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

UNITED STATES OF AMERICA,	)	CASE NO.: 1:13MJ8012
	)	
Plaintiff,	)	MAGISTRATE JUDGE WILLIAM H. BAUGHMAN, JR.
	)	
v.	)	
	)	
SU-CHIAO KUO,	)	GOVERNMENT'S SENTENCING MEMORANDUM
	)	
Defendant.	)	

The Government respectfully requests that the Court sentence Defendant Dr. Su-Chiao Kuo ("Kuo") 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 Kuo purchased and received a total of seven (7) shipments containing four (4) injections/units of Zometa and three (3) vials of Taxotere from Company #1 between March 2006 and January 2007, for which she paid a total of

$39,428. As a result of this information, FDA agents visited Dr. Kuo's office on March 10, 2009.

Dr. Kuo consented to an interview, during which she admitted that she had purchased prescription oncology drugs from Company #1, a Canadian supplier. She admitted that she ordered from the Canadian supplier because it was cheaper than U.S. suppliers. Dr. Kuo admitted that she did not pass on the cost savings to patients. According to the Government's investigation, one of the drugs charged in the Information was significantly cheaper when ordered from Company #1 in Canada:

Drug	Company #1 (Canada)	U.S. Supplier #1	U.S. Supplier #2	Price Difference
Zometa 4mg/5mL	$595	$848.22	$833.76	$238.76

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.[1]

Dr. Kuo stated that Company #1 directed her to a large medical practice in Michigan as a reference, which Dr. Kuo contacted. Dr. Kuo said the office manager there assured her that it was the same medication sold by U.S. suppliers and that Company #1 was "trustable." Dr. Kuo stated that she placed orders over the phone and the drugs shipped to her from the United Kingdom, which Company #1 representatives said was legal.

Misbranding does not require the defendant to be aware that his/her actions are illegal, but Dr. Kuo was aware that at least one shipment had been detained by Customs. Again, Company #1 assured her that it happened sometimes but was still legal; Company #1 simply

[1] See http://www.us.zometa.com

shipped another package to fulfill the order. The United States has confirmed that the FDA sent at least two notices to Dr. Kuo informing her that packages originating from Canada had been detained by Customs on September 12, 2006, and October 17, 2006, though the notices also stated that they do "not in any way accuse [the recipient] of violating the law." The notices indicated that the importations appeared to be a violation of the law because they appeared to contain a new drug without an approved new drug application.

In terms of her use of the foreign 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.

Dr. Kuo produced documentation she retained from Company #1 and United States suppliers, which revealed the following approximate split between American and Canadian purchases:

	2009	2008	2007	2006	2005	Totals
Abbott Laboratories	$3,118.50	$3,118.50	$1,627.45	$1,821.60	$3,965.40	$13,651.45
Oncology Supply	$270,163.15	$276,677.42	$443,308.70	$549,653.22	$705,328.10	$2,245,130.59
Totals for U.S. Supplier	$273,281.65	$279,795.92	$444,936.15	$551,474.82	$709,293.50	$2,258,782.04
Canadian Purchases	$9,713.02	$36,919.00	$76,976.00	$38,219.00	$27,898.00	$189,725.02

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, 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. Dr. Kuo agreed to a civil settlement payment to the United States covering false claims involving federal payors. On December 18, 2013, Dr. Kuo made full payment to the United States of double damages in the amount of $179,840.

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, five other similarly situated defendants have been sentenced. 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	Sentenced 12/6/13 to 1 month Probation or when fine of $5,000 is paid. No restitution because Defendant had already paid double damages of $1,139,532
Poornanand Palaparty	1:13MJ8014	Kenneth S. McHargh	Kytril, Gemzar, Oxaliplatin, Irinotecan, Camptosar, Zometa, Gemcitabine, Campto, Zoledronic Acid and Carboplatin	Sentenced on 11/12/13 to 1 year Probation; no fine; criminal restitution of $128,160 to Medicare and Medicaid ordered.
Timmappa Bidari	1:13MJ8013	Nancy A. Vecchiarelli	Taxotere, Gemzar, Oxaliplatin, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Procytox, Topotecan and Fluororacil	Sentenced on 11/13/13 to 1 year Probation; no fine; no restitution because Defendant had already paid double damages amount of $158,418.
Su-Chiao Kuo	1:13MJ8012	William H. Baughman, Jr.	Taxotere, Gemzar, Eloxatin, Campto, Zometa, Kytril	Sentencing set for 1/14/14 (double damages of $179,840 paid on 12/18/13)
Marwan Massouh	1:13MJ8015	Kenneth S. McHargh	Zometa and Gemzar	Sentenced on 10/16/13 to 1 year Probation; no fine; no restitution owed because Defendant had paid slightly more than single damages of $325,00 and plan to pay remainder of $284,150 over 3 years
David Fishman	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Sentenced on 11/19/13 to 1 year Probation; no fine; no criminal restitution because single damages of $75,000 paid by sentencing with the second $75,000 paid shortly thereafter
Hassan Tahsildar	1:13MJ8016	Greg White	Taxotere, Gemzar, Eloxatin, Irinotecan, Campto, Mitoxantrone, Hycamtin, Zometa, Camptosar, Kytril and Ondansetron	Sentencing set for 1/28/14 ($179,316 double damages already paid)
Legend				Green = sentenced

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 Probation's 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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By: /s/ Michael L. Collyer

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CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of January 2014 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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