IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	**CRIMINAL NO. 24-_____**
v.	**:**	**DATE FILED: _____**
MAURICIO SARMIENTO	**:**	**VIOLATION:**
	:	**21 U.S.C. §§ 331(a), 333(a)(2) (introducing misbranded drugs into interstate commerce – 1 count)**
	:	**Notice of forfeiture**

INFORMATION

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times relevant to this information:

1. The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"). Among the purposes of the FDCA was to assure that human drugs were safe, effective, and bore labeling containing only true and accurate information. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

2. Under the FDCA, drugs were defined as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man (21 U.S.C. § 321(g)(1)(B)); articles intended to affect the structure or any function of the body of man (21

U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

3. Certain drugs were prescription drugs under the FDCA, including: (a) those drugs which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drug; and (b) those drugs limited by an FDA-approved application to use under the professional supervision of a licensed medical practitioner (21 U.S.C. § 353(b)(1)(A), (B)).

4. Under the FDCA, it was a prohibited act to introduce or deliver for introduction, or to cause the introduction or delivery for introduction, into interstate commerce a drug that was misbranded (21 U.S.C. § 331(a)). Interstate commerce was defined in the FDCA as "commerce between any State or Territory and any place outside thereof" (21 U.S.C. § 321(b)(1)).

5. A drug was misbranded if, among other things, (a) its labeling failed to bear adequate directions for its use (21 U.S.C. § 352(f)(1)); (b) its labeling was false or misleading in any particular (21 U.S.C. § 352(a)); or (c) its labeling was in a foreign language (21 U.S.C. § 352(c); 21 CFR § 201.15 (c)).

6. By regulation, the FDA defined "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes for which it is intended" (21 C.F.R. § 201.5). Prescription drugs, by definition, could never contain adequate directions for lay use and were therefore misbranded unless they qualified for an exemption. By regulation, a prescription drug was exempt from Section 352(f)(1) if it met all enumerated conditions, including: (1) 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, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (2) the drug was to be dispensed in accordance with 21 U.S.C. § 353(b), *i.e.*, upon the order of a practitioner licensed by law to administer such drug (21 C.F.R. § 201.100 (a)(1), (2)). The label of the drug also must bear the statement "Rx only" and an identifying lot or control number from which it was possible to determine the complete manufacturing history of the drug (21 C.F.R. § 201.100 (b)(1), (6)). Drugs subject to the New Drug statute in the FDCA must bear labeling authorized by the approved new drug application (21 C.F.R. § 201.100(c)(2)).

7. Defendant MAURICIO SARMIENTO, a citizen and resident of Ecuador, provided "medical care" and prescription drugs to undocumented Ecuadorians residing in the United States. Defendant SARMIENTO was paid for his services by electronic funds transfer. Defendant SARMIENTO claimed that he was a physician in Ecuador. However, defendant SARMIENTO was not licensed to practice medicine and prescribe drugs in the United States.

8. Defendant MAURICIO SARMIENTO administered injections, intravenous vitamins, and other medical services to "patients" in the United States. Defendant SARMIENTO also offered "plasma" therapy whereby a patient's blood was drawn and spun in a centrifuge to separate platelets which were reinjected into the patient. Defendant SARMIENTO sold prescription drugs which were shipped to "patients" with handwritten instructions for administration.

9. From at least in or about January 2023 through in or about June 2024, defendant MAURICIO SARMIENTO, with the assistance of others known and unknown to the

United States Attorney, shipped prescription drugs from Ecuador to the United States to dispense to "patients." During this same period, defendant SARMIENTO "treated" patients in Queens and Brooklyn, New York, New Jersey, Easton, Pennsylvania, and elsewhere.

10. On or about September 10, 2024, in the Eastern District of Pennsylvania and elsewhere, defendant

MAURICIO SARMIENTO,

with the intent to defraud and mislead, introduced into interstate commerce, delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce from Ecuador to the Commonwealth of Pennsylvania, Drug 1, a prescription antibiotic, that was misbranded in that (i) its labeling failed to bear adequate directions for use, as required by Title 21, United States Code, Section 352(f); (ii) its labeling was in a foreign language (Spanish), in violation of Title 21, United States Code, Section 352(c); and (iii) it was dispensed without the prescription of a practitioner licensed by law to administer such drugs, in violation of Title 21, United States Code, Section 353(b), when the defendant advertised that he could provide medical services and administer prescription drugs in the United States even though he was not licensed to do so.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

NOTICE OF FORFEITURE

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

1. As a result of the violation of Title 21, United States Code, Sections 331(a) and 333(a)(2) set forth in this information, defendant

MAURICIO SARMIENTO

shall forfeit to the United States of America, any quantities of drugs which, on or about September 10, 2024, were misbranded when introduced into interstate commerce and may not, under the provisions of Title 21, United States Code, Section 331, be introduced into interstate commerce.

2. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or 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 divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

JACQUELINE C. ROMERO
UNITED STATES ATTORNEY

No. 24-

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania
Criminal Division

THE UNITED STATES OF AMERICA

vs.

MAURICIO SARMIENTO

INFORMATION

Count One

21 U.S.C. §§ 331(a), 333(a)(2)(introducing misbranded drugs into interstate commerce – 1 count)

Notice of Forfeiture

A true bill.

_____
Foreperson

Filed in open court this _____day,
Of _____A.D. 20_____

_____
Foreperson

Bail, $_____

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

INFORMATION

DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 504 W. Hamilton St., #3701, Allentown, PA 18101
Post Office: Allentown County: Lehigh

City and State of Defendant: Easton, Pennsylvania (native of Ecuador)

County: Northampton Register number: _____

Place of accident, incident, or transaction: Eastern District of Pennsylvania

Post Office: Easton County: Northampton

RELATED CASE, IF ANY:
Criminal cases are deemed related when the answer to the following question is "yes".

Does this case involve a defendant or defendants alleged to have participated in the same action or transaction, or in the same series of acts or transactions, constituting an offense or offenses?

YES/NO:
Case Number: Judge:

CRIMINAL: (Criminal Category - FOR USE BY U.S. ATTORNEY ONLY)

1. ○ Antitrust
2. ○ Income Tax and other Tax Prosecutions
3. ○ Commercial Mail Fraud
4. ○ Controlled Substances
5. ○ Violations of 18 U.S.C. Chapters 95 and 96 (Sections 1951-55 and 1961-68) and Mail Fraud other than commercial
6. ◉ General Criminal
   21 U.S.C. §§ 331(a), 333(a)(2)(introducing misbranded drugs into interstate commerce – 1 count)
   Notice of forfeiture

DATE: October 30, 2024

s/ John J. Boscia
John J. Boscia
Assistant United States Attorney

File No. 2023R00579
US v. Mauricio Sarmiento