IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA, Plaintiff, v. JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla", Defendant.	INDICTMENT CRIMINAL NO. 24-364 (PAD) VIOLATIONS: Counts 1 and 2: 21 U.S.C. §331(t), 353(e)(1)(A), 333(a)(2) and 333(b)(1)(D). (Unlicensed Wholesale Distribution of Prescription Drugs) Counts 3 and 4: 21 U.S.C. §331(k) and 333(a)(2). (Misbranding of prescription drugs with intent to mislead and defraud) Counts 5 and 6: 18 U.S.C. §670 (Theft, Trafficking, and Sale of Pre-Retail Medical Products) SIX COUNTS FORFEITURE ALLEGATION

THE GRAND JURY CHARGES:

GENERAL ALLEGATIONS

At all times material to this Indictment and within the District of Puerto Rico:

1. Company A is a medical facility located in Manatí, Puerto Rico, and an entity that purchased prescription drugs from legitimate licensed wholesale distributors of prescription drugs kept as a pre-retail medical product to be used in the operations of the medical facility.

2. Defendant JORGE RIVERA-PEREZ was a Purchasing/Procurement Department employee for Company A and was not a licensed wholesale distributor for prescription drugs.

3. Defendant JORGE RIVERA-PEREZ used his position as a Purchasing/Procurement Department employee to obtain pre-retail medical products unlawfully and intentionally, to wit, prescribed

medications, from the Company A storage warehouse access-controlled area located at the basement of the building and to subsequently sell them to individual pharmacy owners at a steep price discount when compared to legitimate wholesalers.

4. Defendant JORGE RIVERA-PEREZ, as a Purchasing/Procurement Department employee, was one of the few authorized personnel to access Company A's prescription drug storage warehouse.

5. Defendant JORGE RIVERA-PEREZ encouraged his buyers to pick up the unlawfully obtained prescribed medications from his office at Company A.

6. Defendant JORGE RIVERA-PEREZ received payments in cash for the misbranded and diverted medications taken from Company A.

7. The Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.* One purpose of the FDCA was to ensure that drugs sold for consumption or administration to humans were authentic, properly labeled, had been handled and maintained according to FDA requirements and industry standards, had been in the possession of properly licensed entities, and had a verified chain of custody.

8. Diversion refers to processes by which prescription drugs are removed from, and then reintroduced into, the legitimate chain of licensed wholesale distribution. Once a prescription drug is diverted outside of the regulated distribution channels, it becomes difficult, if not impossible, for regulators such as the FDA, law enforcement, or end-users to know whether the prescription drug package actually contains the correct drug or the correct dose. Law enforcement officers, regulators, and end users would not know whether the prescription drug was altered, stored in improper conditions, or had its potency adversely affected.

9. Drug diverters use a number of different methods to obtain prescription drugs at discounted prices and reintroduce them at higher prices. In a practice known as "street diversion," diverters repurchase dispensed medications from Medicaid or other patients, remove the patient labels, and distribute them to others. Another common form of diversion, using pharmacies that are not open to the public (known as closed-door pharmacies), involves the unauthorized resale of pre-retail drugs that manufacturers sell at steep discounts to hospitals and other healthcare entities. Another form of diversion entails relabeling expired drugs with counterfeit labels so that they can be redistributed.

10. Under the FDCA, the term "drug" included articles that (1) were intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; or (2) were intended to affect the structure or any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

11. The FDCA defined "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The term "labeling" was defined as all labels and other printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article. 21 U.S.C. § 321(m).

12. Under the FDCA, a "prescription drug" was any drug intended for use in humans that, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or was limited by an approved application under section 21 U.S.C. § 355 for use under the professional supervision of a practitioner licensed by law to administer such drug. 21 U.S.C. § 353(b)(1).

13. A drug was misbranded under the FDCA if its labeling lacked "adequate directions for use." 21 U.S.C. § 352(f)(1). By regulation, the FDA defined "adequate directions for use" as directions under which the layman could use a drug safely and for the purposes for which it was intended. 21 C.F.R. § 201.5. Prescription drugs could never contain adequate directions for layman use and were therefore

misbranded unless they met certain conditions. *See* 21 C.F.R. §§ 201.100(a), (b)(1), and (c)(1). Therefore, a drug was misbranded if it was a prescription drug and was dispensed without a lawful written or oral order of a licensed practitioner. 21 USC § 353(b).

14. A prescription drug was exempt from the adequate directions for use requirement under 21 U.S.C. § 352(f)(1) if the drug was in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs, in the possession of a retail, hospital, or clinic pharmacy regularly and lawfully engaged in dispensing prescription drugs, or in the possession of a practitioner licensed by law to administer or prescribe such drugs. 21 C.F.R. § 201.100(a)(1). Therefore, a prescription drug that was in the possession of a person *not* regularly and lawfully engaged in the wholesale distribution of prescription drugs would not have adequate directions for use and would be misbranded.

15. To prevent drug diversion, the FDCA prohibited any person from engaging in the wholesale distribution of a prescription drug in any State unless such person was (1) licensed by the State from which the drug was distributed; or (2) if the State from which the drug was distributed did not have a licensure requirement, was licensed by the Secretary of Health and Human Services. 21 U.S.C. § 353(e)(1)(A). The term "State" included the Commonwealth of Puerto Rico. 21 U.S.C. § 321(a)(1). Among other things, the wholesale distribution of prescription drugs meant distribution to someone other than a consumer or patient. 21 U.S.C. § 353(e)(4).

16. At all times relevant to this Indictment, Puerto Rico required wholesale prescription medication distributors to have a license by the Secretary of the Department of Health of the Government of Puerto Rico. PR Laws Title 1, §410i (PR Law 247 (2004)). It is a violation of Puerto Rico law to engage in the wholesale distribution, dispensation, vending, or sale of medications without holding the required licensure. PR Laws Title 20, §411e(a)(9) (PR Law 247(2004)).

17. The FDCA prohibited the doing and causing of the following acts:

a. The doing of any act to a drug, while the drug was held for sale, after the drug's shipment in interstate commerce, which resulted in the drug being misbranded. 21 U.S.C. § 331(k); and

b. The unlicensed wholesale distribution of a prescription drug. 21 U.S.C. § 331(t).

18. Humulin, Epinephrine Injection USP, Lidocaine Hydrochloride Jelly USP, Sodium Bicarbonate Injection USP, DOPamine HCI Inj. USP, Calcium Gluconate Injection USP, hydrALAZINE Hydrochloride Injection USP, Adenosine Injection USP, Phenytoin Sodium Injection USP, Enalapirilat Injection USP, Meropenem, among others, were approved by the FDA as prescription drugs in accordance with 21 U.S.C. § 355. All of the drugs listed above were manufactured outside of Puerto Rico.

COUNT ONE
21 U.S.C. § § 331(t), 353(e)(1)(A), 333(a)(2), and 333(b)(1)(D)
(Unlicensed Wholesale Distribution of Prescription Drugs)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about September 29, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, did knowingly, and with intent to defraud and mislead, engage in the wholesale distribution of prescription drugs listed in the table below in Puerto Rico without being properly licensed in Puerto Rico or with the Secretary of the of Health and Human Services:

PRESCRIPTION DRUG	QUANTITY
Humulin	70 vials
Meropenem	1 box

Enalapirilat Injection USP	2 vials
Epinephrine Injection, USP	1 box
Lidocaine Hydrochoride Jelly USP	3 packs
Sodium Bicarbonate Injection USP	3 vials
DOPamine HCI Inj. USP	3 vials
Calcium Gluconate Injection USP	3 vials
hydrALAZINE Hydrochloride Injection USP	3 vials
Adenosine Injection USP	2 vials
Phenytoin Sodium Injection USP	2 vials

All in violation of 21 U.S.C. §§ 331(t), 353(e)(1)(A), 333(a)(2), and 333(b)(1)(D).

COUNT TWO
21 U.S.C. §§ 331(t), 353(e)(1)(A), 333(a)(2), and 333(b)(1)(D)
(Unlicensed Wholesale Distribution of Prescription Drugs)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about October 4, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, did knowingly, and with intent to defraud and mislead, engage in the wholesale distribution of a prescription drug, to wit: 40 vials of Humulin, in Puerto Rico without being properly licensed in Puerto Rico or with the Secretary of the of Health and Human Services.

All in violation of 21 U.S.C. §§ 331(t), 353(e)(1)(A), 333(a)(2) and 333(b)(1)(D).

COUNT THREE

21 U.S.C. §§ 331(k) and 333(a)(2)

(Misbranding of prescription drugs with intent to mislead and defraud)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about September 29, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, after shipment in interstate commerce, with intent to defraud and mislead, did any act to a drug, while held for sale, which resulted in the prescription drug being deemed misbranded, to wit: the prescription drugs lacked adequate directions for use and were dispensed without a valid prescription, as detailed in the table below:

PRESCRIPTION DRUG	QUANTITY	DATE
Humulin	70 vials	9/29/2023
Meropenem	1 box	9/29/2023
Enalapirilat Injection USP	2 vials	9/29/2023
Epinephrine Injection, USP	1 box	9/29/2023
Lidocaine Hydrochoride Jelly USP	3 packs	9/29/2023
Sodium Bicarbonate Injection USP	3 vials	9/29/2023
DOPamine HCI Inj. USP	3 vials	9/29/2023
Calcium Gluconate Injection USP	3 vials	9/29/2023
hydrALAZINE Hydrochloride Injection USP	3 vials	9/29/2023
Adenosine Injection USP	2 vials	9/29/2023
Phenytoin Sodium Injection USP	2 vials	9/29/2023

All in violation of 21 U.S.C. §§ 331(k), 352(f)(1), 353(b)(1), and 333(a)(2).

COUNT FOUR
21 U.S.C. §§ 331(k) and 333(a)(2)
(Misbranding of prescription drugs with intent to mislead and defraud)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about October 4, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, after shipment in interstate commerce, with intent to defraud and mislead, did any act to 40 vials of Humalin, a prescription drug, while held for sale, which resulted in the prescription drug being deemed misbranded, to wit: the prescription drug lacked adequate directions for use and was dispensed without a valid prescription. All in violation of 21 U.S.C. §§ 331(k), 352(f)(1), 353(b)(1),and 333(a)(2).

COUNT FIVE
18 U.S.C. § 670
(Theft of Pre-Retail Medical Products and Possessing, Transporting
And Trafficking in Stolen Pre-Retail Medical Products)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about September 29, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, using a means and facility of interstate commerce, while employed by an organization in the supply chain for a pre-retail medical product, did knowingly and intentionally embezzle, steal, and unlawfully take and carry away a pre-retail medical product, to wit: *Humulin* and did knowingly possess, transport, and traffic, and with intent to defraud did sell and distribute, a pre-

retail medical product, *Humulin*, that had been stolen, with the value of the medical products involved in the offense being greater than $5,000.

All in violation of 18 U.S.C. §§ 670(a)(1), (a)(3), (a)(5), (b)(1), (c)(2), and (c)(3).

COUNT SIX
18 U.S.C. § 670
(Theft of Pre-Retail Medical Products and Possessing, Transporting
And Trafficking in Stolen Pre-Retail Medical Products)

1. The General Allegations of this indictment are hereby re-alleged and incorporated by reference as though fully set forth herein.

2. On or about October 4, 2023, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla",

the defendant herein, using a means and facility of interstate commerce, while employed by an organization in the supply chain for a pre-retail medical product, did knowingly and intentionally embezzle, steal, and unlawfully take and carry away a pre-retail medical product, to wit: *Humulin* and did knowingly possess, transport, and with intent to defraud did sell and distribute, a pre-retail medical product, *Humulin*, that had been stolen, with the value of the medical products involved in the offense being greater than $5,000.

All in violation of 18 U.S.C. § § 670(a)(1), (a)(3), (a)(5), (b)(1), (c)(2), and (c)(3).

FORFEITURE ALLEGATION
21 U.S.C. § 334 and 28 U.S.C. § 2461
Seized Misbranded Drugs

1. The allegations of this Indictment are hereby re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America of certain property in which defendant, JORGE RIVERA-PEREZ, a/k/a "Jorge Pastilla", has an interest.

2. Upon conviction of any violation of Title 21, U.S.C., Section 331, as alleged in this indictment, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), the defendants shall forfeit to the United States any article of food, drug, device, or cosmetic that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce.

3. If any of the property described above, as a result of any act or omission of the defendant:

   a. cannot be located upon exercise of due diligence;
   b. has been transferred or sold to, deposited with a third party;
   c. has been placed beyond the jurisdiction of the Court;
   d. has been substantially diminished in value; or
   e. has been commingled with other property which cannot be subdivided without difficulty;

the United States shall be entitled to the forfeiture of substitute property under the provisions of Title 21, U.S.C., Section 853(p), as incorporated by 28 U.S.C. § 2461(c).

TRUE BILL

[redacted]
FOREPERSON

Date: September 19, 2024

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