UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA,

Plaintiff,

v.

RICHARD MARSCHALL,

Defendant.

CASE NO. CR11-5222BHS

INFORMATION

The United States Attorney charges that:

COUNT 1
(Causing the Introduction of Misbranded Drugs)

A. INTRODUCTION

At all times relevant to this Indictment:

1. Under the Food, Drug and Cosmetic Act (hereinafter "FDCA"), "interstate commerce" means 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).

2. Under the FDCA, "label" means a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" is 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).

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3. Under the FDCA, "drugs" are defined as, among other things, (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). 21 U.S.C. § 321(g).

4. A "new drug" is any drug which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321(p)(1). In order to be lawfully marketed, sold or dispensed in the U.S., a new drug has to be the subject of a New Drug Application ("NDA") which had been approved by the FDA. 21 U.S.C. § 355.

5. A drug intended for use in 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; or a drug which is limited by an approved application under 21 U.S.C. § 355 to use under the professional supervision of a practitioner licensed by law to administer such drug, can only be dispensed by a practitioner licensed by law pursuant to a lawful prescription. 21 U.S.C. § 353(b)(1). These drugs are commonly known as "prescription drugs." Dispensing a prescription drug without a valid prescription by a licensed practitioner is deemed by statute to be an act with causes the drug to be misbranded while held for sale. 21 U.S.C. § 353(b).

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

7. A drug is also misbranded if the labeling on the drug does not bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" means directions

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under which a layman can use a drug safely and for the purposes for which it was intended without a doctor's supervision. 21 C.F.R. § 201.5.

8. Directions under which a layperson can use a drug safely cannot be written for a prescription drug because such drugs can, by definition, only be used safely (if at all) at the direction, and under the supervision, of a licensed practitioner. Approved prescription drugs dispensed pursuant to a valid prescription are exempt from having adequate directions for use by a layperson. But prescription drugs that are unapproved new drugs or dispensed without a valid prescription are necessarily misbranded for lacking adequate directions for use.

9. Under the FDCA, the doing or causing of the following acts, among others, is prohibited:

a. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded (21 U.S.C. § 331(a));

b. The receipt in interstate commerce of any drug that is misbranded, and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c)); and,

c. The doing of any act with respect to a drug, if such act is done while the drug is held for sale (whether or not the first sale) after shipment in interstate commerce, which results in the drug being misbranded (21 U.S.C. § 331(k)).

10. Human Chorionic Gonadotropin (HCG) is a hormone produced in women during pregnancy. HCG is approved by the FDA for use in certain prescription drugs that treat infertility. HCG is not approved by the FDA to treat obesity or weight loss.

B. INTRODUCTION OF MISBRANDED DRUGS

Beginning on a date unknown, but continuing to on or about January 10, 2010, in Port Angeles, in the Western District of Washington and elsewhere, RICHARD MARSCHALL did, with the intent to defraud and mislead, cause the introduction and delivery for introduction into interstate commerce, from Mumbai, India,

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to various locations within the United States, of drugs, to wit: products containing injectable Human Chorionic Gonadotropin (HCG), which were misbranded as defined at Title 21, United States Code, Section 352(f)(1) in that the drugs lacked adequate directions for use and were not exempt from this requirement.

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

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