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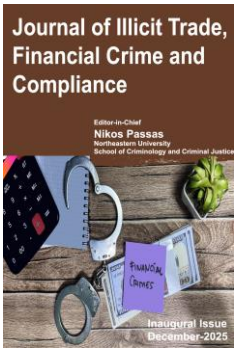

Leveraging the Lanham Act for Anti-Counterfeiting: A Case Study of Gilead Sciences' Successful Civil-to-Criminal Enforcement Strategy in the U.S. Pharmaceutical Market

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ABSTRACT

Over the past five years, Gilead Sciences has used civil enforcement of the Lanham Act, which governs United States trademark law, to stop counterfeiters slipping fake and adulterated HIV medicines into the legitimate drug supply chain. Subsequently, Gilead referred evidence gathered during civil litigation to criminal investigators. This approach led to the fast dismantling of a counterfeit drug operation, effective civil penalties, and the prosecution of bad actors engaging in the distribution of adulterated medicine, forgery, fraud and money laundering. The effective use of Lanham Act civil actions to support criminal prosecutions creates a civil-to-criminal pipeline of counterfeit enforcement. This is a novel model that should be replicated by other healthcare industries in the U.S. and in other countries that have legal frameworks to enable it. By analyzing Gilead's efforts in this arena, we show these acts have protected patient safety. We believe other pharmaceutical manufacturers have a public health imperative to implement it.

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1. Introduction

Criminals have used the U.S. pharmaceutical distribution system to introduce black market medicines into the U.S. supply chain for decades: in 2012, for example, federal attorneys in Manhattan prosecuted a ring that collected medicine from Medicaid patients in New York and redistributed the second-hand pills with false paperwork to legitimate pharmacies via wholesale prescription drug distributors [1]. Stopping schemes like this one, which exposed vulnerable patients to compromised medicines and cost New York's Medicaid program an estimated $500 million, is critical to protect patients and public funds. However, these investigations are often prohibitively resource intensive for law enforcement, who have to balance many priorities. Even when law enforcement is able to prioritize cases like these, it's slow work. The 2012 case required a lengthy investigation that involved the FBI and U.S. Attorney's offices in six states. While that played out, suspects continued to distribute unsafe medicine and defraud Medicaid.

Response was similarly delayed in a different drug counterfeiting case, *USA v Maksym Nienadov and Volodymyr Nikolaienko*. In June 2018, Homeland Security Investigations agents made undercover buys of counterfeit cancer and hepatitis treatments, including the Merck & Co. drug Keytruda, from Ukrainian nationals who had already been shipping counterfeit treatments to the U.S. for three years. Authorities were not able to disrupt the operation until they arrested the men when they travelled to the U.S. in April 2019; sentencing didn't happen until almost two years later [2, 3].

A private model, however, has emerged to quickly halt dangerous black market operations before law enforcement builds criminal cases. Pharmaceutical brand protection teams, who are solely focused on preserving the safety and security of their medicines and patients, have performed in-depth investigations of counterfeiting schemes they have identified, filed civil *Lanham Act* [4] complaints against the main actors, and used *Lanham Act* provisions to shut down counterfeiting activity immediately.

The core of these cases of diverted and counterfeit medicine rests on the "material difference" exception: the *Lanham Act* prevents trademark holders from enforcing rights after they have sold a product, but they can take action against unauthorized sellers if trademarked items they are selling have changed in an important way. A trademark holder could sue a seller for selling secondhand batteries, for example, because buyers confused by their shorter lifespan could come away with a poor impression of the manufacturer's products [5].

Since 2015, drugmakers have used this approach to suppress the U.S. sale of counterfeit and non-FDA approved glucose test strips [6, 7], as well as counterfeit and unapproved sutures sold by a company in Illinois [8]. Dismantling consumer fraud enterprises with civil litigation is a public good for the goal of patient safety in their own right.

Most recently, brand protection team investigators have jumpstarted criminal prosecutions by sharing their findings with U.S. attorneys after successfully halting counterfeiting operations in civil court. This novel approach allows brand investigators to identify black market schemes for law enforcement, validates consumer harm in advance of a public investigation, and leverages both public and private resources to protect patients against dangerous medicines. While one may debate the balance of work or cost between public and private interests in this model, an effective civil-to-criminal pipeline can improve medicine safety for all patients.

2. Case Studies

2.1. Gilead Sciences v Safe Chain Solutions, *et al*.: Halting a Domestic Drug Counterfeiting Scheme

The Partnership for Safe Medicines first became aware of this model after the Wall Street Journal published a story [9] about a July 2021 counterfeit incident with Gilead Sciences' HIV medicines. In the complaint, Gilead Sciences sought an injunction against a network of drug sellers and distributors that sold licensed U.S. pharmacies over 85,000 counterfeit bottles of Gilead-branded HIV medicine [10]. If the medicines had been legitimate, they would have been worth more than $250 million [9].

By September 2022, Gilead's named defendants had expanded to more than 140 individuals and companies involved in an operation that closely resembled the New York case a decade earlier: Florida-based "kingpins" had led a 13-state operation in which teams of people purchased (sometimes empty) bottles of HIV medication from patients; removed patient labels and refilled the empty bottles with whatever was on hand, including antipsychotics or even pebbles; funneled them to distributors who sold them to pharmacies across the country; and laundered the profits [11]. Figure **1** shows the geographic scope of this scheme. Although we have focused on Gilead's civil suit in this article, Johnson & Johnson filed a suit addressing the parallel activity by some of the same defendants in April 2022 [12].

Many pharmacies were taken in by this scheme. They might have questioned the discounts on the medicines they'd purchased, but they were selling patients sealed bottles that looked almost exactly like carefully packaged, legitimate Gilead products. There was no reason for pharmacists to question the contents of those bottles unless patients complained about the medicine inside them. Because the bottles were manufactured to be dispensed as sealed to a patient, pharmacists could not even open them to check the contents without compromising the products' sterility.

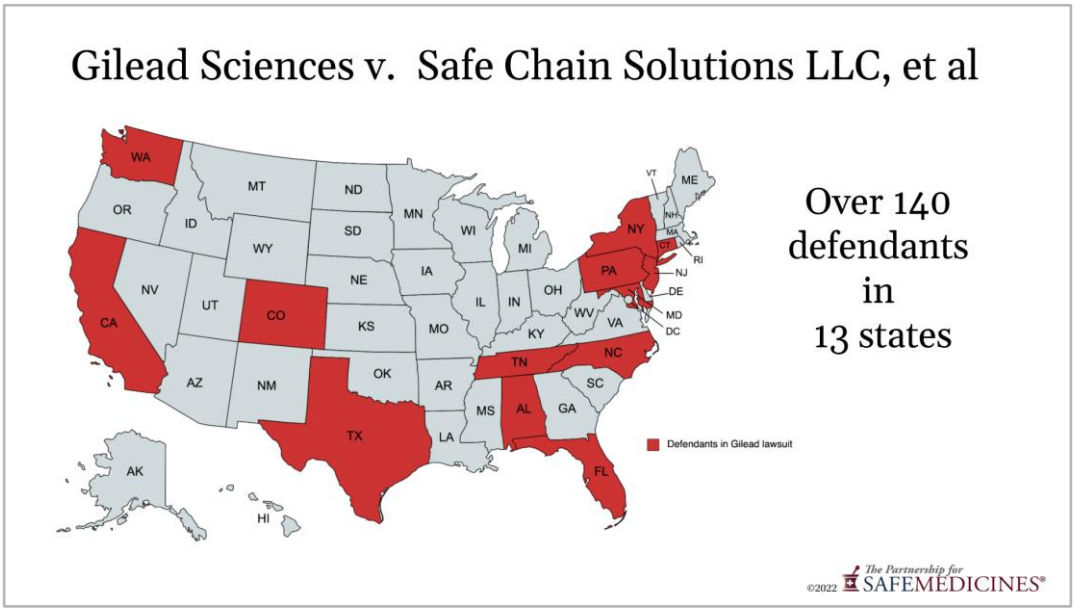

Figure 1: States in which the defendants operated according to court documents filed in *Gilead Sciences v Safe Chain Solutions*. (Image by The Partnership for Safe Medicines).

Because the medicine and packaging is trademarked by Gilead, Gilead was able to leverage the *Lanham Act*, which governs trademark law in the United States, to stop the operation. The company argued that defendants were selling their medicines secondhand, with no assurance of quality control, and with falsified pedigrees, and therefore engaging in trademark infringement that directly harmed its reputation for safe, reliable and effective medicine:

> For the distributors, pharmacies, and patients that buy Gilead's HIV medications, authentic pedigrees that accurately disclose the original sale of the product are an important feature of Gilead's products that guarantee the medication's authenticity and safety. Bottles of Gilead medication that have fake or altered pedigrees, such as those that do not list Gilead's original, authentic sale of the medication, are materially different from authentic Gilead product as Gilead sells it in U.S. commerce [10].

Substituting other medicine for genuine Gilead Sciences HIV treatment medicines was even more appalling than forging the supply chain sourcing paperwork, and an indisputable threat to patient safety.

The approach was fast and effective. PACER, the U.S. federal government's database for court documents, shows that Gilead asked for a temporary restraining order on July 22, 2021, the same day it filed its initial complaint. The following day a judge granted the company a seizure order and froze the assets of the defendants. The first preliminary injunction against Maryland-based Safe Chain Solutions was in place within a week, by July 29 [13].

The *Lanham Act* legally halted dangerous diversion activity as Gilead negotiated settlements with hundreds of defendants. It was also an effective deterrent against infringement, as courts can award trademark owners up to three times the amount of their actual damages. Safe Chain Solutions, for example, ultimately paid $2.7 million in damages to Gilead, and received a permanent injunction preventing it from "importing, purchasing, selling, distributing, marketing, or otherwise using in commerce in the United States any Gilead products" [14].

2.1.1. Subsequent Federal Cases Involving People Named in Gilead Sciences' July 2021 Complaint

A review of Gilead's civil complaints, PACER searches to identify subsequent criminal prosecutions, and careful tracking of those cases shows that their strategy has been a success. Defendants named in *USA v Safe Chain Solutions* have been charged in five related criminal cases as of November 2025. Four pleaded guilty and two were convicted by jury. Three have been cumulatively sentenced to more than 24 years in prison and will pay almost $300 million in forfeitures. Three defendants have not yet been sentenced, and the case against one is still pending.

1. *USA v Lazaro Hernandez:* Lazaro Roberto Hernandez, who Gilead characterized as a kingpin of the black market ring, received a 15-year federal prison sentence after admitting to "running a criminal enterprise" and diverting medicines [15]. He was also required to pay $238.8 million in restitution [16].
2. *USA v Armando Herrera:* Another "kingpin," Armando Herrera, received a 51-month sentence for introducing adulterated and misbranded drugs into interstate commerce [17].
3. *USA v Dhruv Ralhan:* Florida resident and Lazaro Hernandez co-conspirator Dhruv Ralhan was charged with the introduction of misbranded drugs and pleaded guilty in June 2023 [18]. He has not been sentenced.
4. *USA v Adam Brosius, Patrick Boyd and Charles Boyd:* A jury in the Southern District of Florida indicted Safe Chain Solution owners, Adam Brosius, Patrick Boyd and Charles Boyd, with charges related to distributing misbranded and adulterated drugs, trafficking medicine products with false documentation, and wire fraud in 2024 [19]. Brosius pleaded guilty to wire fraud in April 2025 [20]. The Boyd brothers were convicted by jury of conspiracy to introduce adulterated and misbranded drugs to defraud the United States, conspiracy to traffic in medical products with false documentation, and conspiracy to commit wire fraud in October 2025 [21]. At the time of writing, Brosius had received an eight-year sentence [22]. The Boyd brothers await sentencing.
5. *USA v Steven Diamantstein:* Scripts Wholesale owner Steven Diamantstein was indicted in New Jersey federal court in 2023 for allegedly acquiring unapproved, diverted prescription medicines and fraudulently selling to pharmacies with falsified pedigrees and labels to make them look like legitimate drugs [23]. This case is still in progress.

In addition, Christy Corvalan, the owner of Laconia Avenue Pharmacy in the Bronx, New York, which was named in *Gilead Sciences v Safe Chain,* was named in a follow-up suit, *Gilead Sciences v Khaim, et al.* Corvalan was criminally charged along with nine other defendants in *USA v Boris Aminov, et al.* [24]. She pleaded guilty to conspiracy to commit healthcare fraud, and received a nine-year prison sentence, ultimately being ordered to pay $21.3 million in restitution [25].

2.1.2. Beyond Medicine Trafficking: Fly-by-night Distributors and Money Launderers

This case involved more than trademark violations and the distribution of unsafe medicines. Figure **2** summarizes the scheme, which required conspirators to form fraudulent "supplier" companies to launder the second hand drugs on their way from bottle "collectors" to "licensed distributors" that could legally sell to pharmacies. It also required "asset holders" to launder sales revenue, as well as a team of "marketers" to persuade pharmacies to buy the steeply discounted drugs.

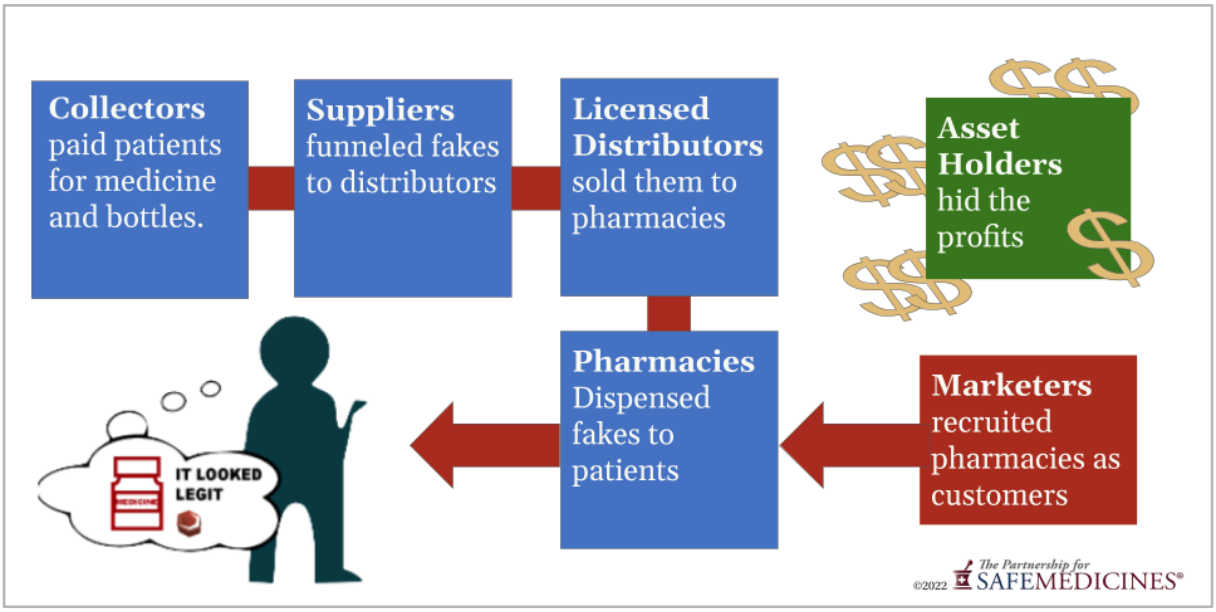

Figure 2: Gilead's October 14, 2021 Memorandum of Law described the roles of various groups inside the counterfeiting operation. (Image by The Partnership for Safe Medicines).

The *Safe Chain* investigation turned up 18 "supplier" companies and 25 individuals that laundered medicine and 22 "asset holder" businesses managed by 17 individuals in five states to launder the profits [13].

Many of the "asset holder" defendants were running shell companies that only existed on paper. Gilead alleged that one example, a Florida-based equipment company, conducted no business at all, but received over $5 million in proceeds from Abacus Distributors, a "supplier" that sprang up in 2019 to sell more than 5,500 bottles of counterfeit HIV medicines to another distributor [11].

Another group of defendants named in *Safe Chain* was indicted in the Southern District of Florida for running an unlicensed money transmitting business [26]. According to Gilead, their activity included hiding tens of millions of dollars of "supplier" profits by buying cellphones and reselling them in Colombia [11].

In their second suit, *Gilead Sciences v Khaim*, Gilead named Boris Aminov, as an "off the books principal" of 15 shell companies used to launder funds from counterfeit medicine distribution [27]. A letter making the government's case for Aminov's sentencing in a subsequent criminal prosecution shared WhatsApp messages in which he listed these companies for a pharmacy owner who owed him payment (Figure **3**) [28].

2.2. Gilead Sciences v Meritain Health, *et al*.: Disrupting the Importation of Unregulated Medicines

On December 10, 2024, Gilead Sciences filed a complaint asking Maryland federal courts to stop a network of health benefits companies that were allegedly supplying patients with non-FDA approved, imported versions of Gilead's medicines via alternative funding programs (AFPs). Gilead learned about the scheme when an insured patient received medicine mailed from a Turkish retail pharmacy. A pharmacy benefit manager had diverted the patient's HIV prescription through a series of companies, ultimately landing with a broker that contracted with foreign pharmacies selling non-FDA approved drugs. The product was only labeled in Turkish, and the patient had no idea whether he had received legitimate medicine. Gilead argued that the defendants were "selling infringing, materially different, and illegally imported medicines that violate[d] Gilead's quality-control efforts," fundamentally threatening U.S. patients, and particularly HIV patients, who rely on effective medication to keep them alive [29].

As with the Safe Chain suit, response was rapid: A federal judge in Maryland issued a temporary restraining order (TRO) on December 13 and scheduled a "show cause" hearing for January 22, 2025 [30]. When Gilead expanded the complaint to add CanaRx, ElectRx, ScriptSourcing, LLC, and related individuals and corporations on October 15, 2025, an injunction was issued on October 31 [31].

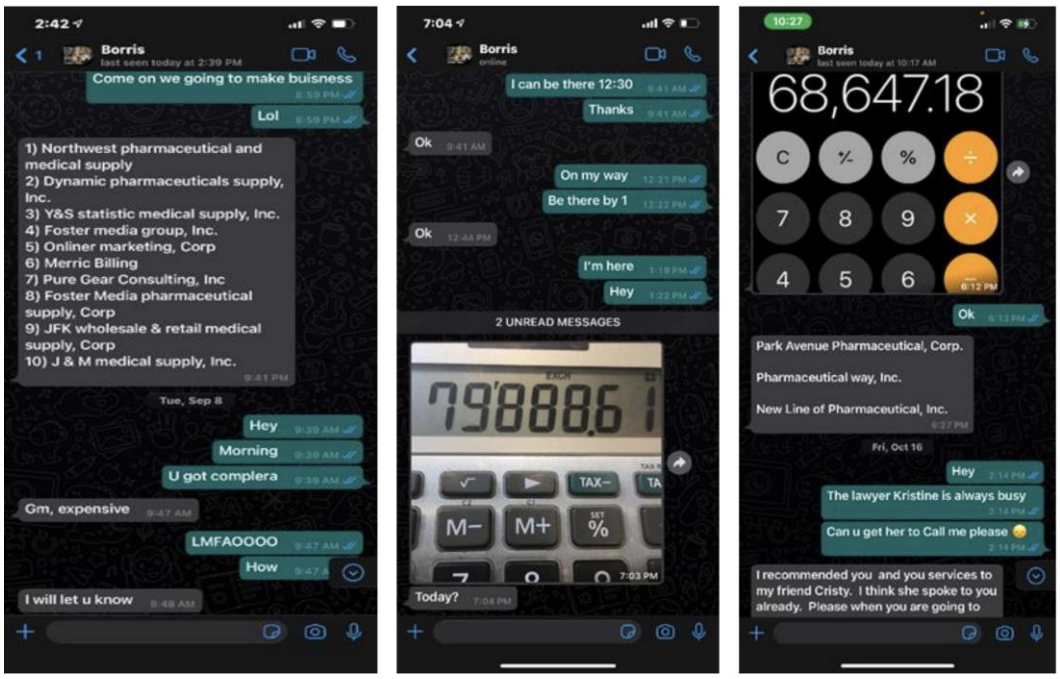

Figure 3: WhatApp messages listing companies Aminov set up to launder funds (Source: U.S. Attorney of the Southern District of New York).

It is too early to know whether this case will also fuel federal prosecutions. However, a June 2025 opinion upholding a preliminary injunction against the initial defendants—Meritain Health, ProAct Inc., Gregory Santulli, Rx Valet, Advanced Pharmacy, and Affordable Rx Meds—asserted that sourcing international medicines through AFPs violated the Food, Drug, and Cosmetic Act because the imported drugs are misbranded. The judge wrote that defendants could not complain that they would "suffer business hardship" if the court interrupted them from illegal practices [32]. The defendants are appealing that ruling in the Fourth Circuit Court of Appeals [30].

Facilitating a drug importation scheme as an insurance practice for multiple patients is not the same as personal importation, which also isn't legal [33]. Whether federal authorities choose to prosecute them, and how many players in these operations, is an open question. A successful civil prosecution will certainly be a factor in their decision to do so.

3. Discussion

In every industry across the globe, anticounterfeiting teams are hard at work protecting customers and their companies from fake versions of their products. Their enforcement covers a variety of activities:

- Investigating counterfeit production and distribution, including test buys online and offline.
- Working with domain name registrars, ecommerce companies, social media networks, and other online platforms to shut down counterfeit sellers.
- Supporting outside counsel in pursuit of civil litigation.
- Conducting preliminary investigation and preparing cases to refer to law enforcement.
- Working with law enforcement and prosecutors to support criminal prosecutions by providing product testing and witness testimony.
- Training customs staff to identify counterfeits and work with anticounterfeiting teams.
- Helping countries with weak oversight to strengthen regulatory systems.
- Building and refining packaging to make counterfeiting more difficult.

- Working with operations to shape the product distribution supply chain to minimize chances for counterfeiting and diversion.

Gilead's recent civil enforcement efforts represent some of the broadest and most effective uses of trademark infringement to protect American patients by a non-state actor. It isn't unusual for corporate anticounterfeiting teams investigating and filing suit over trademark violations to uncover evidence which law enforcement can leverage to pursue criminal charges. It is, however, novel for a team's discovery of hundreds of millions of dollars of wrongdoing to culminate in sprawling legal enforcement in both the civil and criminal sphere.

One of the reasons for this is the cost. In *Gilead v Safe Chain Solutions*, Gilead, their outside counsel Patterson Belknap Webb and Tyler (PBWT), and their private investigators had to unravel the mechanics of the scheme [34] as Gilead funded the investigation, not only to learn how it worked, but to identify the full scope of criminal activity. This included identifying ringleaders who practiced significant operational security to obscure their identities and were unknown to many of the defendants. The final civil suit included over 140 defendants; a massive number of individuals were involved in the scheme.

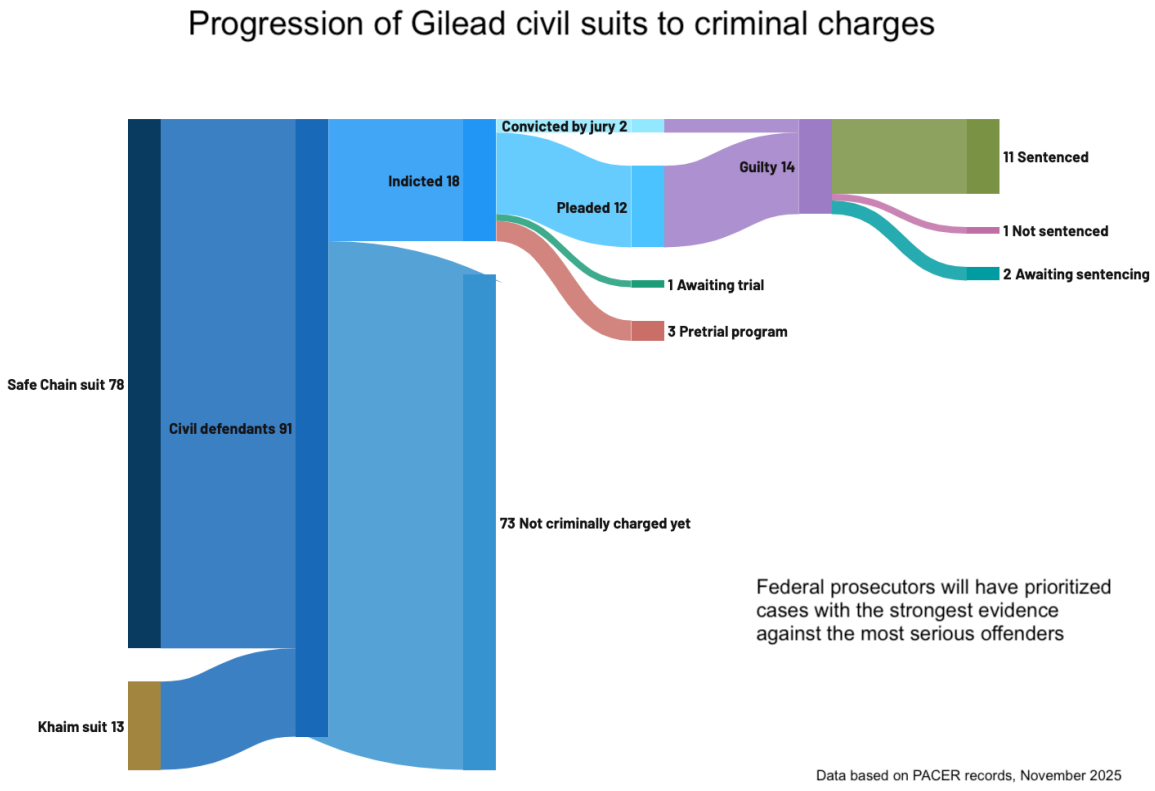

Figure 4: PACER data shows the legal flow from 91 individual defendants in Gilead's *Safe Chain* and *Khaim* suits to criminal prosecutions. (Image: The Partnership for Safe Medicines).

After defining the breadth of the operation, Gilead was faced with adjudicating civil charges against hundreds of defendants (Figure **4**). Extensive pre-trial discovery obtained through powers granted by the *Lanham Act* allowed PBWT to mount strong cases with impressive results. Drug diverters and counterfeiters today may avoid Gilead products in the same way that some criminals avoid counterfeiting controlled substances because the penalties are higher than when counterfeiting non-controlled therapeutic medicines.

3.1. Civil Enforcement is a Strong Tool to Stop Patient Endangerment and can Influence Sentencing in Criminal Prosecutions

In a societal context where counterfeit drug trafficking is not consistently prosecuted, the *Lanham Act*'s civil penalties are a strong tool for pharmaceutical manufacturers seeking to stop the distribution of medicine that

endangers patients. Whether or not defendants deliberately violated trademark holders' rights, courts can enforce injunctions to shut down illegitimate sales [35] and award damages to the plaintiff [36]. If the court finds that the defendant was intentionally infringing the trademark, the plaintiff is entitled to triple the defendant's profits or the plaintiff's damages, as well as an attorney's fee. The court can approve statutory damages as high as $2,000,000 per counterfeit mark per type of goods or services, which can be ruinous to bad actors.

Historically, U.S. sentences for non-controlled substance counterfeiting have not been proportionate to the crime: drug counterfeiters face short sentences even though the fake medicines they are selling can harm or even kill patients [37]. The recent sentencing of Adam Brosius may indicate a new trend. Even after pleading guilty and agreeing to work with the Department of Justice against his co-conspirators, Charles and Patrick Boyd, he still received a total sentence of eight years [22]. The size of that sentence, and the future sentences Charles and Patrick Boyd may receive, will have been buttressed by the thorough investigative history created by Gilead's civil action, which included emails, depositions, and other evidence that not only established their guilt, but the knowing intent that qualifies them for higher sentences.

3.2. Drug Supply Chain Reform in the U.S. has Strengthened Public Safety and Facilitated Prosecution of Drug Counterfeiters

The serialization system enacted by the *Drug Supply Chain Security Act (DSCSA)* [38] and changes to the criminal code from the *SAFE DOSES Act* in 2012 [39] make fighting pharmaceutical counterfeiting more productive in the U.S. than it is for anticounterfeiting enforcement elsewhere.

These reforms fundamentally changed the responsibilities of every participant in the U.S. drug supply chain, establishing requirements for every participant to quarantine suspect medicine, retain transaction records for six years, and rapidly provide records to investigators upon demand. Furthermore, providing false transaction records is a crime under federal law [39]. The Boyds were found guilty of "conspiracy to traffic in pre-retail medical products with false documentation." Because of the recency of *DSCSA* implementation, their sentencing for that charge will establish precedent.

From an investigative point of view, current participants who refuse to supply documentation about a transaction within a few business days are out of compliance immediately. When criminals are forced to supply transaction records, they are either submitting a transaction history that confirms diversion or counterfeiting, or submitting falsified records that violate the law themselves. This is a change from the pre-*DSCSA* era, when documentation requirements were so lax that you could be out of compliance, supply incomplete documentation, and the burden of proof would still fall on the investigator.

3.2.1. Supply Chain Security Improvements: Serial Number Decommissioning

Ultimately, defendants in the Gilead cases were able to infiltrate the U.S. drug supply because the *DSCSA* does not require the decommissioning of unique serial numbers assigned to each package of prescription medicine sold, or require pharmacies to verify the validity of serial numbers before medicine is dispensed. Taken together, serial number decommissioning and last step verification would have ensured that dispensers would have flagged the secondhand bottles of medicine. Pharmacies that were not deliberately participating in the schemes would have quarantined them instead of dispensing them to patients.

A 2024 pilot project by the National Association of Boards of Pharmacy explored the processes that would be required to add these steps to existing track-and-trace functions. The organization found that participants across the supply chain would need to develop standards about when to decommission a product number, as well as systems to determine when to verify the numbers of products being dispensed to patients. Pilot participants concluded that these additions to supply chain security would enhance *DSCSA* reforms, but only if dispensers verified every product they were dispensing. At present, dispensers are only required to verify suspect products, and in the absence of new regulations, study participants felt that gaining compliance from dispensers would be challenging [40].

The rollout of the *DSCSA,* which began in 2013, is only now reaching the last stakeholders in the U.S. drug supply chain at the end of 2025. There have already been successes in using the system to identify illegitimate products more quickly than previously possible [41]. The benefit to patients is proven.

However, criminals innovate, and innovating the *DSCSA* to implement serial number decommissioning would deter crimes like the ones described in this paper. We would urge law enforcement, brand security professionals, regulators, and health care professionals to adopt a "constant learning" attitude to monitor criminal innovation, and update the *DSCSA* requirements to adapt to them.

3.3. Challenges of Reproducing this Playbook in other Industries

The *Lanham Act* is not specific to pharmaceutical trademarks; it spans the entire breadth of U.S. commerce. American companies in any industry that can commit the time and resources to sue counterfeiters and can demonstrate the urgency of criminal prosecution to legal authorities, could also mobilize the civil-to-criminal pipeline we have described here. Recent criminal cases involving counterfeit car airbags are compelling candidates for this same treatment [41, 42].

It's less clear where this technique might be applied in the rest of the world, since it requires a legal framework that responds urgently to trademark infringements and law enforcement and criminal court systems willing to use evidence from civil court cases.

4. Conclusion

Actions like Gilead Sciences' can ensure that medicine counterfeiters face consequences commensurate with the dangers of the fake medicines they are selling.

Companies across all industries that involve consumer safety can be prepared to enact this model by establishing trademark protection for every aspect of their product ahead of any infringement; by conferring with legal counsel to determine how to gather necessary information and witnesses for a *Lanham Act* suit while meeting standards for evidence admissible in potential criminal prosecutions, and by familiarizing themselves with how jurisdictions relevant to them have handled *Lanham Act* actions and whether they have displayed a willingness to take evidence gathered from civil suits.

Regulators and law enforcement can improve drug supply chain safety by considering reforms that would require verifying and decommissioning package serial numbers, enhancing education about supply chain risks for pharmacists and other dispensing professionals, developing connections with corporate anti-counterfeiting teams, and being alert to reports of drug diversion. Finally, law enforcement should be aware of civil suits filed over trademark infringement; they can be a strong indicator of criminal activity, and where appropriate, they may become resources for subsequent criminal action.

In the U.S., the National Intellectual Property Rights Coordination Center (IPR Center) is a model project with federal law enforcement and corporate security teams working alongside each other to share information and enable better, more effective prosecutions [44]. A comprehensive international study of intellectual property laws is beyond the scope of this paper. More research would determine whether other countries could implement this civil-to-criminal model to enhance patient safety.

We don't believe that trademark infringement actions should become a primary source for criminal cases, but we hope this technique encourages other pharmaceutical manufacturers to take up similar civil enforcement actions. We also hope that it encourages law enforcement to be more aggressive about leading these investigations themselves instead of waiting for civil enforcement.

You can follow PSM's coverage of counterfeit medicines in the U.S. drug supply at www.safemedicines.org.

Conflicts of Interest

Shabbir Imber Safdar and Eva Crider Reffell have not received compensation from Gilead Sciences, Paterson Belknap Webb and Tyler, or any company involved in this litigation. They have not been compensated for writing this article except by the Partnership for Safe Medicines, a 501c6 not-for-profit organization that does not receive funding from either Gilead Sciences or Paterson Belknap Webb and Tyler.

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