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

UNITED STATES OF AMERICA,	)	CASE NO.: 4:13MJ8017
	)	
Plaintiff,	)	MAGISTRATE JUDGE KATHLEEN B. BURKE
	)	
v.	)	
	)	
RANJAN BHANDARI,	)	GOVERNMENT'S SENTENCING MEMORANDUM
	)	
Defendant.	)	

The Government respectfully requests that the Court sentence Defendant Dr. Ranjan Bhandari ("Bhandari") within the advisory guidelines range (Level 4 after Acceptance of Responsibility) and not award restitution given the existence of a fully paid 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 Bhandari purchased and received a total of forty-one (41) shipments containing one hundred eighty-six (186) injections/units of Zometa, thirty-three (33) vials of Taxotere, seventy-six (76) vials of Gemzar and four (4) injections/units of Aranesp from Company #1 between March 17, 2006, and February 22, 2007,

for which he paid a total of $176,683.22. As a result of this information, FDA agents visited Dr. Bhandari's office on March 10, 2009.

Dr. Bhandari consented to an interview, during which he admitted that he had purchased prescription oncology drugs from Company #1, a Canadian supplier. He explained that he ordered and received Zometa (approved for the treatment of multiple myeloma and for patients with bone metastases from solid tumors), Taxotere (anti-mitotic chemotherapy medication used mainly for the treatment of breast, ovarian and non-small cell lung cancer) and Gemzar (approved for the treatment of locally advanced or metastatic pancreatic cancer) from Company #1. Although Dr. Bhandari stated he did place orders for Aranesp (indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis), he said Company #1 was not able to deliver it to his practice in the required refrigerated state so he refused the product. Dr. Bhandari added that Company #1 offered to send him a "trial" supply of the product and he refused. According to Dr. Bhandari, this recommendation led him to believe that something "was not quite right" with Company #1. As a result of this feeling and rumors that he heard about Florida pharmacies being shut down for ordering from China, Dr. Bhandari said he stopped ordered from Company #1 (the only foreign supplier he ever purchased from) in approximately August or September 2008. During the interview Dr. Bhandari indicated that he did not have any Canadian drugs on hand at the time and agents observed none.

Misbranding does not require the defendant to be aware that his/her actions are illegal, though it is worth noting that in January and May 2007 the FDA sent Dr. Bhandari four separate notices indicating that foreign drug shipments destined for his office 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. Bhandari (one dated May 18, 2007, for Hycamtin, one dated May 18, 2007, for Gemzar (Gemcitabine), one dated May 18, 2007, for Campto (Irinotecan), and one dated January 5, 2007, for Topotecan). Three of the notices indicated that the packages had been shipped from Phillipsburg in the Netherland Antilles, and the fourth indicated that it shipped from Canada.

Dr. Bhandari explained that he chose to order from Company #1 because of the initial cost difference, which he claimed he passed on to his patients in the form of a savings as well as using some of the profits to help pay expenses associated with the day to day operations of his practice. He estimated the cost savings to be as much as $100-$300 per vial. According to the Government's investigation, by way of example, two of the 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.[1] 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.[2]

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

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

Dr. Bhandari stated the packaging associated with Company #1's products appeared, to the best of his recollection, to have originated in the United Kingdom and Germany. Dr. Bhandari explained that he never told his patients that they were receiving medication from an international source; he also said he billed insurance as if his patients were receiving the United States version of the drug. The Government 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. Bhandari produced some[4] of the invoices he retained from Company #1 as well as purchase information from United States suppliers, which revealed the following approximate split between United States and Canadian purchases:

	2009	2008	2007	2006	2005	Totals
Florida Infusion/Nations Drug	$36,271.90	$251,772.47	$331,886.03	$296,829.00	$87,394.75	$1,004,154.15
Oncology Supply	$1,094,770.10	$983,513.90	$806,918.95	$885,755.43	$562,923.00	$4,333,881.38
Priority Health Care - Express Scripts			$2,563.75	$176,711.20		$179,274.95
Total for U.S. Suppliers	$1,131,042.00	$1,235,286.37	$1,141,368.73	$1,359,295.63	$650,317.75	$5,517,310.48
Canadian Purchases			$ 64,462.00	$ 66,898.00		$ 131,360.00

Dr. Bhandari ordered and received from Company #1 Zometa, Irinotecan, Eloxatin, Gemzar, Hycamtin, and Taxotere.

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*

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[3] Since this was a historical case at the point that FDA agents interviewed Dr. Bhandari 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.

[4] The Government's purchase number of $176,683.22 mentioned above came from a separate source. The table below therefore contains a lower figure and represents the invoices that Dr. Bhandari had retained at the time of his interview and does not represent all of the purchases he made from Company #1. This table though does place the amount of Canadian purchases in context by including the U.S. purchases.

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, 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.
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> 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. Bhandari agreed to a large civil settlement payment to the United States covering false claims involving federal payors. Dr. Bhandari has already made full payment of double damages in the amount of $1,139,532.

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 filed 9/19/13. Sentencing 11/18 after submission of abbreviated PSR.
Timmappa Bidari	1:13MJ8013	Nancy A. Vecchiarelli	Taxotere, Gemzar, Oxaliplatin, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Procytox, Topotecan and Fluororacil	Guilty plea entered 9/20/13. Abbreviated PSR ordered, and a sentencing date in November will be set by the court.
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 filed 9/17/13. Sentencing 10/16 after submission of abbreviated PSR.
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 24th 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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