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Consequences of counterfeit pharmaceutical product sales

The incidence of counterfeit life sciences products in the US has increased in recent years. With the expansion of illicit online pharmacies and rise in unauthorized compounded medications, this trend is expected to persist and potentially worsen.

According to the "2024 Review of Notorious Markets for Counterfeiting and Piracy" report, the counterfeit market is growing.[1] The FDA reports roughly 35,000 active online pharmacies and only about 5% of those pharmacies comply with US laws and standards.[2] Recently, the FDA has raised concerns about counterfeit GLP-1 drugs used for weight loss and diabetes, warning consumers that fraudulently compounded semaglutide and tirzepatide products are being marketed in the US.[3] Similarly, the EMA has warned consumers about the increase in counterfeit medicines being marketed in the EU, many of which are marketed as GLP-1s.[4]

Counterfeit life sciences products include medical devices and medications that: 1) are products produced by the original manufacturer that have not been evaluated or approved by relevant regulatory authorities or fail to meet quality standards and/or specifications; or 2) are illegitimate

1 "2024 Review of Notorious Markets for Counterfeiting and Piracy," *Office of the United States Trade Representative Executive Office of the President*, https://ustr.gov/sites/default/files/2024%20Review%20of%20Notorious%20Markets%20of%20Counterfeiting%20and%20Piracy%20(final).pdf, pp. 3-7.

2 "BeSafeRx: Frequently Asked Questions (FAQs)," *FDA*, https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/besaferx-frequently-asked-questions-faqs.

3 "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," *FDA*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

4 "Warning about sharp rise in illegal medicines sold in the EU," *EMA*, https://www.ema.europa.eu/en/news/warning-about-sharp-rise-illegal-medicines-sold-eu.

products not produced by the original manufacturer that deliberately or fraudulently misrepresent their identity, composition, or source.[5]

The production, distribution, and sale of counterfeit products often involve different groups including individuals, online or brick and mortar pharmacies, and distributors. The actions of these parties endanger patients' lives and violate contract provisions that cause harm to manufacturers. As a result, we have seen a noticeable rise in litigation involving the sale of counterfeit pharmaceuticals and medical devices. This article will explore the different types of counterfeit products encountered by manufacturers and the harms for which manufacturers can be compensated.

Types of counterfeit products

The origins of counterfeit products vary and can include items produced by the legitimate manufacturer that have been altered or represented to be something else as well as unauthorized replicas.

Counterfeit products with legitimate origins may be altered or represented in different ways to trick consumers into thinking these are authorized products. This includes products that have been illegally imported from other jurisdictions. For example, in *Johnson & Johnson and LifeScan, Inc. v. South Point Wholesale Inc. et al.*, Johnson & Johnson alleged the defendants conspired to purchase international diabetes test strips from countries in the Middle East, Europe, and Asia to repackage in US retail trade dress for distribution in the US.[6] And in *United States of America v. Stephen Costa*, it was alleged that medications meant for the treatment of HIV, cancer, and psychiatric illnesses were purchased from patients then cleaned, repackaged, and resold.[7]

Counterfeit products may also be completely falsified products that deliberately or fraudulently misrepresent their identity, composition, or source. These types of products do not include the intended active ingredients and have been packaged to deceive consumers. For example, in *Gilead v. Safe Chain et al.*, it was alleged that authentic-looking bottles of Gilead HIV medications were sold with other medications inside and accompanied with falsified documentation.[8] In April, Novo Nordisk warned consumers about counterfeit semaglutide distributed with legitimate lot numbers and illegitimate serial numbers that were distributed outside of the authorized supply chain.[9] At the time of the announcement Novo Nordisk was testing the contents of the vials.

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5 "The WHO Member State Mechanism on Substandard and Falsified Medical Products," *WHO*, https://iris.who.int/bitstream/handle/10665/332635/WHO-MVP-EMP-SAV-2019.04-eng.pdf?sequence=1, p. 6.

6 Johnson & Johnson and LifeScan Inc. v. South Point Wholesale, Inc. et al., in the United States District Court Eastern District of New York, 08 Civ. 1297 (SLT) (SMG), Sixth Amended Complaint, April 6, 2009, ¶ 99.

7 USA v. Stephen Costa, case number 1:19-cr-20674, in the U.S. District Court for the Southern District of Florida (https://www.law360.com/lifesciences/articles/2368421?nl_pk=f5d0cac5-9331-4dcd-a127-9c4cee3e1321).

8 Gilead Sciences, Inc. and Gilead Sciences Ireland UC v. Safe Chain Solutions, LLC et al., in the United States District Court Eastern District of New York, 1:21-cv-04106-AMD-RER, July 22, 2021, Complaint, ¶¶ 1-2.

9 "Novo Nordisk warns consumers about counterfeit Ozempic® (semaglutide) injection 1 mg in the US," *Novo Nordisk,* https://www.novonordisk-us.com/media/news-archive/news-details.html?id=915970.

Compounded drugs provide a prominent recent example of unauthorized replicas. During drug shortages, licensed pharmacists or physicians are allowed to compound drug products under certain conditions.[10] Since the FDA has determined that drug shortages for GLP-1s tirzepatide and semaglutide have been resolved, these products are no longer authorized to be compounded freely.[11] Novo Nordisk and Eli Lilly have filed lawsuits against entities regarding the unapproved sales of semaglutide and tirzepatide products that continue to be compounded.[12]

Harms to manufacturers

Counterfeit drug products may contain harmful ingredients, the wrong dosage of active ingredients, or no active ingredients at all. This can lead to ineffective medications and severe health consequences, such as allergic reactions, drug interactions, and death. Counterfeit products can also impact manufacturers in the form of financial loss due to lost sales, breach of contract, violation of IP rights, and reputational harm.

Lost sales. When counterfeit products are sold, less revenue is received by the legitimate manufacturer. For life sciences products, which are frequently reimbursed by third-party payors, it is often the case that absent the counterfeit product, individuals would have obtained the legitimate product. To estimate damages from lost sales in these types of matters, one needs to consider the incremental profits that the manufacturer would have realized had it made the sales legally. In *Gilead v. Safe Chain et al.*, it was reported that the retail value of the medications counterfeited was about $250 million.[13]

Breach of contract. Manufacturers often contract with pharmacies and distributors to manage the relationships and obligations in the sale, distribution, and reimbursement of pharmaceuticals and medical devices. When these players purchase drug products from secondary markets, and in turn sell these unauthorized or counterfeit products, contracts with brand manufacturers may be breached. For example, in *Johnson & Johnson and LifeScan, Inc. v. South Pointe Wholesale Inc. et al.*, it was alleged that authorized distributors breached their contracts with Johnson & Johnson and/or LifeScan

10 "Compounding when Drugs are on FDA's Drug Shortages List," *FDA*, https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list. See also, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry," *US Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Office of Compliance/OUDLC*, January 2018, Compounding, https://www.fda.gov/media/98973/download?attachment.

11 "FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize," *FDA*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

12 See for example, Novo Nordisk Inc. v. Axtell's Rite-Value Pharmacy, Inc., in the United States District Court Eastern District of Texas Sherman Division, 4:25-cv-837, Complaint, August 4, 2025, ¶¶ 24, 62-67; Eli Lilly and Company v. Empower Clinic Services, LLC d/b/a Empower Pharmacy, in the United States District Court Eastern District of Texas Houston Division, 4:25-cv-03464, Complaint, July 25, 2025, ¶¶ 157-160, 174, 186.

13 Berg, Lauren, "Gilead Says Counterfeit Ring Swiped its HIV Drug Branding," *Law360*, January 18, 2022, https://www.law360.com/articles/1456303/gilead-says-counterfeit-ring-swiped-its-hiv-drug-branding.

by selling unlicensed LifeScan products that were purchased in a secondary market outside of proper channels and not directly from Johnson & Johnson and/or LifeScan as contractually required.[14]

Violation of IP rights. Generally, manufacturers put forth significant effort to protect their intellectual property rights. Counterfeit products often contain branded trademarks to convey legitimacy. Unauthorized trademarks can cause confusion for the consumer regarding the difference between legitimate and illegitimate drug products, as was noted in *Abbott Laboratories v. Adelphia Supply USA et al.* A New York federal judge found that the defendants violated trademark laws and were ordered to pay more than $33 million to Abbott Laboratories in damages, prejudgment interest, and attorney fees.[15]

Reputational harm. Counterfeit pharmaceuticals pose harm to the reputation of pharmaceutical and medical device manufacturers. When patients and prescribers receive falsified or substandard products it may erode their trust in the manufacturer's product or brand, adversely affecting long-term investments in brand loyalty. Should patients experience adverse side effects from the use of a counterfeit drug product, they may attribute them to the legitimate manufacturer, leading to reputational harm, as was noted in *Eli Lilly v. Gitmed*.[16] For example, in *Novo Nordisk Inc. v. Axtell's Rite-Value Pharmacy, Inc*., Novo Nordisk stated that "[s]emaglutide is synonymous with Novo Nordisk" and "patients who have negative experiences from Defendant's compounded 'semaglutide' may erroneously view Novo Nordisk as the cause of those negative experiences," thus causing harm to Novo Nordisk's reputation.[17]

Conclusion

Counterfeit life sciences products are becoming more prominent with significant consequences for manufacturers and consumers. Harms in the form of lost sales, breach of contract, violation of IP rights, and reputational damage can be compensated by damages, at least in part. Recent counterfeit cases involving life sciences products have been associated with hundreds of millions of dollars in lost sales revenue and have resulted in multimillion dollar damages awards.

14 Johnson & Johnson and LifeScan Inc. v. South Point Wholesale, Inc. et al., in the United States District Court Eastern District of New York, 08 Civ. 1297 (SLT) (SMG), Sixth Amended Complaint, April 6, 2009, ¶¶ 83, 482, 484, 486, 493, 673-676.

15 Hu, Tiffany, "Wholesaler To Pay $33.4M In Abbott Labs Test Strips TM Row," Law360, March 27, 2023, https://www.law360.com/articles/1590351/wholesaler-to-pay-33-4m-in-abbott-labs-test-strips-tm-row.

16 Eli Lilly and Company v. John Derek Gitmed et al., in the United States District Court Eastern District of California, 1:16-at-00090, Complaint for Injunctive Relief and Damages Based on Federal Trademark Counterfeiting, Federal Trademark Infringement, False Designation of Competition, California Common Law Passing Off and Unfair Competition, and California Statutory Unfair Competition, February 8, 2016, ¶ 26.

17 Novo Nordisk Inc. v. Axtell's Rite-Value Pharmacy, Inc., in the United States District Court Eastern District of Texas Sherman Division, 4:25-cv-837, Complaint, August 4, 2025, ¶¶ 65-66.

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