Presented to the Court by the foreman of the Grand Jury in open Court, in the presence of the Grand Jury and FILED in the U.S. DISTRICT COURT at Seattle, Washington
August 5, 2020
WILLIAM M. McCOOL, Clerk
By _____ Deputy

UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA,

Plaintiff

v.

RICHARD MARSCHALL,

Defendant.

NO. CR20-5270 RJB

INDICTMENT

The Grand Jury charges that:

A. INTRODUCTION

At all times relevant to this Indictment:

1. The Food, Drug and Cosmetic Act (hereafter "FDCA") provided the regulatory scheme governing the manufacture and distribution of foods, drugs, medical devices, biologicals, and cosmetics in the United States. In addition to creating requirements for these products, the FDCA also prohibited certain acts pertaining to these products.

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

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3. Under the FDCA, "label" meant 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). Among other things, internet websites from which an article could be obtained or which were associated with the manufacturers or distributors of the article could be labeling for that article.

4. Under the FDCA, "drugs" were defined as, among other things, any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (C).

5. The "intended use" of an article meant the objective intent of the persons legally responsible for its labeling. The intent was determined by such persons' expressions, or could be shown by the circumstances surrounding the distribution of the article. It could, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives; or by the circumstances in which the article was, with the knowledge of such persons or their representatives, offered and used for a purpose for which it was neither labeled nor advertised. The intended uses of an article could change after it was introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intended an article for different uses than those intended by the person from whom she received the article, such packer, distributor, or seller was required to supply adequate labeling in accordance with the new intended uses. 21 C.F.R § 201.128.

6. Under the FDCA, a "prescription drug" was, among other things, a drug which, because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, was not considered safe for use except under the supervision of a practitioner licensed by State law to administer such drugs. 21 U.S.C. § 353(b)(1)(A).

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7. A prescription drug could only be lawfully dispensed to a patient or consumer upon the valid prescription of a practitioner licensed by State law to dispense prescription drugs. The act of dispensing a prescription drug without a valid prescription was deemed an act which resulted in the drug being misbranded while held for sale. 21 U.S.C. § 353(b)(l).

8. Under the FDCA, every person, upon first engaging in the manufacture, preparation, propagation, compounding, or processing of drugs in any establishment they owned or operated was required to immediately register their name, places of business, and all such establishments. 21 U.S.C. § 360(c). The terms "manufacture, preparation, propagation, compounding, or processing" included repackaging or otherwise changing the container, wrapper, or labeling of any drug in furtherance of the distribution of the drug from the original place of manufacture to the person who made the final sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1).

9. A drug was misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with FDA, or if it was not included in a list of drugs manufactured by a facility registered with FDA. 21 U.S.C. § 352(o).

10. A drug was misbranded if, among other things, its labeling was false or misleading in any particular. 21 U.S.C. § 352(a).

11. A drug was also misbranded if the labeling on the drug did not bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" were defined as directions under which a layperson could use a drug safely for the purposes for which it was intended without a doctor's supervision. Directions under which a layperson could use a drug safely could not be written for a prescription drug because such drugs could, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner. Prescription drugs dispensed pursuant to a valid prescription were exempt from the requirement for adequate directions for use by a layperson. But prescription drugs dispensed without a valid prescription were

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necessarily misbranded for lacking adequate directions for use. 21 U.S.C. § 353(b); 21 C.F.R. § 201.5.

12. Under the FDCA, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded drug was prohibited. 21 U.S.C. § 331(a).

B. RICHARD MARSCHALL'S LICENSES AND PRIOR CONVICTIONS

13. Defendant RICHARD MARSCHALL was licensed as a naturopathic physician by the Washington Department of Health on August 26, 1986.

14. On September 26, 2011, RICHARD MARSCHALL was convicted in the Western District of Washington of introducing a misbranded drug into interstate commerce with the intent to defraud and mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

15. On November 20, 2013, RICHARD MARSCHALL's naturopathic physician's license was suspended indefinitely by the State of Washington Department of Health due, in part, to the above-described felony conviction.

16. On October 20, 2017, RICHARD MARSCHALL was convicted in the Western District of Washington of introducing a misbranded drug into interstate commerce after a previous conviction under 21 U.S.C. § 331 had become final, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

17. On October 9, 2018, RICHARD MARSCHALL's credential to practice as a naturopathic physician in the state of Washington was permanently revoked, with no right to reapply, by the Washington Secretary of Health, based on a finding that he "cannot be rehabilitated, nor can he regain the ability to practice with reasonable skill and safety" and finding as aggravating factors the "Gravity of the unprofessional conduct. . . . Failure to comply with multiple Agreed Orders, and state and federal court orders. . . . [and the] Number or frequency of the acts of unprofessional conduct."

18. Both the September 2011 and October 2017 convictions of RICHARD MARSCHALL for his violations of 21 U.S.C. §§ 331 and 333 have become final.

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COUNT 1

(Introduction of Misbranded Drugs into Interstate Commerce)

19. Paragraphs 1-18 of this Indictment are incorporated by reference as if set forth fully herein.

20. On or about March 31, 2020, in Port Angeles, in the Western District of Washington, and elsewhere, RICHARD MARSCHALL, after a conviction of him under 21 U.S.C. §§ 331 and 333 had become final, introduced, delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, from Port Angeles, Washington, to Oakland, California, via the US Postal Service, drugs, to wit: "The Dynamic Duo" products Allimax® Pro (Allimed) and IAG™ Arabinogalactans, which were misbranded in the following ways:

a) the labeling was false and misleading in some particular, in violation of 21 U.S.C. § 352(a), in that it suggested that RICHARD MARSCHALL was a naturopathic doctor by listing him as "Rick Marschall N.D.";

b) the drugs were prescription drugs pursuant to 21 U.S.C. § 353(b)(1), because the drugs' method of use, and the collateral means necessary for their use, rendered them not safe for use except under the supervision of a licensed practitioner, and the drugs were dispensed without a prescription, in violation of 21 U.S.C. § 353(b)(1);

c) the labeling failed to bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), because the drugs were prescription drugs pursuant to 21 U.S.C. § 353(b)(1), because the drugs' method of use, and the collateral means necessary for their use, rendered them not safe for use except under the supervision of a licensed practitioner; and

d) the drugs were manufactured, prepared, propagated, compounded and processed in establishments not registered with the Food and Drug Administration, and the drugs were not included in any list of drugs manufactured, prepared,

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propagated, compounded, and processed in a registered establishment, as required by 21 U.S.C §§ 352(o), 360(b), 360(c), and 360(j).

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

A TRUE BILL:

DATED: 8/5/2020

(Signature of Foreperson redacted Pursuant to the policy of the Judicial Conference of the United States)

FOREPERSON

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