

Gilead Says Counterfeit Ring Swiped Its HIV Drug Branding

By **Lauren Berg**

Law360 (January 18, 2022, 9:37 PM EST) -- Sciences said a massive ring of small-time drug distributors and pharmacists was filling the biotech company's branded HIV medication bottles with potentially dangerous drugs and selling the counterfeit pills to patients, according to a civil case unsealed Tuesday in New York federal court.

Gilead's investigation found that more than 85,000 counterfeit bottles labeled as Gilead-branded medication have been sold to pharmacies over the past two years, altogether worth about \$250 million, according to Lori Mayall, head of anti-counterfeiting and brand protection at Gilead.

"The health and safety of individuals who rely on our life-saving medications is our first priority," Mayall said in a statement Tuesday.

"After becoming aware of counterfeit Gilead HIV medication being distributed we notified federal law enforcement authorities, including the [U.S. Food and Drug Administration], as well as dispensing pharmacies, and then took direct and urgent legal action to halt counterfeit Gilead HIV medication from reaching patients," she added. "We also issued an alert to consumers."

Gilead learned about the counterfeiting operation from patient and pharmacy reports, including complaints that bottles of Gilead HIV medications bought from pharmaceutical distributor Safe Chain Solutions contained an antipsychotic medication with potentially deadly side effects, according to the unsealed complaint.

When Gilead's in-house experts got their hands on some questionable bottles, the company said they confirmed the drugs were counterfeit.

"Safe Chain's counterfeits appeared to use authentic Gilead bottles that once contained authentic Gilead medication," Gilead said. "The original foil on the bottles had been stripped away, the authentic medication removed and replaced with foreign medication, and then a replica of the tamper-evident seal was used to re-seal the bottle."

"Traces of the original tamper-proof seal remained in the grooves of the counterfeit bottles and were visually distinguishable from the replica seal," the company added.

Gilead first filed its suit in July, before filing an amended complaint in August and then a second



Geoffrey Potter
Gilead's Lead Attorney

amended complaint on Oct. 14, court records show. U.S. District Judge Ann M. Donnelly unsealed the case Tuesday. The judge has also ordered that all the counterfeit distributors in the case stop selling Gilead-branded medication, according to court records.

Gilead has developed pioneering medications for people living with life-threatening diseases, including Biktarvy, the first tablet regimen to treat HIV; Descovy, the first prophylactic medicine to prevent HIV infection, and four hepatitis C therapies, according to the complaint.

In the counterfeit bottles, Gilead said the most commonly found drug was quetiapine fumarate, a non-Gilead antipsychotic medication marketed under the brand name Seroquel XR. Quetiapine often has serious side effects, including strong sedation, and one duped patient who unknowingly took the drug said they couldn't speak or walk afterward, according to the suit.

The drug can also pose dangers to patients with high blood pressure, diabetes and low white blood cell counts, Gilead said. The recommended dose of quetiapine for new patients is about 50 milligrams a day, according to the suit, but the pills in the counterfeit Gilead bottles contained 300 milligrams each.

"Patients who ingest quetiapine from a counterfeit bottle of HIV medication have no idea that they are taking a medication with these potential side effects and receive no warning of the possible consequences of doing so," Gilead said. "They have no idea they are not supposed to drive, operate heavy machinery or engage in other activities where sedation or drowsiness are dangerous, and as a result are placed in grave danger of injury or death."

And patients who need HIV treatment must not skip doses of their medication. If they do, the increased viral load will weaken their immune system and result in the progression of the disease, the suit states. Those patients could also unknowingly transmit the disease to their sexual partners, the company said.

Gilead at first assumed Safe Chain did not know it was dispensing counterfeit tablets and tried to work with the company to address the problem, according to the complaint. But Safe Chain did not cooperate and continued to buy thousands of bottles of fake Gilead medication from the same counterfeit suppliers, according to the suit.

Safe Chain then refused to cooperate with Gilead's investigation, according to the suit. Safe Chain also tried to hide counterfeit reports it received from pharmacies, including defendant Maryland Pharmacies Inc., and refused to share that its supplier was Gentek LLC, Gilead said. Gilead also learned that Safe Chain received drugs from Synergy Group Wholesalers LLC, the suit states.

Gilead said Safe Chain and its co-conspirator Worldwide Pharma Sales Group Inc. knew the drugs were counterfeit because they sold them at an "impossible discount" and received obviously fake supply chain documentation.

In July, Judge Donnelly issued an emergency order permitting seizures at Safe Chain, where Gilead said it recovered more than 1,000 bottles of seemingly counterfeit Gilead products. Documents obtained during that seizure show that Synergy "engaged in an elaborate ruse in connection with its sale of Gilead products," according to the suit.

Gilead also learned that ProPharma Distribution LLC had sold potentially dangerous counterfeit drugs that it in turn had bought from Omom Pharmaceuticals Inc., the suit states. Safe Chain had also purchased drugs from Omom, Gilead said.

Judge Donnelly in August issued another emergency order permitting seizures at ProPharma, where Gilead said it found thousands of bottles of counterfeit HIV medications.

"Seized documents and information obtained through third-party discovery have revealed that the known suppliers and distributors of counterfeit Gilead HIV medication are not the disparate actors they appeared to be," Gilead said. "Rather, the counterfeits are being sold through an organized counterfeiting ring: a large-scale, transnational enterprise comprised of numerous individual and entities working in concert to sell counterfeit Gilead-branded HIV medications into the United States supply chain."

The suit includes claims of trademark infringement, false description and designation of origin in commerce, false advertising, dilution, unfair competition, unjust enrichment and violations of the Racketeer Influenced and Corrupt Organizations Act, or RICO, among other things.

Gilead is seeking permanent injunctive relief and at least \$25 million in punitive damages, as well as actual or treble damages, attorney fees and all ill-gotten profits.

Gigio K. Ninan of Shankar Ninan & Co. LLP, who represents defendant VLS Pharmacy Inc. and its pharmacist Gopesh Patel, told Law360 on Tuesday evening that his clients had been serving Brooklyn community since the 1980s and deny any allegations of wrongdoing.

"The health and safety of the people in this community are of paramount importance to VLS and Mr. Patel," Ninan said. "VLS maintains that it was a downstream receiver of the subject medications and had no knowledge of alleged counterfeiting by upstream distributors. To this end, it has brought cross-claims against these upstream distributors and is confident that discovery will be favorable to VLS."

Representatives for defendants Safe Chain, Worldwide Pharma, ProPharma, Synergy, Omom and Maryland Pharmacies did not immediately respond to requests for comment Tuesday. The other defendants could not be immediately reached for comment.

Gilead is represented by Geoffrey Potter, Aron Fischer, Timothy A. Waters, Thomas P. Kurland, Joshua R. Stein and Gizele Rubeiz of Patterson Belknap Webb & Tyler LLP and Benjamin C. Fishman of Yankwitt LLP.

Safe Chain Solutions and Worldwide Pharma Sales Group are represented by Jesse C. Dresser, Lucas W. Morgan, Todd Mizeski, Frank Magaletta and Jonathan E. Levitt of Frier & Levitt LLC, Kelly T. Currie of Crowell & Moring LLP, Robert E. B. Hewitt III of Schwartz Conroy & Hack PC and Leo Shalit.

Worldwide Pharma is additionally represented by Mark A. Berman and Caroline M. Shulim of Hartmann Doherty Rosa Berman & Bulbulia LLP.

ProPharma Distribution is represented by Andrey Spektor of Bryan Cave Leighton Paisner LLP and Gregory T. Everts and Hector Diaz of Quarles & Brady LLP.

Synergy Group Wholesalers is represented by Juan Diego Berrio.

Omom Pharmaceuticals is represented by Henry Eduardo Marines.

Maryland Pharmacies is represented by Richard D. Trenk of Trenk Isabel PC.

VLS Pharmacy and Gopesh Patel are represented by Gigio K. Ninan of Shankar Ninan & Co. LLP.

Counsel information for Gentek LLC and the other defendants was not immediately available.

The case is Gilead Sciences Inc. et al. v. Safe Chain Solutions LLC et al., case number 1:21-cv-04106, in the U.S. District Court for the Eastern District of New York.

--Editing by Peter Rozovsky.

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