IN THE MATTER OF	*	**BEFORE THE MARYLAND**
SAFE CHAIN SOLUTIONS INC. **RESPONDENT**	*	**BOARD OF PHARMACY**
PERMIT NUMBER: D03211	*	**CASE NUMBER: 20-265**

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FINAL CONSENT ORDER

On or about July 17, 2024, the Maryland Board of Pharmacy (the "Board") charged **Safe Chain Solutions Inc.** Permit Number: **D03211** (the "Wholesale Distributor"), under the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. ("Heath. Occ.") §§ 12-101 *et seq.* (2021 Repl. Vol. & 2023 Supp.), Md. Code Ann. Health Gen ("Health-Gen.") §§ 21-201 *et seq.*, and Code of Maryland Regulations ("COMAR"). The pertinent provisions state:

Health Occ. § 12-601. Disciplinary actions.

> (a) *In general* - Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle, Subtitle 6C of this title, or any regulation adopted under Subtitle 6C of this title, the Board may:
>
> (1) Deny a permit to an applicant;
> (2) Reprimand a permit holder;
> (3) Place a permit holder on probation; or
> (4) Suspend or revoke a permit.

Health Occ. § 12-6C-11. Violations; penalties.

> (a) *Fine.* – (1) If a person knowingly violates any provisions of this subtitle or any regulation adopted under this subtitle, the Board may impose a fine not to exceed $500,000.

Health Gen. § 21-256

A person may not

(1) Manufacture or sell any food, drug, device, or cosmetic that is adulterated or misbranded;

(4) Receive in commerce any adulterated or misbranded food, drug, device, or cosmetic;

(5) Deliver or offer for delivery any adulterated or misbranded food, drug, device, or cosmetic, whether or not for pay[.]

COMAR 10.34.22.05 Violations and Penalties.

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

(3) Commits any of the following acts:

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(e) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

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(g) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;

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(i) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(j) Purchases or receives a prescription drug or device from a person who is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

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(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law[.]

COMAR 10.34.22.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution Records.

A. Record Keeping.

(6) Facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Board and the FDA.

B. Written Policies and Procedures.

(2) A wholesale distributor shall include in the written policies and procedures the following:

(f) A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

COMAR 10.34.22.08 Due Diligence.

Wholesale distributors having transactions with persons not licensed by the Board or not certified by a third party recognized by the Board shall have in place policies and procedures to perform due diligence on transactions that take place that include:

A. Verification of alternate licensure;

B. Verification of identity; and

C. Verification of recent inspections by a state or third party entity recognized by the Board.

FINDINGS OF FACT

1. The Respondent was originally issued a wholesale distributor permit on or about August 24, 2011. The Respondent's wholesale distributor permit expires on or about May 31, 2025.

2. At all times relevant hereto, the Respondent's facility is in Maryland.

3. On or about February 2, 2021, the Board received a complaint from the representative (the "Representative")[1] in charge of a wholesale drug distributor located in California (the "California Distributor").

4. The Representative alleged in the complaint that the Respondent purchased various medications from an unlicensed distributor located in Connecticut ("Unlicensed Distributor")

5. An investigation conducted by the Board's staff revealed the following:

1. Between July 2020 and March 2021, the California Distributor purchased Descovy, Prezista, Biktarvy, Genvoya, and Symtuaza from the Respondent.[2]
2. The Respondent purchased these HIV medications from the Unlicensed Distributor.
3. Between June 2020 and November 2020, the Respondent purchased approximately forty-three million dollars ($43,000,000) of HIV medications from the Unlicensed Distributor.
4. On or about June 8, 2023, the Respondent was issued a warning letter (the

[1] For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document. Upon written request, the Administrative Prosecutor will provide the information to the Respondent.
[2] These medications are used in the treatment of patients with HIV.

"Warning Letter") by the Federal Food and Drug Administration (the "FDA") following an inspection of the Respondent's facility.[3] The Warning Letter indicated that during inspection of the Respondent's facility following violations were observed: (1) the Respondent failed to have adequate systems verification in place to enable compliance with verification requirements, in violation of section 382(c)(4)(A) and (B) of the Food, Drug and Cosmetic Act ("FD&C Act"); (2) the Respondent conducted transactions with trading partners that were not authorized, in violation of Section 582(c)(3) of the FD&C Act; (3) the Respondent failed to maintain records of suspected product investigations for at least six years, in violation of Section 582(c)(4)A(iii) of the FD&C Act; and (4) the Respondent failed to respond to a notification of illegitimate product in violation of 582(c)(4)(B)(iii) of the FD&C Act.

5. The Warning Letter indicates that between July 2020 and January 2021, the Respondent purchased bottles of Biktarvy from the Unlicensed Distributor and later sold these bottles of Biktarvy to pharmacy trading partners. The Warning Letter further indicates that the Respondent later received notifications from pharmacy trading partners informing the Respondent that the bottles of Biktarvy sold to them contained a different medication than what was to be present based on the product labeling.

CONCLUSIONS OF LAW

The Board concludes that the Respondent violated Health Gen.§21-256(1), (4), (5); COMAR 10.34.22.05 A (3) (d), (e), (g), (i), (j), and (v); COMAR 10.34.22.07 A(6) and B

[3] When the FDA inspection finds that a wholesale drug distributor has significantly violated FDA regulations, notice of the violation(s) in the form of a warning letter is sent to the wholesale drug distributor.

(2)(f); and COMAR 10.34.22.08.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, a majority of a quorum of the Board hereby:

ORDER that The Respondent is hereby **REPRIMANDED** and is subject to the following terms and conditions:

1. The Respondent shall pay a fine in the amount of one hundred thousand dollars ($100,000) with ninety (90) days of the date of this Order.

2. The Respondent shall make a charitable contribution in the amount of one hundred thousand dollars ($100,000), within six (6) months of the date of this Order, to a non-profit organization focused on public services to the HIV population. The Respondent shall provide the Board proof that the contribution was made.

3. The Respondent shall engage the services of LSPEDIA to facilitate compliance with DSCSA requirements; and it is further

ORDERED that the Respondent shall practice in accordance with the laws and regulations governing the Act; and it is further

ORDERED that in the event the Board finds for any good faith reason that the Respondent has violated any of the conditions herein, or in the event that the Board finds for any good faith reason that the Respondent has committed a violation of Title 12 of the Health Occupations Article or regulations adopted thereunder, the Board may take further disciplinary action, to include summary suspension, against the Respondent's permit, provided that the Respondent is given notice and an opportunity for a hearing; and it is further

ORDERED that this is a final order of the Maryland Board of Pharmacy and as such is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., General Prov. Art., §4-333.

for (12-11-24)

Kristopher Rusinko, Pharm.D.
President
Maryland Board of Pharmacy

CONSENT

I, Amanda Biggart, Chief Operating Officer for the Respondent acknowledges that I had the opportunity to consult with legal counsel before signing this document. By this Consent, the Respondent accepts to be bound by this Consent Order and its conditions and restrictions. I also acknowledge that the Respondent waives any rights to contest the Findings of Fact and Conclusions of Law.

I, Amanda Biggart further acknowledge: (1) the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which the Respondent would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf and to all other substantive and procedural protections as provided by law and (2) the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that the Respondent is waiving the right to appeal any adverse ruling of the Board that might have followed any such hearing.

I, Amanda Biggart sign this Consent Order without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order and understand its meaning and effect.

12/4/2024
Date

Amanda Biggart,
Chief Operating Officer

NOTARY

STATE OF Maryland

COUNTY/CITY OF: Dorchester

I hereby certify that on this 5 day of December, 2024, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared **Amanda Biggart, Chief Operating Officer for the Respondent** and made an oath in due form that the foregoing Consent was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Notary Public

My Commission Expires: Nov. 16, 2027