

## J&J Says Counterfeit Ring Selling 'Dangerous' HIV Meds

By Lauren Berg

*Law360 (April 26, 2022, 10:51 PM EDT)* -- Johnson & Johnson said a ring of drug distributors and a pharmacy were filling the pharmaceutical giant's HIV medication bottles with potentially dangerous drugs and selling the counterfeit pills to patients, according to a lawsuit unsealed Tuesday in New York federal court.

After J&J's subsidiary Janssen Sciences Ireland received complaints from patients who said their bottles of Symtuza HIV medication contained the wrong pills, the company found that the bottles bore indications of counterfeiting, including fake labels and falsified instructions, according to the complaint filed April 7.



Geoffrey Potter

"The pills found inside the counterfeit bottles were different drugs that do not adequately control these patients' viral loads and thus place them at serious risk of disease progression," J&J said.

"Due to the rapidly mutating nature of HIV, missing all or part of a medication regimen can place patients at risk of developing drug resistance, which may persist even after the proper drug regimen is restored," it added. "Counterfeit Symtuza puts patients at risk of suffering permanent harm from disruption in treatment."

J&J said the counterfeit drugs can be traced to wholesalers Safe Chain Solutions, Scripts Wholesale Inc. and ProPharma Distribution LLC, as well as I Care Pharmacy 14 Inc. in New York.

Recently unsealed documents in a similar case brought by Gilead Sciences revealed that the counterfeits Janssen customers complained about were only a small fraction of the defendants' illicit activities, the complaint states.

In Gilead's case — which was initially filed last July and unsealed in January — the biotech company discovered that Safe Chain was selling bottles of Gilead HIV medications that contained an antipsychotic medication with potentially deadly side effects, according to the complaint.

"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."

In its own case unsealed Tuesday, J&J said several groundbreaking Janssen HIV treatments are at the center of the counterfeiting, including Prezista, which contains the protease inhibitor darunavir; Prezcobix, a combination of darunavir and a booster inhibitor; Symtuza, which contains the boosted combination and two other drugs; and Endurant and Intelence.

In November 2020, Janssen received a complaint from a New York pharmacy that a bottle labeled and sold as Symtuza actually contained only Prezcobix tablets, the complaint states. When the pharmacy sent the bottle to Janssen, the company said it confirmed the pharmacist's suspicions.

In December 2020, Janssen said it received a nearly identical complaint from a New Jersey pharmacy, which told Janssen the bottle was purchased from Safe Chain. That same month, a Miami pharmacy made the same complaint and Janssen said the bottle came from the same lot as the previous counterfeits.

Following other pharmacy and customer complaints, ProPharma contacted Janssen in August 2021 asking about the legitimacy of the company's HIV medication that it possessed, according to the complaint. ProPharma told Janssen it was doing its "due diligence," but Janssen said it later learned the company only reached out after Gilead conducted a court-ordered seizure at its warehouse.

Every supply-chain pedigree that ProPharma provided for some of its Janssen medication was counterfeit, the complaint states.

The Gilead lawsuit has shown that there was widespread distribution by Safe Chain, Scripts and ProPharma of millions of dollars worth of counterfeit HIV drugs around the country, J&J said.

This counterfeiting puts HIV-positive patients at risk of serious consequences, including an increased viral load, a weakened immune system and progression of the disease, the pharmaceutical giant said.

"These risks created by illegitimate medication may be even greater for the population prescribed one of Janssen's darunavir-based medications than for the general population of patients undergoing HIV treatment," J&J said. "Darunavir is a protease inhibitor with a particularly high genetic barrier to drug resistance."

"This characteristic means that it is often prescribed to patients who either have already developed resistance to other antiretroviral agents or are at risk for doing so," it added. "A subset of persons living with HIV who are prescribed one of these Janssen HIV drugs are generally at greater risk for the adverse impacts of viral rebound, drug resistance and falling out of care due to distrust in the healthcare system."

J&J's suit includes claims of trademark infringement, false advertising, dilution, deceptive business practices and unjust enrichment. The company is seeking a permanent injunction barring the counterfeit drugs and at least \$25 million in punitive damages, as well as disgorgement of profits, restitution, treble damages and attorney fees.

Representatives for J&J, Safe Chain and ProPharma were not immediately available for comment Tuesday evening. Scripts could not be immediately reached for comment.

J&J and Janssen are represented by Geoffrey Potter, Aron Fischer, Timothy Waters, A. Robert Quirk and

Louis Russo of Patterson Belknap Webb & Tyler LLP.

Counsel information for the defendants was not immediately available.

The case is Janssen Sciences Ireland Unlimited Co. et al. v. Safe Chain Solutions LLC et al., case number 1:22-cv-01983, in the U.S. District Court for the Eastern District of New York.

--Editing by Jay Jackson Jr.

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