FILED

UNITED STATES DISTRICT COUR TOI7 JUN 14 PH 4:00 MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

UNITED STATES OF AMERICA

v.

CASE NO .: 8:17-cr- 301 T24 AAS

RICHARD DAVID MARTIN a/k/a "Doctor Martin" a/k/a "Doctor Rick" 18 U.S.C. § 371 18 U.S.C. § 1341 42 U.S.C. § 1320a-7b(b)

INDICTMENT



The Grand Jury charges:

COUNT ONE (Conspiracy—18 U.S.C. § 371)

A. Introduction

At times material to this Indictment:

The Medicare Program

1. The Medicare program ("Medicare") was a federal health care

program as defined by 42 U.S.C. § 1320a-7b(f), and a health care benefit

program, as defined by 18 U.S.C. § 24(b), that provided medical benefits,

items, and services (collectively "services") to beneficiaries:

- (a) age 65 or older,
- (b) under age 65 with certain disabilities, and
- (c) of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).

2. The Centers for Medicare and Medicaid Services ("CMS") was an agency of the U.S. Department of Health and Human Services ("DHHS"), and was the federal governmental body responsible for the administration of Medicare.

3. Medicare included coverage under component parts. Medicare Part A was a hospital insurance program that covered beneficiaries for, among other types of care, inpatient care in hospitals and other facilities. Medicare Part B was a supplemental medical insurance program that covered doctors' services, outpatient care, and some other medical services not covered under Part A.

<u>Dermagraft</u>

4. Advanced BioHealing, Inc. ("ABH"), was a biopharmaceutical company that developed and commercialized bioengineered tissue products and regenerative medicine therapies. ABH was headquartered in Westport, Connecticut, and operated a manufacturing plant and training facility in La Jolla, California.

5. During 2011, Shire PLC, a United Kingdom specialty biopharmaceuticals group, acquired ABH and operated the company as a wholly owned subsidiary under the name Shire Regenerative Medicine, Inc.

6. Dermagraft was a bioengineered skin substitute approved by the United States Federal Drug Administration ("FDA") solely for the treatment of diabetic foot ulcers. In or about 2006, ABH acquired the rights to Dermagraft and began selling the product to United States customers, such as treating physicians.

7. As approved by the FDA, ABH supplied Dermagraft in a frozen, single-use application consisting of a clear bag containing one piece of 38 square centimeters.

8. Medicare used a system of codes to document treatment covered and paid for by Medicare. These Healthcare Common Procedure Coding System codes, or "HCPCS" codes, were found in the local coverage determinations (called LCDs), including for, among other things, skin substitutes, such as Dermagraft. The HCPCS code for an application of Dermagraft applied to a beneficiary was Q4106. Medicare billing codes, however, could be modified. For example, when a physician or non-physician provider (sometimes called an NPP) applied only part of the single-use application of Dermagraft to the beneficiary, the remainder, known as "wastage," was also reported to Medicare using a modifier. Thus, Medicare was being billed for and paid on a "per square centimeter" basis for the singleuse application of Dermagraft, tracking what was applied to the beneficiary

and what was wasted. In that way, Medicare would pay a physician or nonphysician provider for the entire single-use application.

9. The treating physician was permitted to submit an additional bill to Medicare for the preparation and application of Dermagraft on a Medicare beneficiary, using certain application codes that varied depending upon the date of service. Because Dermagraft and other like products were considered a physician service, Dermagraft was required to be applied by either a physician or a non-physician provider, and not by non-advance practice nurses, therapists, or medical assistants.

10. The LCD explained that for Medicare to consider the use of Dermagraft medically reasonable and necessary, and so cover its usage, it was necessary that all of the following conditions be met:

- (a) The patient had documented type 1 or type 2 diabetes and was then receiving medical management for this condition;
- (b) The full thickness diabetic foot ulcer had been present for a minimum of six weeks duration;
- (c) The ulcer had failed to respond to conservative measures such as non-weight bearing regiment, debridement of necrotic and callused tissue, and acceptable methods of wound care;
- (d) The ulcer extended through the dermis, but did not involve tendon, muscle, joint capsule, or have bone exposure; and

(e) The patient had adequate arterial blood supply to the foot in order to support tissue growth as evidenced by a palpable pulse on the foot.

The LCD also described certain medical record documentation 11. that the treating provider was required to maintain to substantiate the medical necessity of any services billed to Medicare, including services relating to the use of Dermagraft. Thus, for a treating physician to properly bill Medicare for the use and application of Dermagraft on a Medicare Part B beneficiary, the treating physician was required to document in the medical record of the beneficiary, among other information, that: (a) the service was performed, and (b) certain other criteria listed under the "Indications and Limitations of Coverage and/or Medical Necessity" sections within the LCD were met. These criteria included, among others, a description of the wound prior to beginning treatment relative to size, location, stage, and duration, which description was required to be updated throughout the treatment process. The LCD utilization guidelines limited the use of Dermagraft to no more than 8 applications per treatment site over a 12-week period.

Participants

12. Dr. Harvey A. Pearl (or "Pearl") was a Florida-licensed doctor of podiatric medicine, or a "D.P.M." As a D.P.M., Pearl specialized in the prevention, diagnosis, and treatment of foot and ankle disorders, diseases, and

injuries. In his Florida practice, Pearl frequently rendered services to Medicare beneficiaries and electronically presented claims for payment to Medicare for those services. One of the services routinely provided by Pearl to Medicare beneficiaries was the treatment of diabetic foot ulcers using Dermagraft.

13. In or about late 2008, ABH hired the defendant, Richard David Martin, hereinafter "Martin," to market and sell ABH products, including Dermagraft, as a sales representative. Martin was not a doctor or an nonphysician provider. On or about November 22, 2010, ABH banned Martin from entering into any Diversified Clinical Services clinics for a minimum period of ninety days.

B. The Agreement

14. Beginning on an unknown date, but by in or about late 2010, and continuing through on or about June 19, 2012, in the Middle District of Florida, and elsewhere, the defendant,

RICHARD DAVID MARTIN, a/k/a "Doctor Martin," a/k/a "Doctor Rick,"

did knowingly and willfully combine, conspire, confederate, and agree together and with other persons both known and unknown to the grand jury, including Pearl, to:

(a) defraud the United States out of money and property and

by impeding, impairing, obstructing, and defeating the lawful functions of the DHHS, through its agency the CMS in the administration of the Medicare Part B, by deceit, craft, and trickery; and

- (b) commit the following offenses against the United States:
 - (i) mail fraud, in violation of Title 18, United States Code, Section 1341;
 - (ii) health care fraud, in violation of Title 18, United States Code, Section 1347;
 - (iii) soliciting and receiving remuneration, in violation of 42 U.S.C. § 1320a-7b(b)(1); and
 - (iv) offering and paying remuneration, in violation of 42 U.S.C. § 1320a-7b(b)(2).

C. The Manner and Means

15. The manner and means by which Martin and others sought to accomplish the objects of the conspiracy included, among others, the following:

(a) It was a part of the conspiracy that a conspirator would and did order and cause to be ordered Dermagraft from ABH to be delivered to or for Pearl's office for use on Medicare Part B beneficiaries, among others;

(b) It was further part of the conspiracy that a conspirator would and did routinely divide one single-use application of Dermagraft into multiple sections for application on multiple Medicare Part B beneficiaries, notwithstanding that Dermagraft was FDA-approved as a single-use skin substitute, while fraudulently billing Medicare as if one complete graft, that is 38 square centimeters, of Dermagraft was used to treat each of the beneficiaries;

(c) It was further part of the conspiracy that Pearl would and did routinely bill Medicare as if Pearl or a non-physician provider had prepared and applied the Dermagraft on a Medicare beneficiary when, in truth and in fact, on occasion the Dermagraft had been prepared and applied to a beneficiary by conspirator Martin, a non-qualifying person;

(d) It was further part of the conspiracy that, in return for Pearl's purchase and use of Dermagraft, conspirator Martin would and did offer and pay remuneration to Pearl's medical practice directly and/or indirectly in various forms including, but not limited to, free office medical supplies, free Dermagraft samples, multiple meals and other consumables, and uncompensated medical office procedures and services;

(e) It was further part of the conspiracy that conspirator Martin and/or Pearl's medical practice caused to be used the U.S. Mail and/or a private or commercial interstate carrier, such as United Parcel Service, Inc., to receive Dermagraft orders from California; and

(f) It was further part of the conspiracy that conspirators would and did participate in meetings, perform various acts, and make statements to accomplish the objects of the conspiracy and to conceal the conspiracy.

D. Overt Acts

16. In furtherance of the conspiracy and to effect its objects, the following overt acts, among others, were committed by Martin or other co-conspirators in the Middle District of Florida, and elsewhere:

(a) On or about November 29, 2010, a conspirator ordered, or caused to be ordered (order no. SR81581), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice;

(b) On or about December 17, 2010, a conspirator ordered, or caused to be ordered (order no. SR86449), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice;

(c) On or about May 20, 2011, a conspirator ordered, or caused to be ordered (order no. SA39161), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice;

(d) On or about July 15, 2011, a conspirator ordered, or caused to be ordered (order no. SA57102), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice;

(e) On or about January 6, 2012, a conspirator ordered, or caused to be ordered (order no. SB25421), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice; and

(f) On or about June 15, 2012, a conspirator ordered, or caused to be ordered (order no. SB80731), one or more Dermagraft unit(s) from ABH for use in Pearl's medical practice.

In violation of Title 18, United States Code, Section 371.

COUNT TWO (Mail Fraud—18 U.S.C. § 1341)

A. Introduction

1. The Grand Jury hereby realleges and incorporates by reference paragraphs 1 through 13 in the Introduction section of Count One of this Indictment as though fully set forth herein.

B. The Scheme

2. Beginning on an unknown date, but by in or about late 2010, and continuing through on or about June 19, 2012, within the Middle District of Florida, and elsewhere, the defendant,

RICHARD DAVID MARTIN, a/k/a "Doctor Martin," a/k/a "Doctor Rick," did knowingly and willfully devise and intend to devise a scheme and artifice to defraud and for obtaining money and property by materially false and fraudulent pretenses, representations, and promises.

C. Manner and Means

3. The Grand Jury realleges and incorporates by reference

paragraph 15(a) through 15(f) in the Manner and Means section of Count One as though fully set forth herein.

D. The Execution of the Scheme

4. On or about June 15, 2012, within the Middle District of Florida and elsewhere, for the purpose of executing and attempting to execute the scheme and artifice to defraud and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises,

RICHARD DAVID MARTIN, a/k/a "Doctor Martin," a/k/a "Doctor Rick,"

defendant herein, aided and abetted by others and aiding and abetting others, did knowingly and willfully cause to be delivered by mail and any private and commercial interstate carrier, according to the direction thereon, and at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter and thing, that is, a parcel containing one or more Dermagraft unit(s) sent from California to a location in Florida.

In violation of Title 18, United States Code, Sections 1341 and 2.

FORFEITURES

 The allegations contained in Counts One and Two of this
Indictment are hereby re-alleged and incorporated by reference for the purpose of alleging forfeitures pursuant to the provisions of Title 18, United States
Code, Section 982(a)(7).

2. Upon conviction of any or all of the violations alleged in Counts One and Two of this Indictment, punishable by imprisonment by more than one year,

RICHARD DAVID MARTIN, a/k/a "Doctor Martin," a/k/a "Doctor Rick,"

defendant herein, shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property constituting or derived from the proceeds obtained, directly or indirectly, as the result of such violations.

3. The property to be forfeited includes, but is not limited to, a forfeiture money judgment in an amount representing the proceeds obtained as a result of the violations.

4. 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 under the provisions of Title 21, United States Code, Section 853(p),

as incorporated by Title 18, United States Code, Section 982(b)(1).

A TRUE BILL,

roreperson

W. STEPHEN MULDROW Acting United States Attorney

By:

Jay G. Trezevant

Jay G. Trezevant Assistant United States Attorney

By:

Thomas N. Palermo Assistant United States Attorney

By:

Simon A. Gaugush Assistant United States Attorney Chief, Economic Crimes Section June 17

FILED

UNITED STATES DISTRICT COURT Middle District of Florida Tampa Division

2017 JUN 14 PM 5: 10

CLERK. US DISTRICT COURT MIDDLE DISTRICT FLORIDA TAMPA, FLORIDA

THE UNITED STATES OF AMERICA

VS.

RICHARD DAVID MARTIN a/k/a "Doctor Martin" a/k/a "Doctor Rick"

INDICTMENT

Violations: 18 U.S.C. § 371

A true bill.

No.

Foreperson

Filed in open court this <u>14th</u> day

of June 2017.

Clerk

Bail \$_