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

UNITED STATES OF AMERICA,	)	CASE NO.: 1:13MJ8016
	)	
Plaintiff,	)	MAGISTRATE JUDGE GREG WHITE
	)	
v.	)	
	)	
DAVID FISHMAN,	)	GOVERNMENT'S SENTENCING MEMORANDUM
	)	
Defendant.	)	
	)	

The Government respectfully requests that the Court sentence Defendant Dr. David Fishman ("Fishman") within the advisory guidelines range (Level 4 after Acceptance of Responsibility) and award restitution in the amount of $75,000. 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 and co-defendant Tahsildar received six (6) shipments of prescription oncology drugs Novantron and Taxotere from Company #1, a Canadian distributor, between December 2006 and January 2007. As a result of this information,

FDA agents visited Dr. Fishman's office on March 11, 2009, and advised both Dr. Fishman and Dr. Tahsildar that any orders they had received from foreign distributors were illegal and that they should stop administering any unapproved US Food and Drug Administration medication.

Misbranding does not require the defendant to be aware that his/her actions are illegal, though it is worth noting that FDA sent at least four different notices to Dr. Fishman indicating that a foreign drug shipment destined for his office had been detained by the FDA. The notices ranged from May 2, 2008, to November 17, 2008. The notices indicated that the importations appeared to be a violation of the law because they appeared to be new drugs without an approved new drug application. The letter 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. Fishman. One notice indicated that the package had been shipped from Sint Maarten in the Netherland Antilles, while two other notices stated that the packages came from Canada.

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 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.[1]

[1] Since this was a historical case at the point that FDA agents visited Dr. Fishman and Dr. Tahsildar and there was no search for any drugs present at the time of the visit, the Government did not have a way to conduct any testing to determine whether the Canadian drugs contained what was purported by the packaging.

Based on information obtained by the Government, we were able to determine the expenses Dr. Fishman and Dr. Tahsildar incurred for the purchase of drugs from U.S. and Canadian suppliers during the relevant timeframes:

	2009	2008	2007	2006	2005	Totals
BDI Pharma	$57,659.46					$57,659.46
Florida Infusion/Nations Drug		$221,000.72	$547,091.40		$119,475.99	$887,568.11
Oncology Supply	$833,533.94	$280,155.69	$443,681.05			$1,557,370.68
Totals	$891,193.40	$501,156.41	$990,772.45	$0.00	$119,475.99	$2,502,598.25
Canadian Purchases	$40,386.00	$128,044.00	$157,586.00	$19,590.00		$345,606.00
Grand Totals	$931,579.40	$629,200.41	$1,148,358.45	$19,590.00	$119,475.99	$2,848,204.25

Order forms and invoices revealed that Dr. Fishman and Dr. Tahsildar ordered a number of oncology drugs from Canadian sources, including:

- Taxotere
- Gemzar
- Eloxatin
- Irinotecan
- Campto
- Mitoxantrone
- Hycamtin
- Zometa
- Camptosar
- Kytril and
- Ondansetron

According to the Government's investigation, two of these drugs 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.[2] 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.[3]

According to a 2005 study by the U.S. Department of Health and Human Services, the federal reimbursement rates were sufficient to cover the costs of oncologists who purchased from U.S. suppliers.[4] It is also worth noting that during a typical visit that involved infusion of oncology drugs, Dr. Fishman would have also been able to bill for other things in addition to the drugs, like his evaluation of the patient. These billings would presumably also help defray "losses" for U.S. drugs that cost either close to the reimbursement rate or higher.

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

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

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

4 **Govt Exhibit 3**, *Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients*, Report A-06-05-00024, found in the "publications" section of the Office of Inspector General website, www.oig.hhs.gov. At page 5, HHS found that "[r]egardless of their size, physician practices could purchase most drugs within the 39 payment codes reviewed at less than the reimbursement amount." HHS concluded that their study "provided a reasonable basis for concluding that reimbursement was generally adequate because these payment codes represented more than 94 percent of the total Medicare-allowed amount." **Govt Ex. 3**, p. 6.

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, 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. Restitution

Dr. Fishman is currently negotiating a separate civil settlement with the Civil Division of the United States Attorney's Office. The parties have determined that Dr. Fishman received $75,000 from a federal health insurance payor (Medicare) based on the submission of claims involving oncology drugs purchased from outside the United States. The United States therefore seeks restitution to Medicare as relevant conduct in this case in the amount of $75,000.

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). As of this filing, one other similarly situated defendant has been sentenced to one year of probation with no fine and no restitution.

The United States provides the following information regarding all seven oncologists charged with the same offense on the same day as the instant case:

Defendant	Case No.	Magistrate Judge	Drugs Involved	Criminal Case Status
Ranjan Bhandari	4:13MJ8017	Kathleen B. Burke	Zometa, Irinotecan, Eloxatin, Gemzar, Hycamtin, and Taxotere	Sentencing 12/3/13
Poornanand Palaparty	1:13MJ8014	Kenneth S. McHargh	Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid and Carboplatin	Sentencing 11/12/13
Timmappa Bidari	1:13MJ8013	Nancy A. Vecchiarelli	Taxotere, Gemzar, Oxaliplatin, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Procytox, Topotecan and Fluororacil	Sentencing 11/13/13
Su-Chiao Kuo	1:13MJ8012	William H. Baughman, Jr.	Taxotere, Gemzar, Eloxatin, Campto, Zometa, Kytril	Guilty plea entered 9/25/13. Abbreviated PSR ordered, then Court and parties to decide whether full PSR needed.
Marwan Massouh	1:13MJ8015	Kenneth S. McHargh	Zometa and Gemzar	Sentenced 10/16/13. Found to be Offense Level 4, Criminal History Category I; Sentenced to 1 year probation; no fine; no restitution owed
David Fishman	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Sentencing 11/19/13
Hassan Tahsildar	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Sentencing 1/28/14

III. CONCLUSION

The Government respectfully requests that the Court sentence Defendant within the suggested guidelines range, award restitution in the amount of $75,000, 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 restitution and the likelihood of double damages in the civil proceeding[5] (§ 5E1.2(d)(4) and (5)), and the Presentence 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,

STEVEN M. DETTELBACH
United States Attorney

By: /s/ Michael L. Collyer

Michael L. Collyer (OH: 0061719)
Assistant United States Attorney
United States Court House
801 West Superior Avenue, Suite 400
Cleveland, OH 44113
(216) 622-3744
(216) 522-2403 (facsimile)
Michael.Collyer@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of November 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
Michael L. Collyer
Assistant U.S. Attorney

[5] The figure of $75,000 represents the actual amount paid to Dr. Fishman by the federal payors for claims involving oncology drugs purchased from Company #1 in Canada. As part of the civil settlement, it is undersigned counsel's understanding that a settlement will include an agreement to pay double damages. Thus, in addition to the $75,000 in single damages constituting criminal restitution, the United States will also be entitled to an additional $75,000 (the double damages amount).