



August 7, 2025

New York State Education Department's Office of the Professions Office of Professional Discipline 1411 Broadway, Tenth Floor New York, NY 10018

Sent by US Mail and email: conduct@nysed.gov

To whom it may concern,

On behalf of the Partnership for Safe Medicines, a national nonprofit expert on counterfeit medicines, and ADAP Advocacy, a national nonprofit expert on issues affecting people with HIV, we write today to file an official complaint about City Plus Care Pharmacy Inc. (registration # 037515, dba Heal The World Pharmacy). The supervising pharmacist on the license is Nafees Ahman Nauman, license #067063.





Screenshots of active license registration for City Plus Care Pharmacy Inc. for New York State

The attached civil court filing shows that this pharmacy has been accused of gravely endangering patients by dispensing counterfeit HIV medicine to a patient in Queens, NY. Additionally, the counterfeit identified by the drug's legitimate manufacturer in the lawsuit appeared to have professional-quality labels, which suggests that a large volume of patients might have been exposed to these alleged counterfeits.







Screenshots of intercepted counterfeit Biktarvy HIV medicine from Gilead v City Plus Care Pharmacy Inc (Case 1:25-cv-01469)

Counterfeit Biktarvy has irreversible consequences for patients who take it. Their infections could develop viral resistance, and the medicine would stop working to control their HIV altogether.

Modern HIV medicines, when taken as directed under a physician's supervision, make the virus undetectable and untransmittable, or what is commonly referred to as "U equals U" (U=U). Counterfeit HIV medicine can allow the virus to become actively infectious, and it may infect intimate partners with a lifelong, incurable medical condition.

In the complaint, the plaintiffs assert there is a strong possibility that this bottle is not a one-off, but that, for several reasons, many counterfeit bottles may have been a part of this operation. While we understand that typically professional boards await the conclusion of criminal or civil adjudications before acting, the possibility that patients of Heal The World Pharmacy and their partners are being endangered requires immediate scrutiny to ensure that the human toll of this accusation, if found to be true, is minimized.

We urge the State of New York to use its regulatory powers to:





- inspect all premises used by Heal The World Pharmacy to store or dispense medication;
- question staff involved in purchasing or dispensing medication;
- inspect records for purchasing or sales of medicine to other pharmacies.1

Specifically, the board should be inspecting to determine whether Heal the World may have violated the following statutes:

Dispensing a medication that is mislabeled

Dispensing a bottle of medication that contains "False or misleading labeling", or is an "Imitation or counterfeit", or is a "deceptive container" is a violation of New York State Education Law, Article 137, Section 6815.

Only obtaining products from authorized trading partners Failure to maintain records for products purchased or sold

The bottle with counterfeit labeling named in the complaint contains a typographical error and was produced by a counterfeiter. In other similar cases, pharmacies have purchased counterfeit products from unlicensed distributors. NY investigators should match dispensing records for purchases of HIV medicines to purchasing records. They should then verify the licensure of all Heal The World's HIV medicine wholesalers. This would reveal whether they have violated this law.

The violation for a pharmacy that does not purchase from an authorized trading partner is that it is considered a failure to comply with the requirements of section 582 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Such failure is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and is subject to enforcement action under the FD&C Act.

New York Education Law, Article 137, Section 6808 and Section 6808(b)

A dispenser's obligation to maintain transaction information is primarily outlined in section 582(d)(1)(A)(iii) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

¹ We have seen instances where pharmacies sell medicine to other pharmacies for "named patient need" without obtaining a wholesale license. This practice can be done informally between pharmacies that are known to each other. It can also be done through online discussion groups with pharmacies unknown to each other, or through pharmacy-to-pharmacy marketplaces that exploit an exception in the Drug Supply Chain Security Act (DSCSA).





New York Education Law, Section 6808€ - Responsibilities for Drug Quality and Recordkeeping

Failure to identify, quarantine, and verify suspect product

Under the federal Drug Supply Chain Security Act (DSCSA), dispensers are obligated to apply a set of standards to identify suspect product². When deemed to be suspect, they should guarantine and verify this product. Once that process is completed, they will either dispose of the product or return it to the supply chain, notifying all trading partners of the results of that investigation and keeping records of it for six years.

The bottle identified in the complaint is suspicious based on the FDA's standards, and any product purchased from the same entity at that time, or later, may also be considered suspect. They all should have been quarantined, verified, and positioned based on the investigation. Records of all these events should be held by the pharmacy and open to investigators.

Additionally, pharmacy regulators inspecting Heal The World pharmacy should be able to use the new product from the National Associations of Boards of Pharmacy, Pulse, to conduct a first-level verification utilizing a cellphone quickly and the 2D datamatrix printed on every package that might be suspect. We recommend they conduct this scanning verification on all HIV oral dose medicines along with several other products commonly subject to fraud: anticoagulants (Eliquis, Xarelto), diabetes (Jardiance, Januvia, Farxiga, Ozempic, Wegovy, Saxenda, Zepbound), and BTK inhibitor (Imbruvica).

The statutory citation for a dispenser's responsibility to guarantine a suspect product is section 582(d)(4)(A)(i)(I) of the Federal Food, Drug, and Cosmetic (FD&C) Act

New York Education Law, Section 6808€ - Responsibilities for Drug Quality and Recordkeeping

Failure to respond to tracing requests from a member of the supply chain

Under the DSCSA, all supply chain partners must respond to requests for product verification. Gilead has stated in its complaint that it has made repeated attempts to conduct a lawfully mandated tracing request and Heal The World's operators have refused. Investigators should force the pharmacy to

² FDA has published guidance on this topic that all dispensers should heed, See "<u>Drug Supply Chain Security Act</u> Implementation: Identification of Suspect Product and Notification Guidance for Industry"





divulge the records to satisfy these tracing requests or treat these products as knowingly dispensed counterfeits and apply appropriate sanctions.

The statutory citation for a dispenser's responsibility to respond to requests for information during a suspect product investigation is section 582(d)(1)(D) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Should any of the owners or licensed staff deny cooperation with New York Inspectors, we recommend that the license for this pharmacy and any professionals who refuse to comply be suspended immediately.

Additionally, we strongly urge that any adverse findings be immediately referred to the New York Attorney General's Consumer Protection branch (800-771-7755), the U.S. Food and Drug Administration's Office of Drug Security, Integrity, and Response (301-796-3130), and the U.S. FDA Office of Criminal Investigation's New York field office (201-685-6069).

We thank you for your consideration of our request.

Shabbir Imber Safdar **Executive Director**

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Partnership for Safe Medicines

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Cc:

New York Attorney General's Division of Economic Justice Via Health care issues complaint page





List of online pharmacy-to-pharmacy sales platforms and their contact email addresses

Online pharmacy-to-pharmacy sales platforms have been found to be platforms on which counterfeit medicines are bought and sold. A thorough investigation of any pharmacy suspected of dispensing counterfeit medicine should include a request for all listing and sales records from these platforms about any medicines bought and sold by Heal The World pharmacy.

Platform	Contact
MatchRX	compliance@matchrx.com
InStockRX	info@instockrx.com
RXPost	support@rx-post.com
Rph2Rph	support@ezrirx.com
TradeNetRX	support@tradenetrx.com
RXWorld	support@rxworld.com
RXeed	info@Rxeed.com
CityRX	support@cityrx.com