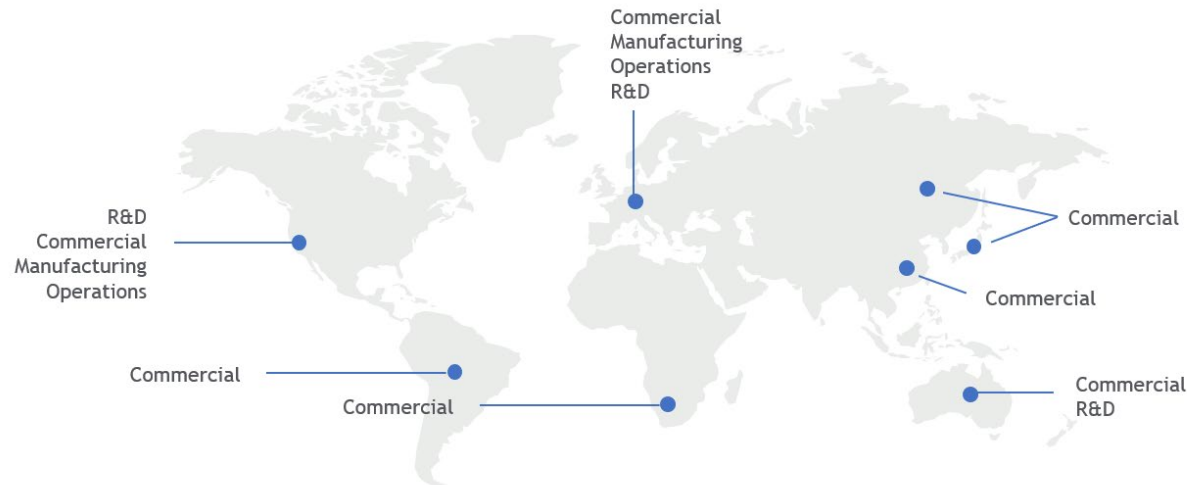
Lori Mayall (Consumer Protection Lawyer)

Head of Anti-Counterfeiting/Global Product Security, Gilead Sciences, Inc.



Gilead Sciences, Inc.

We are a research-based biopharmaceutical company that discovers, develops, and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases.



18,000+ employees, 35+ countries, one shared purpose:

To create a healthier world for all people.



Millions of Healthier Lives

Throughout our history, we have been at the forefront of tackling some of the world's greatest public health challenges, from **HIV** and **viral hepatitis** to **cancer** and **COVID-19**. Through our pioneering access and health equity programs, we have made our medicines available to millions of people to improve the health of communities around the world.



Counterfeits and Other Illicitly Traded Medicines Are A Danger to Patients & Global Public Health

- Counterfeits are intentionally designed to look like genuine medicine, often replicating the packaging, branding, and even the physical appearance of authentic products.
- False representations are used to deceive buyers and patients into believing that the counterfeits and other illegally traded medicines are just like the original and that they are safe and effective.
- These illicitly traded medicines may cause serious and/or life-threatening health risks for patients, as they often do not contain the correct medicine or the correct amount of active ingredient and may contain impurities.
- Their proliferation can contribute to the emergence of drug resistance, exacerbate outbreaks of infectious diseases, and undermine efforts to control epidemics.



A trademark owner is uniquely positioned to stop counterfeiting

U.S. Trademark Act (Lanham Act) 15 U.S. § 1116 (d):

CIVIL ACTIONS ARISING OUT OF USE OF COUNTERFEIT MARKS

(A) In the case of a civil action arising under [section 1114\(1\)\(a\) of this title](#) or [section 220506 of title 36](#) with respect to a violation that consists of using a [counterfeit mark](#) in connection with the sale, offering for sale, or distribution of goods or services, the court may, upon ex parte application, grant an order under subsection (a) of this section pursuant to this subsection providing for the seizure of goods and [counterfeit marks](#) involved in such violation and the means of making such [marks](#), and records documenting the manufacture, sale, or receipt of things involved in such violation.

Joint Statement on *Ex Parte* Seizures Under the Lanham Act

The purpose of the ex parte seizure provision is to provide victims of trademark counterfeiting with a means of ensuring that the courts are able to exercise their jurisdiction effectively in counterfeiting cases. Testimony before both the House and Senate Judiciary Committees established that many of those who deal in counterfeits make it a practice to destroy or transfer counterfeit merchandise when a day in court is on the horizon. The ex parte seizure procedure is intended to thwart this bad faith tactic, while ensuring ample procedural protections for persons against whom such orders are issued. In essence, both the Senate and House bills permitted issuance of an ex parte seizure order if the applicant could show that the defendant would not comply with a lesser court order, such as a temporary restraining order, and that there was no means of protecting the court's authority other than to seize the property in question on an ex parte basis.



Civil Enforcement - Benefits

▶ **Protect Your Customers**

▶ **Protect Your Brands**

▶ **Protect Your Businesses**

▶ **Deter Future Counterfeiters**

▶ **Collect Damages**



Ex Parte Seizure Orders

Locks and vaults may be forcibly opened.
People interfering with seizure may be arrested

Locations:



Offices



Homes



Trucks



Cars



Warehouses

People to Be Present:



Law enforcement



Private investigators



Computer technicians



Locksmiths



Lawyers

Things to Be Seized:



Products



Packaging/manufacturing machinery



Documents



Computers



Mobile phones



Asset Freeze Order



▶ Freezes Defendants' bank accounts

▶ Can be directed to banks worldwide

▶ Preserves Defendants' profits from sale of counterfeits for the benefit of the Plaintiff



U.S. Product Complaints Linked to Licensed Secondary Distributors



Patient reported consuming one tablet of an antipsychotic in bottle of BIKTARVY® and reported being unable to walk or talk for a short time.



◆ WSJ NEWS EXCLUSIVE | HEALTH

Drugmaker Gilead Alleges Counterfeiting Ring Sold Its HIV Drugs

Gilead says HIV drugs were replaced in some cases with an antipsychotic drug or an over-the-counter painkiller



The Gilead Sciences headquarters in Foster City, Calif.
PHOTO: JASON HENRY FOR THE WALL STREET JOURNAL

Company Statements

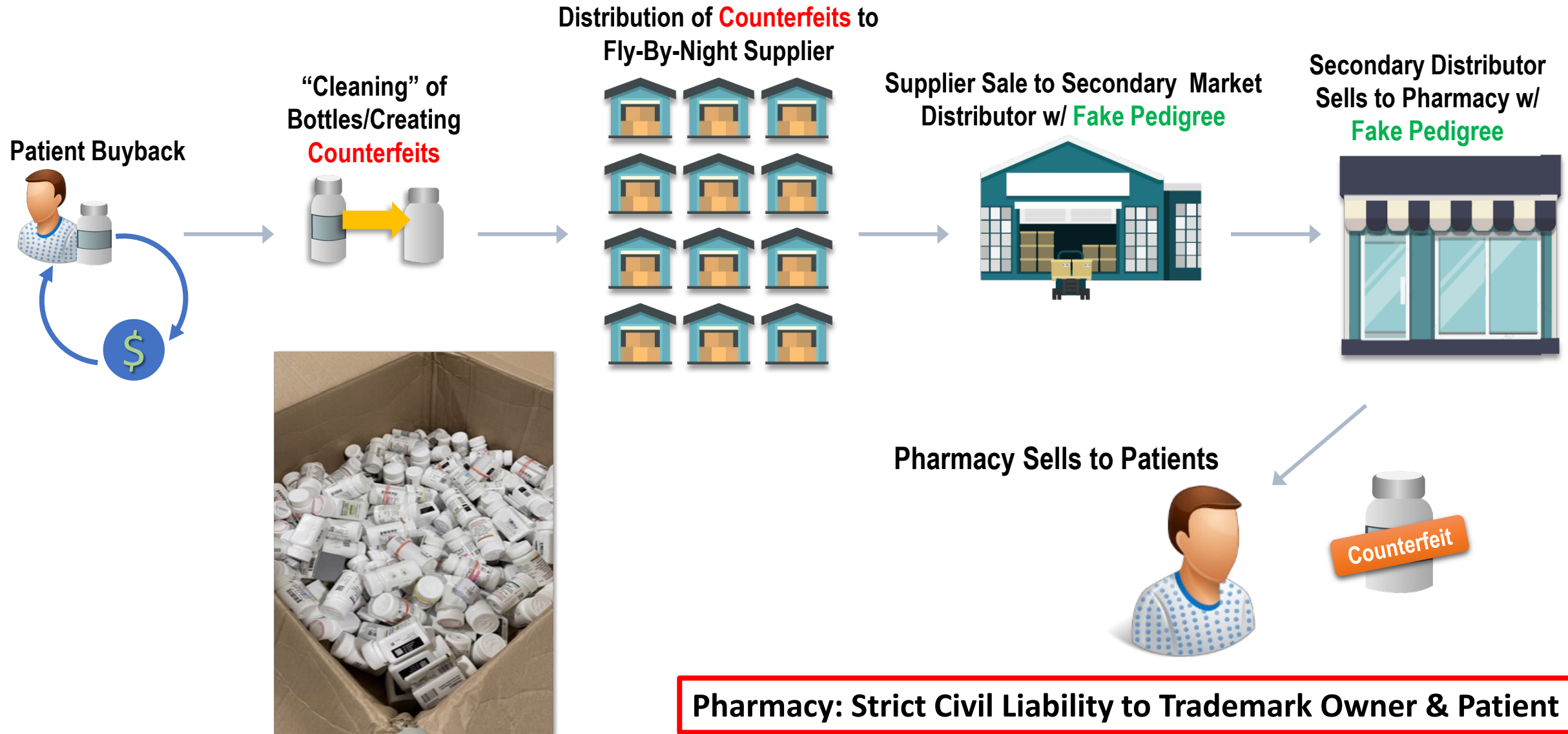
Gilead Announces Actions to Remove Counterfeit HIV Medications from U.S. Supply Chain

Foster City, Calif., January 19, 2022 – Gilead Sciences announced today that the company has taken action to protect the health and safety of the public from an expansive, criminal counterfeiting network responsible for distributing counterfeit and tampered Gilead HIV medication within the U.S. supply chain. As part of an ongoing investigation and litigation, in coordination with the U.S. Marshals and local law enforcement, Gilead has executed seizures at 17 locations in eight states, seizing thousands of bottles of Gilead-labeled medication with counterfeit supply chain documentation, including bottles labeled as the HIV medicines Biktarvy[®] (bictegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg tablets) and Descovy[®] (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets). Gilead continues to work closely with the U.S. Food and Drug Administration (FDA) and law enforcement to remove counterfeit and tampered medication from circulation and to prevent future distribution of counterfeit medications.

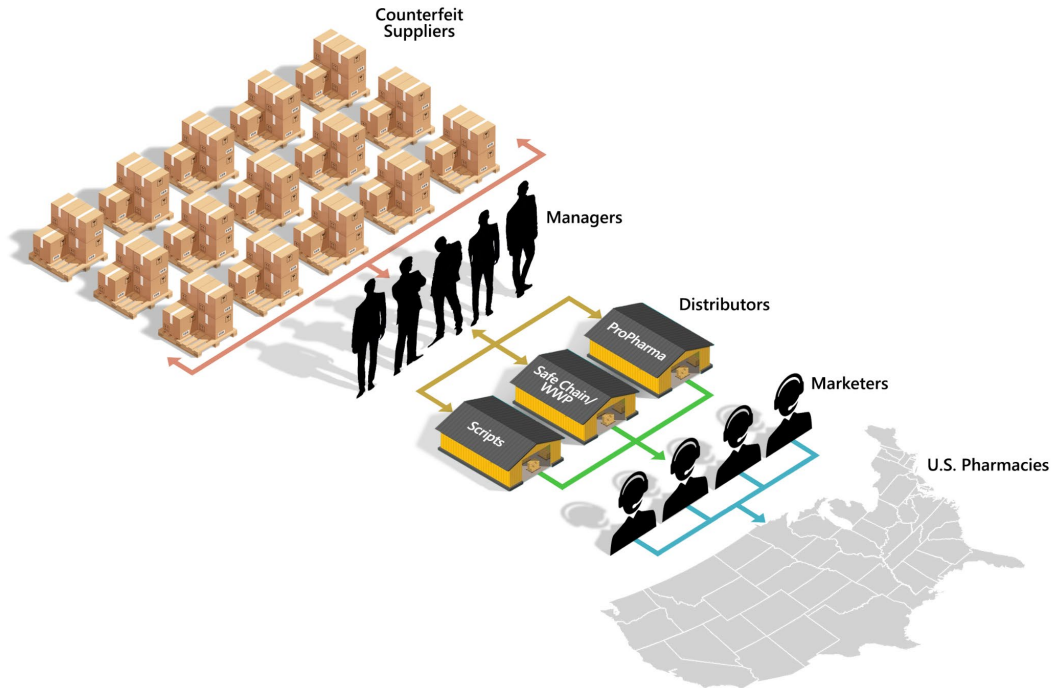
By [Joseph Walker](#) and [Corinne Ramey](#)
Jan. 18, 2022 12:21 pm ET



The Illicit Scheme Infiltrating the Legitimate Supply Chain



Gilead's Enforcement Action Has Immediate Impact



- Executed 26 no-notice seizures
- Stopped a multimillion-dollar complex criminal network selling counterfeits.
- Seized > 4000 illicit bottles
- Over 160 defendants, including some pharmacies
- Every counterfeiter has been enjoined from buying or selling any Gilead products
- Gilead has frozen bank accounts and real estate from dozens of counterfeiters
- Many arrested for their involvement in the scheme, with two already serving time in prison
- Gilead is continuing to work with the Department of Justice, which has a task force dedicated to the scheme and plans to bring many more indictments

Patients and the legitimate supply chain are still vulnerable to the underlying scheme.



Seized Documents

And then earlier in the week [REDACTED], that new wholesaler that [REDACTED] brought on, gave us some fake pedigrees

Just lovely

It just seems too coincidental

That's what happens when you get in bed with shady people

Adam brings such sketchy situations to the table

greedy

Yeah I think that is what it is too

Going to get ourself sued

Seems like it



Seized Documents

Did we get any [REDACTED] news?

All of their shit is counterfeit

Should have inventory today



Civil Enforcement Can Speed Up Prosecution

PHARMA

In fraud case targeting HIV meds, Florida man gets 15 years in prison

By Zoey Becker · Jun 21, 2023 8:50am

Gilead Sciences

HIV

Fraud

Florida



The defendant will also have to make restitution payments. (NiseriN/iStock/Getty Images Plus)

A year after a Florida man was arrested for his alleged involvement in a nationwide scheme to distribute fake HIV medicines, a U.S. district judge has ordered the man to serve 15 years in prison.

PRESS RELEASE

Man Sentenced for Illegally Distributing Over \$16M of Adulterated HIV Medication

Thursday, December 21, 2023

Share >

For Immediate Release

Office of Public Affairs

A Florida man was sentenced today to four years and three months in prison for his role in a nationwide scheme to illegally distribute at least \$16.7 million of adulterated HIV drugs that were ultimately dispensed to unsuspecting patients throughout the country.

According to court documents, Armando Herrera, 43, of Miami, and his co-conspirators established companies in Florida, Texas, Washington, and California, which they used to sell and distribute adulterated prescription drugs, primarily HIV medications, to wholesale pharmaceutical suppliers. Herrera and his co-conspirators created false documentation to make it appear as though the drugs were acquired legitimately when, in fact, they were not. The pharmaceutical suppliers then sold the drugs to pharmacies, which dispensed the adulterated



Civil Enforcement Can Speed Up Prosecution

PRESS RELEASE

Leader Of Black-Market HIV Medication Fraud Scheme Sentenced to Nine Years In Prison

Wednesday, April 17, 2024

Share



For Immediate Release

U.S. Attorney's Office, Southern District of New York

Boris Aminov Was Additionally Ordered to Pay More Than \$13 Million in Restitution

Damian Williams, the United States Attorney for the Southern District of New York, announced that BORIS AMINOV was sentenced today to nine years in prison for engaging in a years-long scheme that exploited vulnerable HIV patients and defrauded Medicaid, Medicare, and private insurance companies out of at least \$20 million. AMINOV previously pled guilty to one count of conspiracy to commit health care fraud before U.S. District Judge Mary Kay Vyskocil, who imposed today's sentence.

U.S. Attorney Damian Williams said: "Boris Aminov orchestrated a scheme to get rich by lying to Medicaid, Medicare, and private insurance companies and by depriving vulnerable HIV patients of legitimate and safe medications."



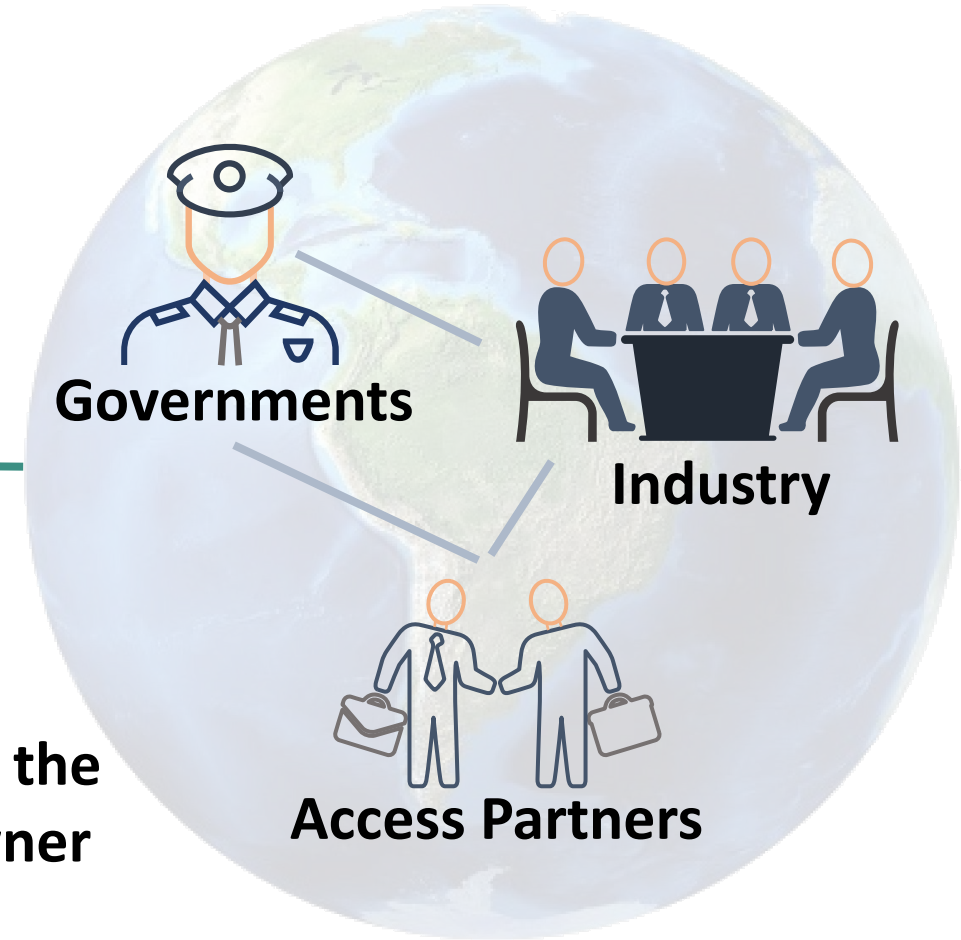
A Shared Responsibility

Ensuring patients receive safe and quality medicine is a responsibility that must be shared by all in the supply chain

The manufacturer can be an effective leader and collaboration partner



The manufacturer has unique knowledge about the product and unique rights as the trademark owner





CNBC INVESTIGATIONS

Fraud in a bottle: How Big Pharma takes on criminals who make millions off counterfeit drugs

PUBLISHED MON, DEC 11 2023 9:00 AM EST



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WATCH LIVE



For a more in-depth overview of the criminal scheme and our work, please check out CNBC's piece.

Thank you!

KEY POINTS

- Counterfeiting lifesaving medications is a lucrative criminal enterprise, part of a \$431 billion worldwide fraud, according to an estimate from the World Health Organization.

