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

UNITED STATES OF AMERICA,
Plaintiff,

v.

[1] ELBERTO BERDUT-TERUEL,
(Counts 1-7)
[2] WANDA L. CARBALLO-CABRERA,
(Counts 1-7)
[3] MARIA SANTOS-CARBALLO,
(Counts 1-7)
[4] MAGNETIC HEALER OF PR INC.,
(Counts 1-7)
Defendants.

INDICTMENT

CRIMINAL NO. 23-038(DRD)

VIOLATIONS:

COUNT ONE
Conspiracy to Introduce Adulterated and Misbranded Devices and to Adulterate and Misbrand Devices with Intent to Defraud and Mislead
18 U.S.C. § 371

COUNT TWO
Conspiracy to Commit Mail Fraud
18 U.S.C. § 1349

COUNTS THREE AND FOUR
Introduction of Adulterated Devices into Interstate Commerce with Intent to Defraud and Mislead
21 U.S.C. § 331(a)

COUNTS FIVE AND SIX
Introduction of Misbranded Devices into Interstate Commerce with Intent to Defraud and Mislead
21 U.S.C. § 331(a)

COUNT SEVEN
Alteration of a Device After Shipment in Interstate Commerce that Results in the Device Being Adulterated or Misbranded
21 U.S.C. § 331(k)

SEVEN COUNTS

THE GRAND JURY CHARGES:

GENERAL ALLEGATIONS

At all times material to this Indictment:

1. The United States Food and Drug Administration (FDA) is 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, 21 U.S.C. § 301-399f (the FDCA). One of the purposes of the FDCA is to ensure that devices and drugs sold for human use are safe and effective for their intended uses and bear labeling that contains true and accurate information and have adequate directions for use.

2. The FDCA defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

3. Devices are classified into one of three categories: Class I (lowest risk), Class II (moderate risk), and Class III (highest risk). 21 U.S.C. § 360c. A device's class determines the type of regulatory controls to which it is subject and any process

it must complete to obtain FDA approval prior to marketing and introduction into interstate commerce.

4. The FDCA defines a "prescription device" as "a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device . . . ." 21 C.F.R. § 801.109.

5. Pursuant to the FDCA, any device that was not in commercial distribution before May 28, 1976 is initially classified as a Class III device unless shown to be substantially equivalent to a legally marketed device. 21 U.S.C. § 360c(f)(1). Apart from certain devices that are exempt from premarket review, "new" devices that come on the market are automatically classified into Class III as a matter of law and require full premarket approval (PMA) by the FDA prior to marketing and use in the United States. 21 U.S.C. §§ 360c(f)(1) and 360e(a). The only way a manufacturer can remove a new device from the automatic, statutory Class III designation, and thereby avoid the PMA process is to obtain an order from the FDA, reclassifying the device into Class I or II (see 21 C.F.R. Part 860, Subpart C-Reclassification), or an order finding the new device "substantially equivalent" to a legally marketed ("predicate") device that does not require PMA (also known as the "510(k)" notification, as described below). 21 U.S.C. §§ 360c(f), 360e(a), and (b); 21 C.F.R. §§ 807.92 and 807.100.

6. Thus, a device classified as Class III is required under 21 U.S.C. § 360e(a)(2) to have an FDA approved application for PMA before the device may be

distributed in interstate commerce, unless, it is a new device that is substantially equivalent to a predicate device, and before the introduction into interstate commerce, the manufacturer files a 510(k) premarket notification to the FDA, as required by 21 U.S.C. § 360(k) and 21 C.F.R. § 807.81(a)(1), and obtains a 510(k) clearance.

7. An approved PMA means that the FDA approved the device after a lengthy application and evaluation process, during which the manufacturer demonstrated that the device was safe and effective when used in accordance with its labeling. 21 CFR § 814.44. In contrast, a 510(k) clearance means that the FDA cleared the device for distribution based on a demonstration that the device is "substantially equivalent" to another device that has gone through the PMA process (a "predicate device"). 21 C.F.R. § 807.92. Before the device can be legally marketed, each 510(k) submitter must receive an order from the FDA which finds the device to be "substantially equivalent" to a predicate device, and states that the device can be marketed in the United States. 21 C.F.R. § 807.100. This order "clears" the device for commercial distribution. *Id.*; *cf.* 21 C.F.R. § 807.97.

8. A device can be adulterated, misbranded, or both.

9. A device is adulterated if it is a Class III device pursuant to 21 U.S.C. § 360c(f) and was required under 21 U.S.C. § 360e(a) to have in effect an approved PMA, but does not have such an approval in effect. 21 U.S.C. § 351(f)(1).

10. A device is misbranded if, among other things, it was required to have a 510(k) premarket notification by the manufacturer and is being exchanged in

interstate commerce without an order from the FDA clearing the device for commercial distribution in the United States. 21 U.S.C. § 352(o).

11. A device can also be misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a).

12. A device is also misbranded if its labeling lacks adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" mean directions under which a layman can use a device safely for the purposes for which it is intended without a licensed practitioner's supervision. 21 C.F.R. § 801.5. Since prescription devices, by definition, are only safe under the supervision of a licensed practitioner, there are no directions that could enable a layman to use a prescription device safely. Therefore, a prescription device is also misbranded if, at a minimum, it is dispensed without a valid prescription. 21 C.F.R. § 801.109; *cf.* 21 U.S.C. § 352(f).

13. A device is also misbranded if its labeling fails to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as is necessary for the protection of its users. 21 U.S.C. § 352(f)(2).

14. The term "label" is defined in the FDCA as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). In turn, "labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

15. The FDCA prohibits, among other things, to knowingly introduce and deliver and caused to be introduced and delivered into interstate commerce a device that is misbranded or adulterated, pursuant to 21 U.S.C. § 331(a).

16. The FDCA defines "interstate commerce" as (1) commerce between any State or Territory and any place outside thereof and (2) commerce within the District of Columbia or within any other territory not organized with a legislative body. 21 U.S.C. § 321(b).

17. **[4] MAGNETIC HEALER OF PR INC.** (Magnetic Healer) was a company incorporated on May 5, 2014 which sold devices with magnets.

18. The devices sold by Magnetic Healer were not in commercial distribution before May 28, 1976, and, as such, they were Class III devices which were required to have in effect an approved PMA.

19. There were no approved PMAs and 510(k) premarket notifications or clearances or both for the devices sold by Magnetic Healer.

20. Magnetic Healer's registered physical address was Progreso Street #54 Corona Office Park, San Juan, PR 00909 with a mailing address of P.O. Box 8787, Fernandez Juncos Station, San Juan, PR 00910-8787.

21. **[1] ELBERTO BERDUT-TERUEL** was the president, secretary, treasurer, and resident agent of Magnetic Healer.

22. **[2] WANDA L. CARBALLO-CABRERA** was an employee of Magnetic Healer.

23. **[3] MARIA SANTOS-CARBALLO** was an employee of Magnetic Healer.

24. Magnetic Healer promoted its devices through social media and several websites including, www.elbertoberdut.com and www.magneticbiotherapy.com.

25. The Magnetic Healer devices were sold online, in websites, which included www.magnetic-healer.myshopify.com and www.magneticbiotherapy.com, and at Magnetic Healer's physical address.

COUNT ONE
18 U.S.C. § 371
(Conspiracy to Introduce Adulterated and Misbranded Devices and to Adulterate and Misbrand Devices)

The allegations in paragraphs 1-25 are incorporated here.

Beginning in or about 2017 and continuing up to and until the date of the return of the instant Indictment, in the District of Puerto Rico and elsewhere, the defendants,

[1] ELBERTO BERDUT-TERUEL,
[2] WANDA L. CARBALLO-CABRERA,
[3] MARIA SANTOS-CARBALLO,
[4] MAGNETIC HEALER OF PR INC.,

did knowingly, intentionally, and unlawfully combine, conspire, confederate, and agree with each other, to commit the following offenses against the United States:

a) To knowingly introduce and deliver for introduction and cause to be introduced and delivered into interstate commerce, with the intent to

defraud and mislead, devices that were adulterated, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2);

b) To knowingly introduce and deliver for introduction and cause to be introduced and delivered into interstate commerce, with the intent to defraud and mislead, devices that were misbranded, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2);

c) To knowingly alter and cause acts to be done to devices after shipment in interstate commerce, with intent to defraud and mislead, resulting in the device being adulterated, in violation of 21 U.S.C. §§ 331(k) and 333(a)(2); and

d) To knowingly alter and cause acts to be done to devices after shipment in interstate commerce, with intent to defraud and mislead, resulting in the devices being misbranded, in violation of 21 U.S.C. §§ 331(k) and 333(a)(2).

Means and Methods of the Conspiracy

26. It was part of the conspiracy that the defendants would unlawfully enrich themselves by using Magnetic Healer to sell devices containing magnets ("healing magnets") which were advertised as being effective in the cure, mitigation, treatment, and prevention of diseases in humans, which included COVID-19, migraines, depression, insomnia, Parkinson's disease, Alzheimer's disease, autism, and cancer, among others. The devices were Class III devices that were adulterated and misbranded. The devices were misbranded within the meaning of 21 U.S.C. § 352(a), (f), and (o) in the following ways:

a) The devices did not have the required 510(k) premarket notifications and approval from FDA for marketing and distribution;

b) The labeling was false and misleading;

c) The labeling failed to bear adequate directions for use; and

d) The labeling failed to bear adequate warnings.

The devices were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) because they were Class III devices which were required to have in effect an approved PMA, but did not have such an approval in effect.

27. It was further part of the conspiracy that the parts for the devices would be obtained via the mail from vendors outside of Puerto Rico

28. It was further part of the conspiracy that the devices would be assembled in Puerto Rico.

29. It was further part of the conspiracy that, with intent to defraud and mislead, acts were to be done to devices, while the devices were held for sale, after components of the devices had been shipped in interstate commerce, which acts would result in the devices being adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(a), (f), and (o).

30. It was further part of the conspiracy that the devices would be promoted in social media and websites.

31. It was further part of the conspiracy that the defendants would claim that the devices did not require FDA approval; had been submitted for FDA approval; and were FDA Authorized, using an official "FDA authorized" logo.

32. It was further part of the conspiracy that the defendants would sell the devices online, in websites, and at Magnetic Healer's physical address.

33. It was further part of the conspiracy that payments were received for the devices via PayPal.

34. It was further part of the conspiracy that the devices would be sent via mail to the customers that purchased the devices online.

Overt Acts

For the purpose of carrying out the conspiracy and to effect the objects thereof, the following overt acts among others, were committed by the defendants within the District of Puerto Rico, and elsewhere:

a) On or about October 19, 2020, the defendants caused a Kidney and Pulmonary Cancer Device to be mailed from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico, 00910-8787.

b) On or about October 19, 2020, the defendants caused a Leukemia and Blood Cancer Device to be mailed from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico 00910-8787.

c) On or about August 19, 2022, the defendants caused one Antivirus and Bacterial Device to be sold at the Magnetic Healer's physical address.

All in violation of 18 U.S.C. § 371.

COUNT TWO
18 U.S.C. § 1349
(Conspiracy to Commit Mail Fraud)

The allegations in paragraphs 1-34 are incorporated here.

Beginning in or about 2017 and continuing up to and until the date of the return of the instant Indictment, in the District of Puerto Rico and elsewhere, the defendants,

[1] ELBERTO BERDUT-TERUEL,
[2] WANDA L. CARBALLO-CABRERA,
[3] MARIA SANTOS-CARBALLO,
[4] MAGNETIC HEALER OF PR INC.,

did knowingly combine, conspire, and agree with each other and with other persons known and unknown to commit the following offense: devise and intend to devise a scheme and artifice to defraud and willfully participated in, with knowledge of its fraudulent nature, for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, and for the purpose of executing the scheme and artifice and attempting to do so knowingly deposited and caused to be deposited mail matter to be sent and delivered by a private and commercial interstate carrier, in violation of 18 U.S.C. § 1341.

Purpose and Object of the Conspiracy

The purpose and object of the conspiracy in this Count was to devise and intend to devise a scheme and artifice to defraud and willfully participated in it, with knowledge of its fraudulent nature for obtaining money and property belonging to customers purchasing devices sold by Magnetic Healer by means of materially false

and fraudulent pretenses, representations, and promises. The purpose and object of the conspiracy involved violations of 18 U.S.C. § 1341.

All in violation of 18 U.S.C. §§ 1341 and 1349.

COUNTS THREE AND FOUR
21 U.S.C. § 331(a)
(Introduction of Adulterated Devices into Interstate Commerce with Intent to Defraud and Mislead)

The allegations in paragraphs 1-34 are incorporated here.

On or about the dates listed below, in the District of Puerto Rico and within the jurisdiction of this Court, the defendants,

[1] ELBERTO BERDUT-TERUEL,
[2] WANDA L. CARBALLO-CABRERA,
[3] MARIA SANTOS-CARBALLO,
[4] MAGNETIC HEALER OF PR INC.,

aiding and abetting each other, with intent to defraud and mislead, did knowingly introduce and deliver and caused to be introduced and delivered into interstate commerce devices that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) as more fully described below:

Count	Date of Mailing	Adulterated Device	Introduction into Interstate Commerce
3	October 19, 2020	Kidney and Pulmonary Cancer Device	Via Postal Service from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico, 00910-8787
4	October 19, 2020	Leukemia and Blood Cancer Device	Via Postal Service from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico 00910-8787

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

COUNTS FIVE AND SIX
21 U.S.C. § 331(a)
(Introduction of Misbranded Devices into Interstate Commerce with Intent to Defraud and Mislead)

The allegations in paragraphs 1-34 are incorporated here.

On or about the dates listed below, in the District of Puerto Rico and within the jurisdiction of this Court, the defendants,

[1] ELBERTO BERDUT-TERUEL,
[2] WANDA L. CARBALLO-CABRERA,
[3] MARIA SANTOS-CARBALLO,
[4] MAGNETIC HEALER OF PR INC.,

aiding and abetting each other, with intent to defraud and mislead, did knowingly introduce and deliver and caused to be introduced and delivered into interstate commerce devices that were misbranded within the meaning of 21 U.S.C. § 352(a), (f), and (o) as more fully described below:

Count	Date of Mailing	Misbranded Device	Introduction into Interstate Commerce
5	October 19, 2020	Kidney and Pulmonary Cancer Device	Via Postal Service from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico, 00910-8787
6	October 19, 2020	Leukemia and Blood Cancer Device	Via Postal Service from P.O. Box 8787, Fernandez Juncos Station, San Juan, Puerto Rico 00910-8787

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

COUNT SEVEN
21 U.S.C. § 331(k)
(Alteration of a Device After Shipment in Interstate Commerce that Results in the Device Being Adulterated or Misbranded)

The allegations in paragraphs 1-34 are incorporated here.

Between at least April 2020 and September 2022, in the District of Puerto Rico and within the jurisdiction of this Court, the defendants,

[1] ELBERTO BERDUT-TERUEL,
[2] WANDA L. CARBALLO-CABRERA,
[3] MARIA SANTOS-CARBALLO,
[4] MAGNETIC HEALER OF PR INC.,

aiding and abetting each other, with intent to defraud and mislead, did cause acts to be done to devices, while the devices were held for sale, after components of the device had been shipped in interstate commerce, which acts resulted in the device being adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(a), (f), and (o).

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

FORFEITURE ALLEGATION

The allegations contained in Count Two of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c).

Upon conviction of the violation of 18 U.S.C. § 1349 set forth in Count Two of this Indictment, the defendants, **[1] ELBERTO BERDUT-TERUEL, [2] WANDA L. CARBALLO-CABRERA, [3] MARIA SANTOS-CARBALLO,** and

[4] MAGNETIC HEALER OF PR INC. shall forfeit to the United States of America, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offense. The property to be forfeited includes, but is not limited to, the following: $327,047.56.

If any of the property described above, 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, the United States of America shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c).

All pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c).

TRUE BILL,

[redacted]

Date: January 1, 2023

W. STEPHEN MULDROW
United States Attorney

SETH ERBE Digitally signed by SETH ERBE Date: 2023.01.30 14:22:15 -04'00'

Seth A. Erbe
Assistant U.S. Attorney
Chief, Financial Fraud and
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VICTOR ACEVEDO-HERNANDEZ Digitally signed by VICTOR ACEVEDO-HERNANDEZ Date: 2023.01.30 09:45:10 -04'00'

Victor O. Acevedo-Hernandez
Assistant U.S. Attorney