

SEALED

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

Case No. 8:25-cr-438-KKM-SPF
18 U.S.C. § 371
18 U.S.C. § 545
21 U.S.C. § 331(i)(3), 333(a)(2)

SWAPNADIP ROY
a/k/a "Eric Roy"
and
VICKY RAMANCHA

SEALED

INDICTMENT

The Grand Jury charges:

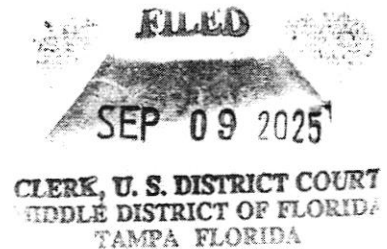
COUNT ONE
(Conspiracy)

At all times material to this Indictment:

A. Introduction

The Defendants

1. Defendant SWAPNADIP ROY, a/k/a Eric Roy, was a resident of Dubai, United Arab Emirates and a citizen of India.
2. Defendant VICKY RAMANCHA was a resident of Dubai, United Arab Emirates and a citizen of India.
3. Defendants ROY and RAMANCHA sold various products to customers in the United States and utilized several business entities to conduct their international trade operations.



The Food and Drug Administration's Regulation of the Prescription Drug Supply Chain

4. 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, among other things, enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*

FDCA Definitions

5. The term "drug" was defined under the FDCA to include articles that (1) were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; and (2) that were intended to affect the structure or any function of the body. 21 U.S.C. §§ 321(g)(1)(B) and (C).

6. The term "prescription drug" was defined under the FDCA to include "a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A).

7. The term "counterfeit drug" was defined under the FDCA as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to

have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.” 21 U.S.C. § 321(g)(2).

8. The term “suspect product” was defined under the FDCA as “a product for which there is reason to believe that such product:

- a. Is potentially counterfeit, diverted, or stolen;
- b. Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- c. Is potentially the subject of a fraudulent transaction; or
- d. Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.”

21 U.S.C. § 360eee(21).

9. The term “illegitimate product” was defined under the FDCA as “a product for which credible evidence shows that the product:

- a. Is counterfeit, diverted, or stolen;
- b. Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- c. Is the subject of a fraudulent transaction; or
- d. Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.”

21 U.S.C. § 360eee(8).

The Drug Supply Chain Security Act ("DSCSA")

10. The FDCA included specific requirements to enhance the security of the prescription drug supply chain in the United States and protect patients from counterfeit drugs. These requirements were added to the FDCA by the Drug Supply Chain Security Act ("DSCSA"), codified at 21 U.S.C. § 360eee, *et seq.* The DSCSA governed various aspects of prescription drug distribution, including product documentation, product labeling, and mandatory investigation and reporting requirements for "suspect" and "illegitimate" products.

DSCSA Documentation Requirements

11. Under the DSCSA, when a drug manufacturer transferred ownership of its product to another party in the supply chain, the manufacturer was required to provide the subsequent owner with detailed information about the product. 21 U.S.C. § 360eee-1(b)(1)(A)(i).

12. Specifically, a drug manufacturer was required to provide the subsequent owner with three categories of information — "transaction information," a "transaction history," and a "transaction statement" — in a single document. 21 U.S.C. § 360eee-1(b)(1)(A)(i). The "transaction information" included specific details about the type of product being sold, the name and address of the person from whom ownership was being transferred, and the name and address of the person to whom ownership was being transferred. 21 U.S.C. § 360eee(26). The "transaction history" was a statement that included the transaction information for each prior transaction going back to the manufacturer of the product. 21 U.S.C. § 360eee(25).

The “transaction statement” was a written confirmation (in paper or electronic form) that the entity transferring ownership was operating in compliance with requirements of the DSCSA, and did not knowingly provide false transaction information, or knowingly alter the transaction history. 21 U.S.C. § 360eee(27). The requirement for trading partners to provide a transaction history “sunset” on November 27, 2023. However, the requirement to provide transaction information and a transaction statement remained in effect after the sunset. *See* 21 U.S.C. § 360eee-1(k)(1).

13. In the United States prescription drug distribution industry, the document containing the “transaction information,” “transaction history,” and “transaction statement” was commonly referred to as a “T3.”

DSCSA Unique Serial Number Requirement

14. The DSCSA also included labeling requirements that protected the United States prescription drug supply chain from counterfeit drugs. For example, the DSCSA required drug manufacturers to include a “product identifier” on each package and homogenous case of a product intended for distribution. 21 U.S.C. § 360eee-1(b)(2)(A). The “product identifier” included a “standardized numerical identifier” with a unique alphanumeric serial number. 21 U.S.C. §§ 360eee(14), (20). The unique serial number requirement strengthened the ability of drug manufacturers and the FDA to identify suspect, illegitimate, and counterfeit drugs.

DSCSA Product Investigation and Reporting Requirements

15. The DSCSA also established requirements regarding the quarantine, disposition, and reporting of “suspect” and “illegitimate” products. *See* 21 U.S.C. §

360eee-1(b)(4) (requirements for manufacturers); 21 U.S.C. § 360eee-1(c)(4) (requirements for wholesalers); 21 U.S.C. § 360eee-1(d)(4) (requirements for dispensers); 21 U.S.C. § 360eee-1(e)(4) (requirements for repackagers).

Prohibited Acts and Penalties

16. Under the FDCA, failure to comply with the requirements of 21 U.S.C. § 360eee-1 was prohibited. 21 U.S.C. § 331(t). The FDCA also prohibited the sale, or the holding for sale, of counterfeit drugs. 21 U.S.C. § 331(i)(3).

17. A violation of 21 U.S.C. § 331(t) or 21 U.S.C. § 331(i)(3) was a misdemeanor unless it was committed with an intent to defraud or mislead, in which case it was a felony. 21 U.S.C. §§ 333(a)(1)-(2).

The National Association of Boards of Pharmacy

18. The National Association of Boards of Pharmacy (“NABP”) was a non-profit organization that worked to support prescription drug safety in the United States. One specific area of focus for the NABP was protecting the prescription drug supply chain. NABP offered a Drug Distributor Accreditation program for companies in the prescription drug supply chain, including companies that offered warehousing and logistics support for prescription drug distribution. A company seeking accreditation was required to undergo a supply chain inspection, which evaluated, among other things, the company’s procedures to protect the security of the prescription drug supply chain and the company’s compliance with the DSCSA.

The Counterfeit Drug

19. Ozempic was the brand name for an FDA-approved prescription drug manufactured by Novo Nordisk A/S ("Novo Nordisk"), a drug manufacturer based in Denmark. Ozempic contained the active ingredient semaglutide and was indicated to improve glycemic control in adults with type 2 diabetes mellitus. Ozempic was also approved to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and known heart disease. Ozempic was administered through an injection pen and was a prescription drug, and thus available only with a prescription.

20. Ozempic, although it lacked FDA-approval for weight loss, was popularly used for this purpose and was in high demand in the United States.

21. Defendants ROY and RAMANCHA distributed counterfeit Ozempic in interstate commerce to customers in the Middle District of Florida and elsewhere in the United States. ROY and RAMANCHA obtained counterfeit Ozempic from sources in China. The counterfeit Ozempic distributed by ROY and RAMANCHA included counterfeit containers (the outer packaging of the drug), counterfeit labeling, and counterfeit needles. Many units of the counterfeit Ozempic distributed by ROY and RAMANCHA did not include unique serial numbers. Instead, thousands of units displayed false and fraudulent serial numbers (including 430834149057, 460731416852, 406755318617, and 406964336774) on containers that were designed to mimic the packaging manufactured by Novo Nordisk for authentic Ozempic that was lawfully distributed in the United States. The containers

on the product distributed by ROY and RAMANCHA were not, in fact, manufactured by Novo Nordisk.

22. On December 21, 2023, the FDA issued a public notification warning that a counterfeit version of Ozempic had appeared in the United States supply chain. The FDA's warning stated that the counterfeit Ozempic discovered by the agency was labeled with lot number NAR0074 and serial number 430834149057.

B. Conspiracy

23. Paragraphs 1 through 22 of the preceding sections are re-alleged and incorporated by reference as though fully set forth herein.

24. From in or around July 2023, through in or around April 2024, in the Middle District of Florida and elsewhere, the defendants

SWAPNADIP ROY
a/k/a "Eric Roy"
and
VICKY RAMANCHA

did knowingly and voluntarily combine, conspire, confederate, and agree with each other and with others, both known and unknown to the Grand Jury, to commit offenses against the United States, specifically violations of 18 U.S.C. § 545, and to defraud the United States by interfering with, impairing, obstructing, and defeating the lawful functions of the United States Food and Drug Administration ("FDA") through deceit, craft, and trickery.

25. The objects of the conspiracy were the following:

(a) fraudulently and knowingly importing and bringing into the United States merchandise, specifically product labeled as "Ozempic," contrary to the documentation and unique serial number requirements of the Drug Supply Chain Security Act (21 U.S.C. § 360eee-1(b)(1)(A)(i) and 21 U.S.C. § 360eee-1(b)(2)(A)), in violation of 18 U.S.C. § 545;

(b) facilitating the transportation, concealment, and sale of product labeled as "Ozempic" after importation into the United States, knowing the same to have been imported and brought into the United States contrary to law, specifically the documentation and unique serial number requirements of the Drug Supply Chain Security Act (21 U.S.C. § 360eee-1(b)(1)(A)(i) and 21 U.S.C. § 360eee-1(b)(2)(A)), in violation of 18 U.S.C. § 545; and

(c) preventing the FDA from carrying out its function to enforce the laws that protect the United States prescription drug supply chain by: (1) concealing ROY and RAMANCHA's prescription drug distribution scheme to avoid detection by FDA; (2) encouraging participants in the scheme to ignore concerns about compliance with the law and the possibility of FDA enforcement; (3) warning individuals not to notify FDA about the scheme; and (4) continuing the scheme even after FDA seized the product and issued a public warning that the product was counterfeit, in violation of 18 U.S.C. § 371.

C. Manner and Means

26. The manner and means utilized by ROY, RAMANCHA, and coconspirators known and unknown to the Grand Jury to achieve the objects of the conspiracy included, among others, the following:

- (a) Obtaining product labeled as "Ozempic" from sources in China that were not authorized by Novo Nordisk to distribute Ozempic in the United States;
- (b) Selling the purported "Ozempic" from China to buyers in the United States at deeply discounted prices;
- (c) Storing the product in warehouses in the United States and distributing the product to the Middle District of Florida and elsewhere;
- (d) Concealing the role of ROY and RAMANCHA in the distribution scheme;
- (e) Attempting to maintain secrecy about the distribution scheme and limiting the distribution of the product;
- (f) Facilitating the distribution scheme by issuing warnings and threats; and
- (g) Enhancing secrecy and "security" around the distribution scheme after FDA seized product distributed by ROY and RAMANCHA and issued a public warning.

D. Overt Acts

27. In furtherance of the conspiracy and to effect the illegal objects thereof, ROY, RAMANCHA, and coconspirators known and unknown to the Grand Jury

committed and caused to be committed the following overt acts, among others, in the Middle District of Florida, and elsewhere:

(a) On or about July 12, 2023, RAMANCHA executed a Sales and Purchase Agreement with Company A, based in Lakeland, Florida, agreeing to supply Company A with product described as "Ozempic" at deeply discounted pricing.

(b) On or about August 18, 2023, RAMANCHA executed a Sales and Purchase Agreement with Company B, based in Sanford, Florida, agreeing to supply Company B with product described as "Ozempic Syringes" at deeply discounted pricing.

(c) On or about September 15, 2023, ROY and RAMANCHA facilitated the shipment of approximately 47 units of product labeled as "Ozempic" lot NAR0074, serial number 430834149057, to Company A, in Lakeland, Florida.

(d) On or about October 22, 2023, ROY urged Co-conspirator A in the United States to ignore compliance concerns and reminded him that he was obtaining product "cheap." ROY stated: "...see if you want the product cheap, you have to understand that there are some corners being cut..."

(e) On or about October 23, 2023, ROY urged Co-conspirator A to ignore concerns about FDA enforcement, stating: "it's not everyday FDA is going to come and look up your [expletive], you know, it's fine...."

(f) On or about November 1, 2023, Co-conspirator A warned ROY and RAMANCHA that the warehouse storing their product was under an audit by the

NABP. Co-conspirator A wrote: "Jesus the [expletive] NABP is auditing them...."

Co-conspirator A instructed ROY and RAMANCHA to postpone further deliveries until after the audit was complete, stating: "do not deliver the 5 cases until NABP is gone on Friday afternoon." RAMANCHA replied: "I am on it."

(g) On or about November 13, 2023, Co-conspirator A warned ROY to limit the distribution of the product, stating: "We can control this process and keep this alive for years but we need to make sure we are air tight. It's the plant I get it but this lands in the wrong hands and they will go looking." ROY responded: "They are already informed on it." Co-conspirator B stated: "Tell them we will buy all they have but they can't do this Fda will shut this down and everyone will be [expletive]."

(h) On or about November 15, 2023, ROY utilized threats to facilitate the distribution of product in the United States. Specifically, ROY wrote: "Listen i am not your friend okay? I am not that guy. I am the guy that will cut some one [expletive] headoff and [expletive] peoples dead wives corpse with it. You [expletive] up Solve the [expletive] problem Get the truck over there today [sic]."

(i) On or about November 19, 2023, Co-conspirator C warned RAMANCHA that identical serial numbers appeared on each unit of product distributed by RAMANCHA and ROY. Co-conspirator C wrote: "All pharmaceutical drugs in the US must be packaged with unique serial numbers, per the 2018 DSCSA requirements." Co-conspirator C also warned RAMANCHA that, "When a trading partner identifies any lack of compliance, the products will be

suspect and they are required, by law, to quarantine the product, and file report with the FDA on Form 3911.”

(j) On or about November 19, 2023, RAMANCHA forwarded a warning to several individuals, including Co-conspirator C, about reporting concerns to FDA. The warning stated: “we have to make sure that who ever you are engaging with is under NDA and keeps their mouth shut and dosent [sic] make any headache going to fda and this and that....If anyone makes too much noise then it will be very big problem [sic]....”

(k) On or about November 20, 2023, ROY and RAMANCHA facilitated the shipment of 1008 units of product labeled as “Ozempic” lot NAR0074, serial number 430834149057, to Company A in Lakeland, Florida.

(l) In or about December 2023, ROY and RAMANCHA became aware that FDA seized some of the product they distributed from warehouses in the United States. On or around December 7, 2023, RAMANCHA discussed the FDA seizure with affiliates of Company B, stating: “Looks bad on the factory if they don’t let the goods get taken. Best course of action.” Co-conspirator C replied: “Yes.” Co-conspirator D replied: “I agree. That also leaves everyone else out of the FDA crosshair.” RAMANCHA also stated: “So we are all on same page Nothing van [sic] ever go out.” Co-conspirator C replied that he was preparing “a document control procedure for your review and approval to make sure nothing like this ever happens again.”

(m) On or about December 21, 2023, RAMANCHA sent images of the FDA public warning regarding counterfeit Ozempic to affiliates of Company B. Co-conspirator E asked RAMANCHA whether the FDA warning would impact a pending order for 60,000 additional units of Ozempic. RAMANCHA replied, "Not at all. But you have to make sure your client [sic] are not being idiotic."

(n) On or about March 22, 2024, RAMANCHA explained to affiliates of Company B that the delivery of additional product was delayed due to "security." RAMANCHA wrote: "I was informed the product cleared customs couple days ago, and yes it was suppose [sic] to be delivered to you. However, again according to Chinese they are doing it on their own timetable for maximum security."

(o) On or about March 28, 2024, RAMANCHA caused and facilitated the delivery of approximately 11,000 units of counterfeit Ozempic to a warehouse in Ohio.

All in violation of 18 U.S.C. § 371.

COUNTS TWO THROUGH FOUR
(Smuggling)

28. The allegations contained in Section A of Count One of this Indictment are realleged and incorporated by reference as though fully set forth herein.

29. On or about the dates below, in the Middle District of Florida, and elsewhere, the defendants,

SWAPNADIP ROY
a/k/a "Eric Roy"
and
VICKY RAMANCHA

fraudulently and knowingly imported and brought into the United States merchandise contrary to the documentation and unique serial number requirements of the Drug Supply Chain Security Act (21 U.S.C. § 360eee-1(b)(1)(A)(i) and 21 U.S.C. § 360eee-1(b)(2)(A)), specifically product labeled as “Ozempic” lot NAR0074, serial number 430834149057, and facilitated the transportation, concealment, and sale of that product after importation into the United States, knowing the same to have been imported and brought into the United States contrary to law, specifically the documentation and unique serial number requirements of the Drug Supply Chain Security Act (21 U.S.C. § 360eee-1(b)(1)(A)(i) and 21 U.S.C. § 360eee-1(b)(2)(A)), as set forth below:

COUNT	PRODUCT	RECIPIENT	DELIVERED ON OR ABOUT
TWO	Approximately 47 units of product labeled as “Ozempic” lot NAR0074, serial number 430834149057	Company A, in Lakeland, Florida	September 15, 2023
THREE	Approximately 924 units of product labeled as “Ozempic” lot NAR0074, serial number 430834149057	Company A, in Lakeland, Florida	November 10, 2023
FOUR	Approximately 1008 units of product labeled as “Ozempic” lot NAR0074, serial number 430834149057	Company A, in Lakeland, Florida	November 20, 2023

All in violation of 18 U.S.C. §§ 545 and 2.

COUNTS FIVE THROUGH SIX
(Sale of Counterfeit Drugs)

30. The allegations contained in Section A of Count One of this Indictment are realleged and incorporated by reference as though fully set forth herein.

31. From in or around July 2023 through in or around December 2023, in the Middle District of Florida, and elsewhere, the defendants,

SWAPNADIP ROY
a/k/a "Eric Roy"
and
VICKY RAMANCHA

acting with an intent to defraud and mislead, sold and dispensed, and held for sale and dispensing, a counterfeit drug, specifically product labeled as "Ozempic" lot NAR0074, serial number 430834149057, that included containers and labeling that, without the authorization of Novo Nordisk, the manufacturer of the FDA-approved prescription drug Ozempic, bore the trademark, trade name, and other identifying marks of Novo Nordisk, and thereby falsely purported and represented to be the product of, and to have been packed and distributed by, Novo Nordisk, as set forth below:

COUNT	PRODUCT	RECIPIENT	DELIVERED ON OR ABOUT
FIVE	Approximately 84 units of counterfeit drugs labeled as "Ozempic" lot NAR0074, serial number 430834149057	Company B, in Sanford, Florida	November 10, 2023
SIX	Approximately 504 units of counterfeit drugs labeled as "Ozempic" lot NAR0074, serial number 430834149057	Company A, in Lakeland, Florida	December 7, 2023

All in violation of 21 U.S.C. §§ 331(i)(3) and 333(a)(2), and 18 U.S.C. § 2.

FORFEITURE

1. The allegations contained in Counts One through Six are incorporated by reference for the purpose of alleging forfeiture pursuant to 18 U.S.C. §§ 982(a)(2)(B) and 545, 21 U.S.C. § 334, and 28 U.S.C. § 2461(c).

2. Upon conviction of a violation of 18 U.S.C. § 545, or a conspiracy to violate section 545 (18 U.S.C. § 371), the defendant shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(2)(B): (a) any property constituting, or derived from, proceeds obtained, directly or indirectly, as a result of the offense; and (b) pursuant to 18 U.S.C. § 545 and 28 U.S.C. § 2461(c), any merchandise introduced into the United States in violation of § 545, or the value thereof.

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

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;

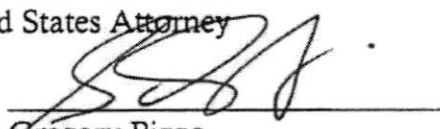
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b)(1) and 28 U.S.C. § 2461(c).

A TRUE BILL,

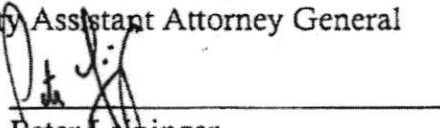

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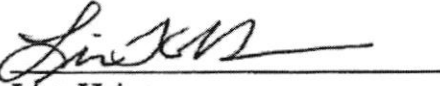
GREGORY W. KEHOE
United States Attorney

By: 
Gregory Pizzo
Assistant United States Attorney

By: 
Carlton C. Gammons
Assistant United States Attorney
Chief, Economic Crimes Section

JORDAN CAMPBELL
Deputy Assistant Attorney General

By: 
Peter Leisinger
Trial Attorney
Consumer Protection Branch
Department of Justice

By: 
Lisa Hsiao
Acting Director
Consumer Protection Branch
Department of Justice

No.

UNITED STATES DISTRICT COURT
Middle District of Florida
Tampa Division

THE UNITED STATES OF AMERICA

vs.

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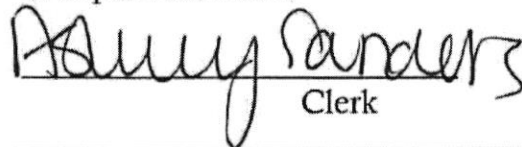
Violations: 18 U.S.C. § 371
18 U.S.C. § 545
21 U.S.C. § 331(i)(3), 333(a)(2)

A true bill,


Foreperson

Filed in open court this 9th day

of September 2025.


Clerk

Bail \$ _____
