IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	CASE NO.: 1:13MJ8015
	)	
Plaintiff,	)	MAGISTRATE JUDGE KENNETH S. MCHARGH
	)	
v.	)	
	)	
MARWAN MASSOUH,	)	GOVERNMENT'S SENTENCING MEMORANDUM
	)	
Defendant.	)	

The Government respectfully requests that the Court sentence Defendant Dr. Marwan Massouh ("Massouh") within the advisory guidelines range (Level 4 after Acceptance of Responsibility) and not award restitution given the existence of a civil settlement agreement between Defendant and the United States. The United States here concentrates on the nature, circumstances and seriousness of the offense. 18 U.S.C. § 3353(a)(1).

I. THE NATURE, CIRCUMSTANCES, AND SERIOUSNESS OF THE OFFENSE

A. Offense Conduct and Investigation

FDA agents developed evidence that Defendant received fourteen (14) shipments of prescription oncology drugs Zometa and Gemzar from Company #1, a Canadian distributor, between January 2006 and January 2007. As a result of this information, FDA agents visited Dr. Massouh's office on March 11, 2009.

Dr. Massouh consented to an interview, during which he admitted that he had purchased prescription oncology drugs from a Canadian supplier. Dr. Massouh claimed that he was unaware that his Canadian purchases were illegal;[1] he added that the Canadian supplier's literature implied that it was legal to import the drugs from Canada.[2] He explained that many physicians advised patients to purchase their drugs from Canada, though he conceded that physician purchases from Canada were a "grey area." Dr. Massouh stated that he became uncomfortable with the practice and attempted to get a local pharmacist to determine the ingredients in his Canadian purchases, but the pharmacist advised she could not comply with his request. Dr. Massouh said that he then stopped ordering from Canada. Dr. Massouh indicated that he did not have any Canadian drugs on hand at the time of the interview and agents observed none.

According to Dr. Massouh, Canadian drug supplier representatives solicited his business. Dr. Massouh placed his orders by fax. He then checked the package against his order to verify that he received what he ordered. He did not maintain invoices longer than a month or two. In terms of his use of the Canadian drugs, the Government did not develop any evidence concerning whether patients were informed that the drugs Defendant infused were purchased from a

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[1] Misbranding does not require the defendant to be aware that his/her actions are illegal, though it is worth noting in connection with this claim that in 2006 and 2007 the FDA sent Dr. Massouh two separate notices indicating that foreign drug shipments destined for his house had been detained by the FDA as their importation appeared to be a violation of the law because they were unapproved new drugs that could be purchased from U.S. suppliers. Each one of these letters though also included a statement that the notice "does not in any way accuse [the recipient] of violating the law." **Govt Exhibit 1**, reprinted copies of FDA Notices to Dr. Massouh (one dated July 19, 2006, for Kytril and one dated July 16, 2007, for Oxaliplatin).

[2] Attached is a flyer Dr. Massouh provided the Government, which purports to be a printout from the Whitehouse's web site with a large quote excerpted in the middle of the page: "Obama and Biden . . . support allowing seniors to import safe prescription drugs from overseas, and will prevent pharmaceutical companies from blocking cheap and safe generic drugs." **Govt Exhibit 2**, Sales Flyer.

Canadian supplier. Given the nature of the arrangement and the explanations offered, a reasonable inference is that patients were not informed of the origin or the cost difference in the Canadian drugs. The Government also did not develop any evidence of patient harm from the Canadian drugs, nor did we learn of any evidence that the drugs were counterfeit.[3]

Dr. Massouh elaborated that he normally ordered approximately $700,000 worth of prescription oncology drugs each year and that his Canadian purchases were a small percentage of that amount. Based on the information obtained by the Government, we were able to determine the expenses Dr. Massouh incurred for the purchase of drugs from U.S. and Canadian suppliers during the relevant timeframes:

	2009	2008	2007	2006	2005	Totals
Purchases from U.S. Suppliers	$732,123.90	$630,374.01	$660,961.29	$1,003,434.62	$1,199,164.12	$4,226,057.94
Purchases from Canadian Suppliers	$57,192.00	$196,322.14	$129,733.00	$151,232.00	$194,658.00	$729,137.14
Totals	$789,315.90	$826,696.15	$790,694.29	$1,154,666.62	$1,393,822.12	$4,955,195.08

In a later meeting with the Government, Dr. Massouh was able to provide some more detail about his Canadian purchases, clarifying that certain oncology drugs were cheaper to obtain from Canada, while some drugs were no cheaper in Canada. Dr. Massouh only purchased five types of drugs from Canada:

- Eloxatin and Oxaliplatin - 70% purchased from Canada
- Gemzar and Gemcitabine - 90% purchased from Canada
- Kytril - 100% ordered from Canada
- Taxotere - 50% from Canada
- Zometa and Zoledronic - 100% from Canada

[3] Since this was a historical case at the point that FDA agents interviewed Dr. Massouh and he did not have any imported Canadian drugs on hand during the interview, the Government did not have a way to conduct any testing to determine whether the Canadian drugs contained what was purported by the packaging.

For example, according to the Government's investigation, the two drugs charged in the Information were significantly cheaper when ordered from Company #1 in Canada:

Drug	Company #1 (Canada)	U.S. Supplier #1	U.S. Supplier #2	Price Difference
Gemzar 1 g	$340.00	$699.67	$693.14	$353.14
Zometa 4mg/5mL	$595.00	$848.22	$833.76	$238.76

GEMZAR® (gemcitabine for injection) is a chemotherapy drug used to treat several types of cancer like breast cancer, lung cancer, pancreatic cancer, and ovarian cancer.[4] ZOMETA® (zoledronic acid) 4 mg/5 mL Injection is a treatment for hypercalcemia of malignancy (HCM; a condition resulting in high calcium blood levels due to cancer) and is also used to reduce and delay bone complications due to multiple myeloma and bone metastases from solid tumors.[5]

B. Seriousness of the Offense

Understanding federal law regarding the importation of drugs is critical to appreciating the nature and seriousness of this offense. The Eighth Circuit Court of Appeals in *In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 790-91 (8th Cir. 2006), held that imported drugs with the same chemical composition as FDA-approved drugs are illegal and misbranded because they are manufactured outside the United Sates' closed system of drug distribution that protects consumers from potentially unsafe pharmaceuticals:

> The [Food, Drug, and Cosmetic Act] comprehensively regulates the manufacture, importation, and sale of prescription drugs. Before a new drug may be introduced into interstate commerce, the FDA must approve the manufacturing process, labeling, and packaging. 21 U.S.C. § 355(b)(1). The approval process addresses the chemical composition of the drug, id. § 355(b)(1)(B), (c), the drug's safety and effectiveness, id. § 355(b)(1)(A), and elements of the drug's distribution, such as "the methods used in, and the facilities and controls used for,

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4 See http://www.gemzar.com/Pages/index.aspx

5 See http://www.us.zometa.com

> the manufacture, processing, and packing" of the drug, id. § 355(b)(1)(D), and the "labeling proposed to be used" for the drug. Id. § 355(b)(1)(F). The approval process is specific to each manufacturer and each product. See 21 C.F.R. § 314.50.
>
> Drugs that are manufactured and distributed in Canada are not approved pursuant to this statutory framework. The approval process requires, among other things, that a manufacturer provide "the proposed text of the labeling for the drug." 21 C.F.R. § 314.50(c). Because foreign labeling differs from domestic labeling, approval granted to a particular manufacturer for a particular product to be distributed in the United States does not constitute approval of another drug-even one with the same chemical composition-to be distributed in Canada with different labeling, and then imported into the United States.

As discussed above, any drug manufacturer must prove to the FDA that each drug it markets to U.S. consumers is properly manufactured and distributed and therefore safe and effective *before* the drug can be legally sold in the United States. No one can legally "roll the dice" by providing U.S. consumers with drugs that have not first been proven to be safe with the FDA, even if the unapproved drugs end up being chemically similar to other approved drugs.

As the Eighth Circuit found in the *Canadian Import Antitrust Litigation* case at 470 F.3d at 790-91, importing foreign drugs of unknown pedigree is not a minor violation of federal law:

> [Misbranding] . . . is not merely a "hyper-technical" violation of the FFDCA. It is, rather, a manifestation of a congressional plan to create a "closed system" designed to guarantee safe and effective drugs for consumers in the United States. *Vermont v. Leavitt*, 405 F.Supp.2d 466, 472 (D.Vt.2005). Drugs that are not properly labeled for sale under federal law sometimes may be similar in substance to those that are sold legally within the United States. In other cases, however, they may be drugs with chemical compositions that are not yet approved by the FDA, drugs not manufactured in accordance with FDA rules, or drugs not transported or stored in a manner that is deemed safe by the FDA. ... [T]he labeling requirements cannot be segregated from other FFDCA requirements in this way. Instead, they work in conjunction with the other statutory standards and FDA regulations to create a system that excludes noncompliant and potentially unsafe pharmaceuticals. This "closed system" ensures that approved prescription drugs are "subject to FDA oversight" and are "continuously under the custody of a U.S. manufacturer or authorized distributor," thus helping to ensure that the quality of drugs used by American consumers is consistent and predictable.

United States v. Rx Depot, Inc., 290 F.Supp.2d 1238, 1241-42 (N.D.Okla. 2003).

C. No Need for Restitution

Given the existence of a separate civil settlement with the Civil Division of the United States Attorney's Office, the United States is not seeking an award of restitution in this case and has agreed in the plea agreement that restitution is not appropriate. Dr. Massouh has agreed to a large civil settlement payment to the United States covering false claims involving federal payors. Dr. Massouh has already made payment for more than single damages (actual reimbursement made by federal payors) in the amount of $325,000 with a payment plan to cover the payment of an additional $284,150 plus 3% interest over the course of three years.

II. DEFENDANTS CHARGED WITH SIMILAR CONDUCT

The Sentencing Guidelines also provide that this Court should consider the "need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct." 18 U.S.C. § 3553(a)(6). Though no other similarly situated defendants have been sentenced, the United States provides the following information regarding other oncologists charged with the same offense on the same day as the instant case:

Defendant	Case No.	Magistrate Judge	Drugs Involved	Case Status
Ranjan Bhandari	4:13MJ8017	Kathleen B. Burke	Zometa, Irinotecan, Eloxatin, Gemzar, Hycamtin, and Taxotere	Guilty plea entered 8/29/13. Simultaneous sentencing memoranda due 9/24/13.
Poornanand Palaparty	1:13MJ8014	Kenneth S. McHargh	Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid and Carboplatin	Guilty plea entered 9/5/13. Simultaneous sentencing memoranda due 9/19/13.
Timmappa Bidari	1:13MJ8013	Nancy A. Vecchiarelli	Taxotere, Gemzar, Oxaliplatin, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Procytox, Topotecan and Fluororacil	Arraignment and plea scheduled for 9/20/13
Su-Chiao Kuo	1:13MJ8012	William H. Baughman, Jr.	Taxotere, Gemzar, Eloxatin, Campto, Zometa, Kytril	Arraignment and plea scheduled for 9/25/13
Marwan Massouh	1:13MJ8015	Kenneth S. McHargh	Zometa and Gemzar	Guilty plea entered 9/3/13. Simultaneous sentencing memoranda due 9/17/13.
David Fishman	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Arraignment and plea scheduled for 9/30/13
Hassan Tahsildar	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Arraignment and plea scheduled for 9/27/13

III. CONCLUSION

The Government respectfully requests that the Court sentence Defendant within the suggested guidelines range and award no restitution given the existence of the civil settlement agreement between Defendant and the United States, and grant such other and further relief as the Court deems just and proper. Other relief could include imposition of a fine. As a technical matter, the statutory maximum fine pursuant to 18 U.S.C. § 3571(b)(5) is $100,000 for this Class A misdemeanor. The Sentencing Guidelines, which focus on the offense level, recommend a $5,000 maximum. U.S.S.G. § 5E1.2(c)(3) (recommending a minimum fine of $250 and a maximum fine of $5,000 for individuals whose sentencing range is either Level 4 or 5; the United States agrees that Defendant is a Level 4 after acceptance of responsibility). The United States leaves it to the Court to determine, given the facts surrounding the offense conduct (§ 5E1.2(d)(1)), the amount of the civil settlement (§ 5E1.2(d)(4) and (5)), and the Pretrial Services report regarding Defendant's assets, income and expenses (§ 5E1.2(d)(2) and (3)), whether a fine is appropriate and, if so, how much to impose.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of September 2013 a copy of the foregoing document was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. All other parties will be served by regular U.S. Mail. Parties may access this filing through the Court's system.

/s/ Michael L. Collyer
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