UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Civil Action No. __
	)	
v.	)	
	)	
NOVO NORDISK INC.	)	
	)	
	)	
Defendants,	)	
	)	
	)	

COMPLAINT

NOW COMES the United States of America, by and through the undersigned attorneys, and respectfully states as follows:

NATURE OF ACTION

1. The United States brings this action pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act"), 21 U.S.C. § 332, and under the Court's inherent equitable authority, in order to obtain equitable disgorgement of the defendant's ill-gotten gains from the unlawful sale of its drug liraglutide, with the tradename Victoza ("Victoza"). Specifically, the United States alleges that the defendant, Novo Nordisk Inc. ("NNI") introduced Victoza into interstate commerce while such drug was misbranded pursuant to 21 U.S.C. § 352(y) in that it failed to comply with the Victoza Risk Evaluation and Mitigation Strategy ("REMS"), in violation of 21 U.S.C. § 331. When approved by the Food and Drug Administration ("FDA" or "Agency") to treat patients with type 2 diabetes, Victoza's FDA-approved labeling contained a boxed warning about the unknown risk of a certain form of thyroid cancer, medullary thyroid carcinoma ("MTC"). Moreover, as part of the

approval, FDA required NNI to implement a REMS program in order to communicate to prescribers the unknown risk of MTC. However, NNI provided its sales force with certain messages and tactics that created the false or misleading impression that the boxed warning and the Victoza REMS MTC risk message were erroneous, irrelevant, or unimportant. As a result of this unlawful conduct, NNI is subject to disgorgement of ill-gotten gains.

2. NNI is a U.S. company and a subsidiary of Novo Nordisk U.S. Holdings, Inc., which in turn is a subsidiary of Novo Nordisk A/S with its U.S. headquarters in Plainsboro, New Jersey. NNI distributes, sells, and markets pharmaceutical products throughout the United States and internationally, including the drug liraglutide with the tradename Victoza. NNI introduced Victoza into interstate commerce for shipment throughout the United States, including in this district.

3. FDA is an agency of the United States responsible for protecting the public by assuring that, among other things, drugs intended for use in humans are safe and effective for their intended uses and that the labeling of drugs is true and accurate. FDA regulates the manufacture, labeling, and shipment in interstate commerce of drugs.

JURISDICTION AND VENUE

4. This court has jurisdiction over this action under 28 U.S.C. § 1345, pursuant to 21 U.S.C. § 332(a), and under the court's inherent equitable authority.

LEGAL FRAMEWORK

5. Victoza and NNI are regulated by the FDCA. Under the FDCA, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man is a drug. 21 U.S.C. § 321(g). A "new drug" is any drug that is "not generally recognized, among

[qualified] experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested" in its labeling. *Id.* § 321(p).

6. The FDCA as codified in Title 21, United States Code, Section 301 *et. seq.*, and its implementing regulations require that before a new drug may be distributed legally in interstate commerce, a sponsor of a new drug must submit a new drug application ("NDA") and receive approval of that application from FDA pursuant to 21 U.S.C. § 355.

7. In 2007, Congress amended the FDCA to authorize the Agency to require, either as part of an NDA approval or after approval based on new safety information, that a REMS is necessary in order to ensure that the benefits of the drug outweigh the risks. 21 U.S.C. § 355-1.

8. The FDCA provides that the REMS may include specific elements to ensure the benefits of the drug outweigh the risks, including, *inter alia*, a Communications Plan that provides for disseminating important risk information to healthcare providers. 21 U.S.C. § 355-1(e)(3).

9. Under the FDCA, a drug is misbranded if the responsible person, as defined by the statute, fails to comply with a REMS requirement. 21 U.S.C. 352(y).

10. The FDCA prohibits the introduction of a misbranded drug into interstate commerce. 21 U.S.C. § 331(a).

FACTS

11. FDA approved the NDA for the injectable drug Victoza on January 25, 2010, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

12. At the time of approval and at all times since, Victoza's FDA-approved labeling has contained a boxed warning about the unknown risk of MTC in humans, based on the fact

that some rodents exposed to Victoza developed thyroid C-cell tumors (MTC is a form of thyroid tumor) during premarket testing of the drug.

13. Because the relevance to humans of the premarket rodent findings could not be determined, the boxed warning states that it "is unknown whether Victoza causes thyroid C-cell tumors, including MTC, in humans, as human relevance could not be determined by clinical or nonclinical studies."

14. FDA approved the NDA for Victoza with a REMS to ensure the benefits of Victoza outweighed the risks, including specifically, the unknown risk of MTC.

15. The Victoza REMS required NNI to develop and implement a Communication Plan, which included specific steps for communicating information to healthcare providers about the unknown risk of MTC. The Victoza REMS Communication Plan required NNI to communicate this information in various forms including in a letter to likely prescribers, and in a "Highlighted Information for Prescribers" ("HIP-D") document provided by NNI sales representatives who met with healthcare providers for the primary purpose of increasing the number of Victoza prescriptions those healthcare providers issued.

16. Directly following FDA's approval of the Victoza NDA with the REMS on January 25, 2010, NNI provided the sales force with training to appropriately implement the REMS but also provided them with information to counter and neutralize the required MTC risk message. NNI provided the information to counter and neutralize the MTC risk message despite the fact that FDA had specifically required the REMS Communication Plan as part of the NDA approval in order to ensure that the benefits of Victoza outweighed the risks. The overall effect of the NNI training was to arm the sales force with messages that could

create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant.

17. As part of its training, NNI provided its sales representatives with statements and tactics that could give physicians the impression that the REMS MTC risk message was erroneous, irrelevant, or unimportant, including:

a. certain NNI marketing employees performed a skit in front of the entire sales force related to the REMS obligations. One marketing manager implied during the skit that the risk of MTC associated with Victoza existed only in rodents by stating: "do you [FDA] think we're treating mice and rats? I mean really!" and

b. sales representatives were coached by managers to minimize the importance of the MTC message by "sandwiching" information about it between promotional messages regarding the efficacy of the drug. The tactic was intended to provide physicians a false or misleading assurance that Victoza posed no risk of cancer or danger to patients.

18. Following the training, certain NNI sales representatives made statements or implemented tactics to convey to physicians that the REMS MTC risk message was erroneous, irrelevant, or unimportant. For example, after delivering the required letter and HIP-D, certain NNI sales representatives made statements that included:

a. the risk of MTC associated with Victoza is only applicable to rats and mice;

b. all diabetes drugs have boxed warnings and Victoza is no different and no less safe than those other drugs;

c. because of differences between rodents and humans it is implausible that humans would contract MTC from the use of Victoza;

d. physicians should not be concerned about MTC because it is easy to treat if a patient does get it; and

e. sandwiching the MTC risk information between promotional messages to provide physicians a false or misleading assurance that Victoza posed no risk of cancer or danger to patients.

19. In March 2011, as part of its ongoing REMS obligations, NNI conducted surveys of endocrinologists and primary care physicians to gauge their awareness and understanding of the unknown risks of MTC associated with Victoza. The survey showed that only approximately half of primary care physicians called on by NNI were aware of the boxed warning on the Victoza labeling that explained the unknown risk of MTC associated with Victoza. The survey also showed primary care physicians' awareness at rates significantly lower than surveyed endocrinologists.

20. On May 5, 2011, FDA informed NNI that the Agency considered the "lack of knowledge among primary care physicians of the boxed warning for thyroid C-cell tumors" to be new safety information under the REMS. Based on this new safety information, FDA informed NNI that a modification to the REMS, to include an additional letter to primary care physicians, was necessary. The letter was intended to increase awareness of the unknown risk of MTC associated with Victoza among primary care physicians.

21. NNI worked with FDA to draft the letter to be provided to primary care physicians.

22. NNI did deliver the required letter to primary care physicians. However, despite clear instruction from FDA that the survey results constituted new safety information that

resulted in a modification of the REMS, NNI directed its sales force also to deliver a verbal message to primary care physicians intended to mislead them as to the purpose of the letter.

23. In June 2011, NNI's Vice President of Marketing for Victoza sent a recorded voicemail message to the Victoza sales force regarding the letter required pursuant to the REMS modification. The Marketing Vice President stated, "when you are in front of your primary care physicians, make sure you provide context. Qualify with them that there are no new safety concerns. Again, there are no new or additional safety concerns reported. Remind them that this is part two of the REMS requirement, and that you had the same discussion a year ago. Then transition to the promotional messaging...." NNI's direction contravened the requirement of the REMS modification which was specifically to ensure that primary care physicians were made aware of the potential risks of Victoza that they might not previously have been aware of.

24. Sales representatives provided primary care providers with the required letter in June 2011 but also told primary care physicians that there were no new safety concerns with Victoza and that the letter was simply the second part of the REMS requirement. The information provided by NNI's sales force to primary care physicians contradicted FDA's instructions in that the Agency deemed this to be new safety information that required a modification to the REMS and not "part two" of the REMS requirement. This message could give primary care providers the impression that the REMS modification and MTC risk message were erroneous, irrelevant, or unimportant.

Misbranded Drug – 21 U.S.C. §§ 331 and 352(y)

25. The United States incorporates by reference paragraphs 1 through 24 as if fully set forth in this paragraph.

26. NNI's sales force training in 2010 and implementation of the REMS modification in 2011 were designed to, and did in fact, avoid and circumvent the requirements of the Victoza REMS Communication Plan, contradicting or neutralizing the required MTC risk message. The overall effect of NNI's instruction to the sales force was to create the false or misleading impression that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant. These actions did not comply with the Victoza REMS Communication Plan, which was designed specifically to make health care providers aware of an unknown risk of MTC associated with the use of Victoza in order to ensure that the benefits of the product would outweigh the risks.

27. Because FDA approved the Victoza NDA with a REMS, and because NNI failed to comply with the requirements of the Victoza REMS Communication Plan, Victoza was misbranded within the meaning of the Act, 21 U.S.C. § 352(y). NNI shipped the misbranded Victoza in interstate commerce between February 2010, through and including December 2012, in violation of the Act, 21 U.S.C. § 331.

28. By reason of the foregoing, NNI should be subject to disgorgement of ill-gotten gains pursuant to 21 U.S.C. § 332 and the Court's inherent equitable authority.

WHEREFORE, the United States of America prays that the following relief be granted:

(a) Novo Nordisk be subject to an equitable disgorgement of $12,150,000 in ill-gotten gains;

(b) the United States of America be granted such other and further relief that the Court deems just and proper.

Dated: July 26, 2017

Respectfully submitted,

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