UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

UNITED STATES OF AMERICA,	)	DOCKET NO.: 3:21 cr 215 - MOC
	)	
	)	**BILL OF INFORMATION**
v.	)	
	)	
JAMES W. HEROMAN,	)	Violations: 21 U.S.C. §§ 331(c) and
Defendant	)	333(a)(1) (Class A Misdemeanor)
	)	

The Acting United States Attorney Charges:

INTRODUCTION

At all times pertinent to this Bill of Information:

The Offense Conduct

1. Beginning no later than September 9, 2013 and continuing through the present, Dr. James W. Heroman, M.D., defendant herein, operated Carolina Retina and Vitreous Consultants (CRVC), an ophthalmology clinic with offices in Charlotte and Concord, North Carolina. During this time, Defendant caused CRVC to order and receive, in interstate commerce, the prescription drug Lucentis intended for distribution in countries other than the United States, at CRVC's offices in Charlotte, North Carolina, within the Western District of North Carolina, where he subsequently delivered and proffered delivery of said drug for pay.

2. Because this drug was intended for foreign markets, it was not approved for use within the United States by the Food and Drug Administration (FDA). The foreign market Lucentis received in interstate commerce by Defendant and CRVC was misbranded in that the packaging for said prescription drug did not include FDA required warnings such as "Rx only." Defendant purchased foreign, unapproved Lucentis because it did not cost as much as Lucentis® approved

by the FDA for use in the United States. Nevertheless, Defendant caused CRVC to bill Medicare for non-covered and non-reimbursable foreign, unapproved Lucentis as if it were FDA approved and kept the difference in price as profit.

The Federal Food, Drug, and Cosmetic Act

3. The FDA is the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs are safe and effective for their intended uses and bear labeling that contains true and accurate information. FDA's responsibilities include regulating the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs. FDA carries out its responsibilities by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA) and other pertinent laws and regulations.

4. The FDCA defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles...intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B) and (C).

5. Under the FDCA, drugs are "misbranded" if, among other things, any word, statement, or other information, required to appear on the drug's label or labeling, is not prominently placed thereon. 21 U.S.C. § 352(c). Under FDA's implementing regulations, a drug may be misbranded under section 352(c) unless "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language. . . " *See* 21 C.F.R. § 201.15(c)(1).

6. "Labeling" is defined under the FDCA 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). In turn, the term "label" includes "written, printed, or graphic matter upon the immediate container of any article." *Id.* at § 321(k).

Prescription Drugs Under the FDCA

7. Prescription drugs are drugs that, because of their toxicity and other potential for harmful effects, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(l)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. 21 U.S.C. § 353(b)(l)(B).

8. A prescription drug is deemed to be "misbranded" if its label does not bear the symbol "Rx only" at any time prior to dispensing. 21 U.S.C. § 353(b)(4)(A).

Lucentis®

9. Lucentis®, which contains the active pharmaceutical ingredient (API) ranibizumab, is an anti-vascular endothelial growth factor (anti-VEGF) product manufactured in the United States by Genentech, Inc. Anti-VEGFs are a class of prescription drugs typically used to treat various ocular conditions. Injectable Lucentis® manufactured in the United States is FDA-approved to treat patients with the following indications: Neovascular (Wet) Age- Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy in patients with DME.

COUNT ONE
Receiving and Delivering Misbranded Lucentis®
(21 U.S.C. §§ 331(c), 353(b)(1)(4)(A), and 333(a)(1))

10. Paragraphs 1 through 9 of this Bill of Information are re-alleged and incorporated by reference as though fully set forth herein.

11. From on or about September 9, 2013, continuing through on or about June 27, 2018, in Mecklenburg County, within the Western District of North Carolina, and elsewhere, the defendant,

JAMES W. HEROMAN,

did receive, and cause CRVC to receive, in interstate commerce, foreign market Lucentis, which was not approved by the FDA for use in the United States and was misbranded within the meaning of Title 21, United States Code, Section 353(b)(1)(4)(A), in that, prior to dispensing, said prescription drug's labeling failed to bear the required statement "Rx only."

12. Defendant through CRVC, administered, delivered, and proffered delivery of misbranded Lucentis® for pay and otherwise.

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1) and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATION
(28 U.S.C. § 2461(c), 18 U.S.C. § 981(a)(1)(C) and 21 U.S.C. §§ 334 and 853(p))

13. Upon conviction of a violation of 21 U.S.C. §§ 331(c) and 333(a)(1), as set forth in Count One of this Information, Defendant shall forfeit to the United States pursuant to Title 21, United States Code, Section 334, Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), any quantities of drugs which were misbranded when introduced into interstate commerce or when received in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and any proceeds of such violations.

14. If, as a result of any act or omission of the defendant, any of the property describe above:

a. cannot be located upon 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 this Court;

d. has been substantially diminished in value; or

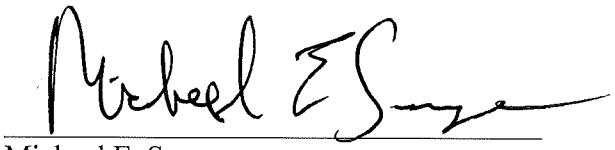
e. has been commingled with other property that cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the forfeitable property described above.

15. Further, defendant agrees to the entry of a forfeiture money judgment in the amount of $125,000 on one or more of the bases set forth herein.

All pursuant to Title 21, United States Code, Sections 334 and 853(p), Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

WILLIAM T. STETZER
ACTING UNITED STATES ATTORNEY



Michael E. Savage
Assistant United States Attorney