UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 2:13-CR-56**
	)	
ANINDYA KUMAR SEN and PATRICIA POSEY SEN,	)	
	)	
Defendants.	)	

UNITED STATES' TRIAL BRIEF

Comes the United States of America, by and through William C. Killian, United States Attorney for the Eastern District of Tennessee, and submits the following Trial Brief to assist the Court.

The Third Superseding Indictment:

A Third Superseding Indictment was filed against Defendants, Anindya Kumar Sen ("Dr. Sen") and Patricia Posey Sen ("Posey"), on November 20, 2013. (R.94). In the Third Superseding Indictment, Counts 1 through 29 charge Dr. Sen with misdemeanor violations of 21 U.S.C. § 331(a) for the introduction or causing the introduction into interstate commerce of misbranded drugs. 21 U.S.C. § 333(a)(1)(misdemeanor penalty). Posey is charged in the same counts with felony violations of § 331(a), the charges alleging that she acted with the intent to defraud and mislead. 21 U.S.C. § 333(a)(2) (felony penalty). Counts 30 through 36 charge Posey with receiving merchandise imported contrary to law in violation of 18 U.S.C. § 545. Counts 37 through 81 charge Posey with engaging in a scheme to defraud health care benefit programs in violation of 18 U.S.C. § 1347. In Count 82, Posey is charged with making a false material statement on March 27, 2012 to a Special Agent of the Food and Drug Administration

Office of Criminal Investigation; Posey is charged in Count 83 with making a similar false material statement on April 5, 2012 to the same agent. In addition to the substantive charges, the indictment also seeks forfeiture from Posey of any proceeds of the health care fraud.

Factual Summary:

Dr. Sen was a medical doctor licensed to practice medicine in the State of Tennessee and practiced as East Tennessee Hematology Oncology and Internal Medicine (hereinafter "ETHOIM" or "the practice"), also known as East Tennessee Cancer and Blood Center. The practice had its primary location in Greeneville, Tennessee at 1406 Tusculum Boulevard, Suite 2000, and a satellite clinic in Johnson City, Tennessee. Dr. Sen, the sole physician in the practice, provided care and treatment for patients with cancer and blood diseases.

Assisting Dr. Sen in the management of ETHOIM was Sen's wife, Posey, who was employed as the practice manager. As a part of the treatment of patients, the practice purchased prescription drugs, including chemotherapy drugs, which were then prescribed by Dr. Sen and administered and dispensed to patients. Reimbursement for the drugs and their administration was sought from Medicare and Medicaid (through the TennCare program), as well as other health care benefit programs.

In April 2009, Posey began ordering and directing others to order drugs from Clinical Care. Clinical Care was a business with a reported address in Calgary, Alberta, Canada, who offered for sale to physicians and other health care providers in the United States drugs which had been obtained from foreign sources and which had not been approved by the FDA for distribution or use in the United States. In some instances, the drugs obtained from Clinical Care bore the same names as FDA-approved drugs; for other drugs, the drugs bore names completely different from the FDA-approved drugs. The misbranded unapproved drugs were then

administered to patients and claims for reimbursement for the drugs were submitted to Medicare, TennCare and other health care benefit programs.

As set out in more detail below, an FDA investigation into the drugs provided by Clinical Care determined that some of the drugs were from foreign manufacturers that were not registered with or inspected by the FDA; other drugs, while possibly coming from registered establishments, had not been listed with FDA for distribution and use in the United States. The drugs sold by Clinical Care included drugs which had been previously distributed in Turkey, India, the European Union and elsewhere. Drugs were received by ETHOIM from Clinical Care by two routes. Some drugs, particularly drugs that were required to be kept refrigerated, were sent through a reshipping service/freight forwarder in Wood Dale, Illinois called Meiko America. Other drugs would be sent directly to the practice by Royal Mail from Beeston, Nottingham, United Kingdom. Because the drugs were not manufactured or otherwise intended for distribution in the United States, the labels and labeling for the drugs did not comply with requirements of the Food, Drug and Cosmetic Act ("FDCA"). For example, some of the drugs' labels, labeling and package inserts were in foreign languages. Other drugs' labels and labeling did not provide dosage information, express the potency of the drugs in a standard format or contain the required "Rx only" symbol. Most of the drugs purchased from Clinical Care did not come from drug establishments registered with the FDA and none of the drugs were annually listed as drugs being produced at the establishments for distribution and use in the United States, the result being that drugs were being brought into the United States and administered to patients which had not been manufactured with the required FDA oversight.

As an example, the practice received a version of a prescription drug containing rituximab[2] provided by Clinical Care which was labeled "MabThera®." The drug MabThera® was manufactured at a drug establishment located in Switzerland that did not list MabThera® with the FDA in any annual list of drugs manufactured at the establishment for distribution in the United States. By contrast, the FDA-approved version of Rituximab that is made for distribution and use in the United States is labeled "Rituxan®" and is manufactured at an establishment registered with the FDA and the drug establishment annually lists the drug Rituxan® with the FDA as a drug that it is manufactured at that facility for distribution in the United States. Clinical Care invoices reflected the MabThera® sold to ETHOIM was intended for distribution in the European Union and Turkey.

The practice, ETHOIM, also received a version of a drug containing bevacizumab[3] from Clinical Care labeled as "Altuzan®." Altuzan® is a drug manufactured by a drug establishment located in Switzerland that did not list Altuzan® with the FDA on an annual list of drugs

[2] Rituximab is used alone or with other medications to treat certain types of non-Hodgkin's lymphoma (NHL), a type of cancer that begins in a type of white blood cells that normally fight infection. Rituximab is also used with another medication to treat the symptoms of rheumatoid arthritis, a condition in which the body attacks its own joints, causing pain, swelling, and loss of function in people who have already been treated with a certain type of medication called a tumor necrosis factor (TNF) inhibitor. Rituximab is in a class of medications called biologic antineoplastic agents. It treats NHL by causing the death of blood cells that have multiplied abnormally. It treats rheumatoid arthritis by causing the death of certain blood cells that may cause the immune system to attack the joints.

[3] Bevacizumab is used with chemotherapy to treat cancer of the colon (large intestine) or rectum that has spread to other parts of the body. Bevacizumab is also used with chemotherapy to treat certain types of lung cancer. Bevacizumab is also used to treat glioblastoma (a certain type of cancerous brain tumor) that has been already treated with other medications. Bevacizumab is also used in combination with another medication to treat renal cell cancer (RCC, a type of cancer that begins in the kidney) that has spread to other parts of the body. Bevacizumab is in a class of medications called antiangiogenic agents. It works by stopping the formation of blood vessels that bring oxygen and nutrients to tumors. This may slow the growth and spread of tumors. Bevacizumab had also previously been used to treat some breast cancers and is used to treat wet age-related macular degeneration.

manufactured there and was distributed after manufacturing by another company located in Turkey. Records reflect that all of the bevacizumab obtained from Clinical Care by the practice from on or about March 3, 2011 to February 9, 2012 was labeled "Altuzan®." By contrast, the FDA-approved version of bevacizumab that is made for distribution and use in the United States is labeled "Avastin®." Avastin® is manufactured in a registered drug establishment that annually lists the drug Avastin® with the FDA as a drug that it is manufactured at that facility. Clinical Care invoices reflected that the Altuzan® sold to ETHOIM was intended for distribution in Turkey, and the labels and labeling for thate version of Altuzan® are in Turkish.

As noted earlier, Posey began ordering drugs from Clinical Care in April 2009. In 2009, the chemotherapy nurses and other staff raised concerns that labels, labeling and particularly package inserts for the drugs were in foreign languages. In response, Posey told the staff that there were no problems with the drugs, or words to that effect. Over the next three years, the practice ordered more chemotherapy and chemotherapy supportive drugs from Clinical Care than from the practice's legitimate U.S. drug supplier, Oncology Supply, purchasing approximately $3.4 million from Clinical Care.

Records obtained from Oncology Supply revealed that no Avastin®, the approved U.S. version of bevacizumab, had been sold to the practice between March 30, 2011 and February 17, 2012. Further, the invoices provided by Clinical Care reflected that all of the drug bevacizumab sold to ETHOIM from March 2011 to February 2012 was the unapproved drug Altuzan®, the invoices describing the drugs with the country of distribution as "Turkey." Eight patients received the drug Altuzan® between April 2011 and January 2012, and claims for reimbursement were submitted to Medicare, BlueCross BlueShield of Tennessee, and United Healthcare for the drugs and their infusion.

Current and former nurses at the practice state that in mid-February 2012, they became aware of an announcement by Genentech, the U.S. manufacturer of Avastin®, that counterfeit Avastin® (bevacizumab) had been found in the United States. The nurses examined the bevacizumab at the Greeneville clinic and confirmed that the drug was the unapproved drug Altuzan®. One of the nurses recalled that lot numbers on the Altuzan at the practice matched the lot numbers of the suspected counterfeit drugs. The nurses advised Posey that they would not use the Altuzan, and a patient who was scheduled for treatment had his treatment delayed a week until approved Avastin could be obtained from Oncology Supply.

Although the Altuzan had been identified as possibly counterfeit and clearly unapproved, Posey did not immediately dispose of the drugs, nor did she notify FDA or other authorities. Not until March 7, 2013, when an employee brought to assistant manager Larry Edgell's attention the news reports concerning the FDA search at McLeod Cancer the previous evening, did Edgell and Posey take action. However, instead of notifying the FDA that ETHOIM may have obtained counterfeit drugs, Posey removed the Altuzan and had Edgell mail the drugs back to the United Kingdom.

In total, ETHOIM obtained misbranded unapproved drugs from Clinical Care from approximately April 2009 to March 2012. ETHOIM purchased over $3 million in misbranded unapproved drugs during this timeframe, provided the drugs to patients and billed Medicare, TennCare and other government and private health benefits programs approximately $3.2 million for the misbranded unapproved drugs.

Applicable Laws

The Food, Drug and Cosmetic Act –

Introduction of Misbranded Drugs into Interstate Commerce (21 U.S.C. § 331(a))

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et. seq*., has been recognized as one of the most important pieces of legislation ever enacted by Congress under the Commerce Clause. Federal courts at all levels regard the statute as *sui generis* by virtue of its "salutary" and "remedial" qualities, and have lauded the statute's "overriding purpose to protect the public health." *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026, 1028 (10th Cir. 1994); *United States v. Varela-Cruz*, 66 F.Supp.2d 274, 279 (D.P.R. 1999). As Justice Frankfurter explained, "[t]he purposes of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." *United States v. Dotterweich*, 320 U.S. 277, 280 (1943).

Most importantly, the Supreme Court has construed the FDCA broadly to effect its purpose, protecting the public health. Regard for public health "should infuse construction of the [FDCA] if it is to be treated as a working instrument of government and not merely as a collection of English words." *Id.* The general principle has emerged out of these cases that public health statutes like the FDCA deserve a liberal construction despite the strict interpretation ordinarily given criminal statutes. *United States v. Kordel*, 164 F.2d 913, 917 (7th Cir. 1947), *aff'd*, 335 U.S. 345 (1948); *United States v. Research Lab.*, 126 F.2d 42, 45 (9th Cir. 1942) ("The rule of strict construction . . . has little or no application to statutes designed, as the [FDCA] is designed, to prevent injury to the public health."); *A.O. Andersen & Co. v. United States*, 284 F. 542, 543 (9th Cir. 1922) (same); *United States v. Omar*, 91 F. Supp. 121, 123 (D. Neb. 1950) (same); *United States v. Commercial Creamery Co.*, 43 F. Supp. 714, 715 (E.D. Wash. 1942) (same). *Cf. Liparota v. United States*, 471 U.S. 419, 427 (1985) ("[T]he rule of

lenity is not to be applied where to do so would conflict with the implied or expressed intent of Congress[.]"). The United States Food and Drug Administration ("FDA") is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA.

In order to effectuate the purposes of the FDCA, the Act sets out a number of prohibited acts, 21 U.S.C. § 331, and penalties for those acts. 21 U.S.C. § 333. Further, § 331 prohibits the acts and "the causing thereof." 21 U.S.C. § 331. Many of the prohibited acts deal with food and drugs which are "adulterated" or "misbranded." 21 U.S.C. § 352 defines when a drug is "misbranded."

As noted earlier, Counts 1 through 29 of the third superseding indictment allege that Dr. Sen and Posey caused the introduction into interstate commerce of a quantity of prescription drugs that were "misbranded" within the meaning of the FDCA in that:

(a) The drugs came from a foreign drug establishment and that drug was not annually listed with the FDA by that establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment, 21 U.S.C. §§ 352(o), 360(j); [5]

(b) The drug's labeling failed to bear the symbol "Rx only," 21 U.S.C. § 353(b)(4)(A); 21 C.F.R. § 201.100(b)(1), or

(c) The drug's labeling failed to bear adequate directions for use, 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5 and 201.100.

[5] In that charges may be made in the conjunctive and proven in the disjunctive, *United States v. Stone*, 954 F.2d 1187, 1192 (6th Cir. 1992), "misbranding" may be proven if either the drug came from an establishment not registered with FDA *or* the drug was not annually listed as one of the drugs being manufactured for commercial distribution in the United States at that establishment.

To prove that the defendants introduced misbranded drugs into interstate commerce, the United States must prove the following elements: (1) the item charged in the indictment was a drug; (2) the item was introduced or delivered for introduction into interstate commerce by the defendants; and (3) the item was misbranded at the time it was introduced into interstate commerce. 21 U.S.C. 331(a); *United States v. Guardian Chemical Corp.*, 410 F. 2d 157, 162 (2nd Cir. 1969). In addition, because a felony violation of 21 U.S.C. § 331(a) has been alleged against Posey, a fourth element, that Posey acted with the intent to defraud or mislead, will need to be proven by the government. *See* 21 U.S.C. § 333(a)(2) (a violation of 21 U.S.C. § 331(a) done with the intent to defraud or mislead is punishable as a felony).

Because of the purposes of the Act, the FDCA imposes strict liability for misdemeanor violations, that is, there is no requirement that the prosecution prove a knowing or willful violation, or even that the defendant knew of the violation. A *prima facie* case is made against a "responsible person" by introducing evidence to show authority to prevent or correct a violation, and failure to do so. To that end, the elements which the United States must prove as to a "responsible person" are: (1) the defendant held a position of responsibility in the business entity; (2) the business introduced into interstate commerce[6] or caused the introduction into interstate commerce the drugs; and (3) the drugs were misbranded at the time of their introduction. 2B Fed. Jury Prac. & Instr. §§ 63:01 et seq. (6th ed.). An individual may be strictly liable under the FDCA if he held, at the time of the criminal conduct, "a position of sufficient authority and responsibility in the conduct of the business" regarding the processes and acts of the business that resulted in the challenged conduct. *United States v. H.B. Gregory Co.*,

[6] "Interstate commerce" means commerce between any State and any place outside a State and includes "foreign commerce." *United States v. Themy-Kotronakis*, 140 F.3d 858, 862-63 (10th Cir. 1998).

502 F.2d 700, 705 (7th Cir. 1974), *cert. denied*, 422 U.S. 1007 (1975). In *United States v. Park*, 421 U.S. 658 (1975), the Supreme Court noted "[w]e are satisfied that the [FDCA] imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions." *Id.* at 676. The Supreme Court further found that, "in providing sanctions which reach and touch the individuals who execute the corporate mission, … the [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *Id.* at 672. To the extent that a charged individual claims that his or her actions or authority as a corporate officer do not "bring him within the corporate liability standard," that is an affirmative defense that the individual has the burden of raising at trial. *Id.* at 673. "[R]equirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous," according to the Supreme Court, "but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them." *Id.* at 672.

Accordingly, any claimed good faith, mistake, or lack of knowledge is irrelevant as to misdemeanor liability under the FDCA. That Dr. Sen was a responsible person in his practice is beyond serious dispute. He was the sole owner of and the only doctor in the practice. He had authority and responsibility to oversee his medical practice. Had Dr. Sen exercised his authority and responsibility, he could have prevented or ended the shipments of unapproved misbranded drugs. The fact that Dr. Sen failed to do either is enough to subject him to misdemeanor liability. *Id.* at 674-75 (individual culpability found where the corporate officer involved had the authority and the capacity to stop the challenged conduct and thus could have prevented the adulteration or

misbranding merely by the exercise of his or her actual corporate authority). The only defense a defendant may raise as to such liability is "impossibility," that is, that the defendant was "powerless" to prevent or correct the violation. *Id.* at 673. Dr. Sen was not powerless to stop the purchase of the misbranded drugs. As a result, if the United States proves the three elements required by section 331(a), then Dr. Sen will be strictly liable. Similarly, should the United States prove that she caused the introduction of misbranded drugs, regardless of any claims of lack of knowledge or being misled by the Clinical Care employee, Posey will be strictly liable for the misdemeanor offense.

The elements of a felony prosecution are the same as a misdemeanor, plus intent to defraud or mislead. 21 U.S.C. § 333(a)(2); *United States v. Hiland*, 909 F.2d 1114, 1128 (8th Cir. 1990). This intent requires knowledge of the basic facts constituting the violation, but not specific intent to commit the precise FDCA violation charged. *Id.* The fraudulent intent may be aimed at consumers, or at regulators the defendant intends to frustrate by operating outside the realm of their regulatory activities. *United States v. Mitcheltree*, 940 F.2d 1329, 1347 (10th Cir. 1991); *United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991); *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988).

(1) Item Charged in the Indictment was a Drug:

The first element that must be established to prove a violation of 21 U.S.C. § 331(a) is that the items charged in the indictment were in fact drugs and, therefore, covered by the FDCA. "Drug," as used in the FDCA, is defined as an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and articles intended for use as a component of any such articles. *See* 21 U.S.C. § 321(g)(1). In

addition, a drug is a "prescription drug" if the drug, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measure necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;" or the drug "is limited by an approved [new drug application] to use under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1).

All of the items listed in the indictment are articles used to treat individuals with cancer and, therefore, meet the definition of a "drug" under 21 U.S.C. § 321(g)(1) because they are intended for use in the treatment, cure, mitigation or prevention of disease in humans. In addition, all of the drugs were "prescription drugs" because of their toxicity or other potentiality for harmful effect and because the drugs could be lawfully dispensed only upon the prescription of a practitioner licensed by law to administer such drugs.[7]

(2) Item was Introduced or Delivered for Introduction into Interstate Commerce:

Under Section 331(a), parties who receive misbranded or adulterated items from other parties (including middlemen who, in turn, pass the item on to another) are subject to the prohibitions of Section 331(a). *See United States v. Tuente Livestock*, 888 F. Supp. 1416, 1427 (S.D. Ohio 1995). The Supreme Court in *United States v. Sullivan*, 332 U.S. 689 (1948), held that products may still be "in" interstate commerce even though the interstate shipment is complete and the products are being held for local or interstate transactions. The Court stated that "the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment." *Id*. at 696. Because of the broad protection intended by

[7] Notably, all of the FDA approved versions of the drugs listed in the indictment are available in the United States only through a prescription.

Congress, products are covered by the FDCA "from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." *Id.* Therefore, in this case, the act of ordering and receiving the drugs listed in the indictment before dispensing the drugs to patients in the course and scope of ETHOIM's practice constituted introduction or delivery for introduction into interstate commerce.

(3) Item was Misbranded at the time it was Introduced into Interstate Commerce:

The drugs at issue are alleged to be "misbranded" in one or more of three ways. The first, and most obvious evidence that the drugs were misbranded under the FDCA, is that the drugs were not manufactured in compliance with 21 U.S.C. § 352(o). Pursuant to section 352(o), "[a] drug … shall be deemed to be misbranded … [i]f it was manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under section 360 of [Title 21]," or if the drug "was not included in a list required by section 360(j) of [Title 21]."

In this case, many of the establishments who were manufacturing, preparing, propagating, compounding or processing the drugs received by the practice from Clinical Care were not registered with the Secretary of Health and Human Services in accordance with 21 U.S.C. § 360(i). Accordingly, any drugs manufactured by those establishments and introduced into the United States were "misbranded."

In addition to registering with the Secretary under section 360(i), "*every person who registers with the Secretary* under subsection … (i) of this section shall, *at the time of registration* under any such subsection, file with the Secretary a list of all drugs … which are being manufactured, prepared, propagated, compounded or processed by him for commercial distribution." 21 U.S.C. § 360(j) (emphasis added). Therefore, if the establishments had not registered themselves with the Secretary, it is also impossible them to have complied with

section 360(j) and its mandate. In addition, even if some of the manufactures had complied with section 360(i), they still would be required to list the particular drug under section 360(j).

21 U.S.C. § 352(o) clearly states that a drug is misbranded if it was manufactured in an establishment not registered with the Secretary or if the drug was not included on a list required under section 360(j); because none of the drugs from Clinical Care were drugs included on a list as required by section 360(j), the drugs were clearly misbranded under 21 U.S.C. § 352(o).

The second way the drugs were misbranded was for failing to comply with 21 U.S.C. § 353(b)(4(A) and 21 C.F.R. § 201.100(b)(1). Section 353(b)(4)(A) states that all prescription drugs, which because of their toxicity or other potentiality for harmful effect, or method of its use, or the collateral measure necessary to its use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, "shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only.'" As mentioned *supra*, all of the FDA approved versions of the drugs being ordered from Clinical Care were prescription drugs. Furthermore, even though the Clinical Care drugs were not FDA approved, they were still subject to 21 U.S.C. § 353(b)(4)(A) because, as chemotherapy drugs, their toxicity or other potential harmful effect and their method of use (generally intravenous injections) rendered them not safe for use except under the supervision of a licensed practitioner. This is demonstrated by the fact the drugs were infused, that is, administered intravenously, under close medical supervision.

As a result of their toxicity, harmful effect and method of use, all of the drugs at issue were required by the FDCA to bear the symbol "Rx only." Any failure to bear this symbol would render the drugs misbranded under the clear mandate of 21 U.S.C. § 353(b)(4)(A). In this case, because the drugs were not originally manufactured for distribution in the United States, the

drugs' labels and labeling failed to contain the "Rx only" symbol and, therefore, were misbranded.

The final way in which the drugs were misbranded was in violation of 21 U.S.C. § 352(f)(1), which requires a drug's labeling bear adequate directions for use. Pursuant to this section, a drug is deemed misbranded "[u]nless its labeling bears adequate directions for use."

"Adequate directions for use" is defined as directions under which a layman can use the drugs safely. 21 C.F.R. § 201.5; *see also United States v. Articles of Drug et al.*, 625 F.2d 665, 671-75 (5th Cir. 1980) (upholding FDA's interpretation that 21 U.S.C. § 352(f)(1) requires directions that are adequate for self-administration by a layman). The drugs at issue in this case were prescription drugs as discussed previously. Therefore, because the drugs could not be administered by anyone other than a licensed practitioner, by definition, adequate directions for use by a layman could not be written for the prescription drugs at issue in this case. *Id.* at 673-75. As a result, prescription drugs are always misbranded under 21 U.S.C. § 352(f)(1); however, the law contains several exemptions that allow prescription drugs to move in interstate commerce despite this status.

In order to qualify for an exemption from 21 U.S.C. § 352(f)(1), all of the requirements of 21 C.F.R. § 201.100 must be met.[8] These include: (1) the drug, at the time it was introduced into interstate commerce, was in the possession of a practitioner licensed by law to administer or prescribe prescription drugs; (2) the drug's label contained all of the following information: the statement "Rx only;" the recommended or usual dosage; the route of administration, if it is not

[8] While the United States proffers the "Rx only" symbol as an example *infra*, it should be noted that the defendants bear the burden of producing evidence that the drugs in this case met the exemption. If the defendant can meet this burden, then the government bears the burden of persuasion to refute that claim. *See United States v. Titterington*, 374 F.3d 453, 456 (6th Cir. 2004) (c*iting McKelvey v. United States*, 260 U.S. 353, 357 (1922) (explaining government need not negate statutory exemptions, rather defendant must establish he meets such exemptions)).

for oral use; the quantity or proportion of each active ingredient; if the drug is for other than oral use, the names of all inactive ingredients; and identifying lot or control numbers from which it is possible to determine the complete manufacturing history of the package of the drug; (3) at the time the drug was introduced into interstate commerce, the labeling on or within the package from which the drug was to be dispensed bore adequate directions for its use; and (4) if the drug was subject to Section 505 of the FDCA, the labeling on or within the package from which the drug was to be dispensed was the labeling authorized by an approved New Drug Application or abbreviated New Drug Application on file with the FDA. *See* 21 C.F.R. §§ 201.5 and 201.100. The "adequate directions for use" required for such prescription drugs must be in English (unless the drugs are distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English). 21 C.F.R. § 201.15(c)(1). Accordingly, a drug (other than a drug for distribution in Puerto Rico or a Territory) which bears a language other than English on the labels and labeling does not meet the requirements of "adequate directions for use" and is therefore misbranded.

Of particular relevance to this case is the requirement that the drug's label contain the statement "Rx only." None of the prescription drugs imported by the defendants in this case contained the "Rx only" symbol. Even minor deviations from the specific requirements of the regulation will disqualify a drug from exemption. *See In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 789-90 (8th Cir. 2006) (finding drugs misbranded where their labels did not bear the required "Rx only" symbol, even though they were labeled "Pr," which was the Canadian equivalent of "Rx only").

(4) Intent to Defraud or Mislead

In addition to the three elements outlined above, as to Posey the United States bears the burden of proving a fourth element: the intent to defraud or mislead. The intent to defraud or mislead is not limited to conduct intended to defraud the ultimate consumer and encompasses conduct intended to mislead or defraud government agencies. *United States v. Bradshaw*, 840 F.2d 871, 874 (11th Cir. 1988) (extending the intent to defraud or mislead language to representations made to FDA and state enforcement authorities). In this case, Posey acted with the intent to defraud or mislead three people.

First, Posey intended to defraud and mislead the patients of ETHOIM (the ultimate consumers) who were not receiving the drugs which they were being prescribed. For instance, using the earlier example of Altuzan, patients were prescribed Avastin®; however, Posey ordered Altuzan from Clinical Care with the intent to defraud and mislead the patients who reasonably expected to receive the drugs they were prescribed, not the cheapest alternative Posey could order.

Second, Posey intended to defraud the health care benefit programs[9] making payments for the services involving the misbranded drugs. For example, Posey ordered the Altuzan from Clinical Care with full knowledge that she was not receiving Avastin®; however, this fact did not stop Posey from billing public and private health care benefit programs under the HCPCS/CPT code for Avastin®. The only possible reason Posey would act in such a way is in order to mislead and defraud the health care benefit programs into paying for the misbranded Altuzan and connected services.

Finally, Posey is guilty of intending to defraud and mislead based on her false statements made to the FDA. Posey made false statements on two separate occasions as to whether she was

[9]Health care benefit programs are defined and discussed at length on pages 14-19 of this Trial Brief.

receiving foreign drugs to FDA Special Agent, Robert West. Under the Eleventh Circuit's decision in *Bradshaw*, these misleading statements to the FDA are sufficient to find the intent to defraud and mislead. In conclusion, Posey's behavior and knowledge of the misbranded nature of the drugs being ordered by ETHOIM, as well as her false statements to the FDA, subject her to the penalties for a felony violation of 21 U.S.C. § 331(a) for acting with the intent to defraud and mislead.

Receiving Merchandise Imported Contrary to Law (18 U.S.C. § 545)

Counts 30 through 36 of the Third Superseding Indictment allege that Posey, in violation of 18 U.S.C. § 545, did fraudulently and knowingly import and bring into the United States and cause to be imported and brought into the United States merchandise, that is, prescription drugs, contrary to law, in that:

(a) The drugs were unapproved for introduction into interstate commerce in the United States, in violation of 21 U.S.C. §§ 331(d) and 355; and

(b) The drugs were misbranded, in violation of 21 U.S.C. §§ 331(a), 352(f), 352(o), 360(j) and 353(b)(4)(A).

18 U.S.C. § 545 provides that:

> Whoever fraudulently or knowingly imports or brings into the United States, any merchandise contrary to law, or receives, conceals, buys, sells or in any manner facilitates the transportation, concealment or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law … shall be fined under this title or imprisoned not more than 20 years, or both.

In addition, section 545 states that "[p]roof of [a] defendant's possession of such goods, unless explained to the satisfaction of the jury, shall be deemed evidence sufficient to support [a] conviction." *Id.* Thus, in order to convict Posey, the United States must prove the following elements: (1) the defendant fraudulently or knowingly; (2) imported or brought into the United

States; (3) any merchandise; (4) contrary to law. *United States v. Teh*, 535 F.3d 511, 517 (6th Cir. 2008). *See also United States v. Davis*, 597 F.2d 1237, 1238 (9th Cir. 1979)(elements are (1) merchandise was imported into the United States; (2) the importation was contrary to law; and (3) the defendant knowingly accomplished the importation).

(1) Fraudulently or knowingly:

The first element required to prove a violation of section 545 is that the defendant knowingly or fraudulently imported merchandise contrary to law. *See United States v. Bader*, 678 F.3d 858, 879 (10th Cir. 2012). "With respect to the knowledge element, it is not necessary for the defendant to have known the specific statute violated. It is enough if he acts knowing that his conduct is illegal in some respect." *Babb v. United States*, 218 F.2d 538, 540 (5th Cir. 1955). Thus, all that is required is that defendants knew they were bringing in merchandise contrary to law.

In this case, Posey's knowledge that the importation was contrary to law can be shown from several facts. For instance, in 2009 Posey asked a Clinical Care employee about whether a certain drug was "FDA approved," illustrating that Posey was aware of the necessity of drugs being approved by FDA for use in the United States. The fact that Posey was purchasing the drugs from Clinical Care at approximately 80% of the costs of FDA-approved drugs from Oncology Supply also place Posey on notice that the importation was unlawful. Similarly, the fact that the unapproved drugs did not bear National Drug Code (NDC) numbers like the FDA-approved drugs, NDC numbers that were required to determine the correct HCPCS/CPT billing code, placed Posey on notice that the importation was unlawful. Finally, Posey's efforts to conceal the unlawful importation further evidences her knowledge that the importation was unlawful.

(2) Imported or Brought into the United States:

Under section 545, an importation takes place whenever merchandise is brought within the territorial waters of the United States with the intent to illegally bring such merchandise into the country. *See Callahan v. United States*, 53 F.2d 467 (3rd Cir. 1931), *aff'd*, 285 U.S. 515 (1932). As such, the offense is established even when goods are brought into the country contrary to law but never unladen. *See Gillespie v. United States*, 13 F.2d 736 (2nd Cir. 1926). In this case, the proof will establish that the drugs identified in Counts 30 through 36 were sent to the practice by Royal Mail from the United Kingdom.

(3) Merchandise:

While "merchandise" is not defined in Title 18, it is defined in Title 19, which was part of the same act as Title 18 and, therefore, Title 19 should control the definition of "merchandise" for purposes of 18 U.S.C. § 545. *United States v. Garcia-Paz*, 282 F.3d 1212, 1214 (9th Cir. 2002). Title 19 defines "merchandise" as "goods, wares, and chattels of every description, ... includ[ing] merchandise the importation of which is prohibited." *Id.* (*citing* 19 U.S.C. § 1401(c)). In this case it is obvious that the prescription drugs at issue, while undoubtedly prohibited from being imported, are well within the broad definition of merchandise.

(4) Contrary to Law:

The phrase "contrary to law" as used in section 545 is not confined in its application to the customs laws. Rather, it means contrary to any existing law and even includes administrative regulations having the force and effect of law. *See, e.g. United States v. Alghazouli*, 517 F.3d 1179 (9th Cir. 2008) (violation of a Clean Air Act regulation sufficient under section 545); *United States v. Mitchell*, 39 F.3d 465, 468-70 (4th Cir. 1994)(violation of fish and wildlife regulation). The Ninth Circuit in *Roseman v. United States*, 364 F.2d 18 (9th Cir. 1966) held that

violations of the FDCA misbranding statutes constituted sufficient legal basis for finding importation contrary to law. In this case, much like in *Roseman*, the FDCA misbranding statutes rendered the importation of the prescription drugs contrary to law in that misbranded drugs are specifically prohibited from being introduced into interstate commerce. *See* 21 U.S.C. § 331(d).

Health Care Fraud (18 U.S.C. § 1347)

Counts 37 through 81 charge Posey with scheming to defraud and obtain money by false pretenses from public and private health care benefit programs in violation of 18 U.S.C. § 1347. Specifically, Title 18, United States Code, § 1347 provides:

> (a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice
>
> (1) to defraud any health care benefit program; or
>
> (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,
>
> in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both.
>
> (b) With Respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

18 U.S.C. § 24(b) defines "health care benefit program" to mean:

> any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

In this case, the *public* health care benefit plans against which Posey executed a scheme to defraud included Medicare and Medicaid (through Tennessee's TennCare program). The

private health care benefit programs included BlueCross BlueShield of Tennessee and United Healthcare.

The fact that both the public and private health care benefit plans in this case affected commerce cannot be disputed. Affecting interstate commerce means any action, which in any way, interferes with, changes, or alters the movement or transportation or flow of goods, merchandise, money or other property in commerce between or among the states. Furthermore, the effect can be minimal. As the Fifth Circuit has concisely stated, "it cannot seriously be contended that [Medicare, Medicaid and large private insurance companies] and their functions do not affect commerce." *United States v. Hickman*, 331 F.3d 439, 444 (5th Cir. 2003).

Public Health Care Benefit Programs:

Medicare:

In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Health Insurance for the Aged and Disabled Program, popularly known as Medicare, to pay for the costs of certain health care services. The Medicare Program is a federally funded health insurance program that provides funds for health care services to persons aged 65 and above and to certain disabled persons. *See* 42 U.S.C. §§ 1395 *et seq*. The Medicare Program has several parts, including Part B which authorizes payment for medical and other health services, including physician services, and a limited number of prescription drugs. Included under Part B are injectable or intravenous drugs, including chemotherapy drugs, furnished incident to a physician's services.

The United States, through the Department of Health and Human Services ("HHS"), administers the Medicare Program. HHS has delegated the administration of the Medicare Program to its component agency, Centers for Medicare and Medicaid Services ("CMS"). The

United States pays Medicare claims from the Medicare Trust Fund through CMS, which contracts with private insurance carriers to process and pay Medicare claims. In this case, the private insurance carrier who was under contract with CMS was, and still is, Cahaba Government Benefits Administrators.

Health care providers desiring to treat Medicare beneficiaries must apply to Medicare for a provider number, which is used to process and pay claims (also known within the context of the Medicare Program as reimbursement). To become a Medicare provider and thus eligible for Medicare reimbursement, health care providers must certify that they agree to abide by Medicare laws, regulations and program instructions and conditions. All providers that bill Medicare for services also have a duty to be knowledgeable about the statutes, regulations and program instructions and conditions regarding coverage for services for which they seek reimbursement. Medicare providers certify that they understand that reimbursement of a claim by Medicare is conditioned upon the claim and underlying transaction complying with the laws, regulations and program instructions and conditions and on the provider's ongoing compliance with all applicable conditions of participation in the Medicare Program. With each submission of a claim for payment to the Medicare Program, the provider certifies to CMS that the claim is correct, complete and that it is properly payable. It is a condition of the Medicare Program that Medicare provides reimbursement only for drugs approved by FDA for use in the United States.

Medicare Part B currently covers a limited number of outpatient prescription drugs and biologicals (collectively referred to as drugs). Those that are covered include injectable drugs administered by a physician; certain self-administered drugs, such as oral anti-cancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines. For chemotherapy drugs, physicians are also reimbursed for the cost of "infusing,"

that is, administering the drugs. Coverage for such drugs and the infusion of the drugs is also provided by TennCare and other health care benefit programs.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 established a new methodology for Medicare Part B reimbursement of most covered drugs. Effective January 1, 2005, reimbursement to physician practices for drugs is generally set at 106 percent of the average sales price (ASP). The ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that quarter. The ASP is net of any price concessions and excludes certain sales, including those at a nominal charge.

For Medicare, TennCare, and other public and private health care benefit programs to ensure that claims for reimbursement from health care providers are processed in an orderly and consistent manner, requirements for standardized coding of such claims have been established, to include the Health Care Financing Administration Common Procedure Coding System (HCPCS) and National Drug Codes (NDC),[10] as maintained and distributed by the U.S. Department of Health and Human Services, and Current Procedural Terminology (CPT), as maintained and distributed by the American Medical Association. 42 U.S.C. § 1320d-2; 42 C.F.R. § 414.40(a); 45 C.F.R. § 162.1002. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, to include the chemotherapy and supportive drugs listed above. The authority to maintain and distribute HCPCS codes has been delegated to the Centers for Medicare and Medicaid Services (CMS). In

[10] The Drug Listing Act of 1972 requires registered drug establishments to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. 21 U.S.C. § 360. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs approved for human use in the United States.

addition to the HCPCS codes, CMS maintains and distributes a "crosswalk" identifying the HCPCS codes and the corresponding FDA- approved and listed drugs identified by the drugs' NDC numbers. These standardized codes, to include the HCPCS codes for chemotherapy and chemotherapy supportive drugs (often referred to as "J" codes due to the first character of the codes), are used in completion of the CMS Form 1500, Health Insurance Claim Form, which is submitted by the health care provider seeking reimbursement to the health care benefit programs.

Medicaid/TennCare:

On January 1, 1994, Tennessee began a new health care reform program called TennCare. This program essentially replaced the Medicaid program in Tennessee. TennCare was designed as a managed care model and was to extend coverage to uninsured and uninsurable persons who were not eligible for Medicaid. The TennCare program was implemented as a five-year demonstration program approved by the Federal Health Care Financing Administration (HCFA), which is now known as CMS. The program received several extensions after the original expiration date of December 30, 1999 and has continued on operating at all times relevant to this case.

The current TennCare program is really two programs. There is TennCare Medicaid, which is for persons who are Medicaid eligible, and TennCare Standard, which is for persons who are not Medicaid eligible but who have been determined to meet the state's criteria as being either uninsured or uninsurable. Historically, individuals in both programs have received the same services. TennCare Standard enrollees with family incomes at or above the poverty line are required to pay premiums and co-pays, however.

TennCare services are offered through several managed care entities. Each enrollee has a

Managed Care Organization ("MCO") for his primary care and medical/surgical services, a Behavioral Health Organization for his mental health and substance abuse treatment services and a Pharmacy Benefits Manager for his pharmacy services. Enrollees are allowed to choose the MCO they wish from among those available in the areas in which they live. Traditionally, MCOs have been "at risk," meaning that their compensation was based on a per member, per month capitation fee for each enrollee, regardless of how many services the enrollee used.

Each TennCare member uses their Social Security number as their cardholder ID number to identify them for TennCare benefits. Health care providers use the member ID number to identify the member when completing claims to the proper TennCare Managed Care Contractor ("MCC") (the MCOs) for payment of the services performed by the provider.

In order for a health care provider to bill TennCare, they must be "credentialed" through the MCCs and receive a provider number as a participating provider. The credentialing process ensures the provider's participation status and that the provider is a licensed professional in good standing. A participating provider agrees to accept TennCare assignment (i.e. accepting the reimbursement rates offered by the MCC) and abide by the rules and regulations of the TennCare MCC. Participating providers are notified of billing criteria, rules and regulations through the MCC Provider Manual and other MCC issued publications.

The MCCs are responsible for processing and paying claims according to the rules and regulations from the State's Bureau of TennCare. Additional MCC responsibilities include coordinating electronic data interchange for electronic claims processing, handling provider enrollment, performing medical reviews as deemed appropriate and maintaining an anti-fraud and abuse program/unit(s).

Private Health Care Benefit Programs:

In addition to the public health care benefit programs, Posey also submitted claims for reimbursement to private health care benefit programs namely, Blue Cross-Blue Shield of Tennessee and United Healthcare. Both of these plans are commercial health care benefit plans. Claims are submitted to these private programs in a similar manner as claims are submitted to Medicare and TennCare providers. In addition to similar claim submission procedures, private health care benefit programs also only reimburse providers for FDA approved drugs and ancillary services related to the FDA approved drugs. The main distinction between the public and private health care benefit programs is the fact that public health care benefit programs are completely, partially or jointly funded by federal and/or state funds.

Elements of Health Care Fraud:

In order to establish a violation of 18 U.S.C. § 1347, the prosecution must prove beyond a reasonable doubt that Posey "(1) knowingly devised a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items, or services; (2) executed or attempted to execute this scheme or artifice to defraud; and (3) acted with intent to defraud." *United States v. Martinez*, 588 F.3d 301, 314 (6th Cir. 2009) (*quoting United States v. Hunt*, 521 F.3d 636, 645 (6th Cir. 2008)).

(1) Knowingly Devised a Scheme or Artifice to Defraud a Health Benefit Program:

The first element that the prosecution must prove beyond a reasonable doubt is that Posey knowingly devised a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items or services. A scheme to defraud, or to obtain the money or property of another, is not defined according to any technical standards; however, it must involve some sort of fraudulent misrepresentation or omission reasonably calculated to deceive ordinary persons. *See Neder v. United States*, 527 U.S. 1, 27

(1999). Furthermore, the fraudulent representation or statement must relate to a material fact or matter, *id.,* and a material fact is one which would reasonably be expected to be of concern to a reasonable and prudent person in relying upon the representation or statement in making a decision. *United States v. Gaudin*, 515 U.S. 506, 509 (1995).

In this case, the scheme and artifice knowingly devised by Posey to defraud health care benefit programs, and the materially fraudulent misrepresentation, relate to the misuse of particular billing codes by Posey. More specifically, Posey devised a scheme where the practice was able to increase its profits by billing health care benefit programs under a HCPCS/CPT code that represented that the FDA-approved version of bevacizumab, Avastin®, was administered to patients. On claims sent to health care benefit programs for payment for services, the practice used HCPCS/CPT code "J9035." J9035 is the code for the FDA-approved version of Avastin®, identified specifically by two NDC numbers, and the only permissible use of code J9035 that is properly reimbursable by health care benefit programs is for administering Avastin®. However, from March 2011 to February 2012, the practice was not administering Avastin®, but rather, Altuzan, an unapproved version of bevacizumab manufactured for distribution outside the United States.

By purchasing and administering Altuzan, Posey was able to increase the practice's profits. As noted earlier, Medicare, as well as other health care benefit programs, reimburse physicians for chemotherapy drugs based upon a percentage of the "average sale price," the percentage for Medicare being 106%. Medicare publishes quarterly the average sale price for reimbursable drugs and the allowable reimbursement for the drugs based on sales information received from drug manufacturer. Because the reimbursement amount is fixed, the only way to increase profits is to purchase the drug cheaper. With the unapproved drugs from Clinical Care

costing approximately 80% of the cost of the approved drugs from Oncology Supply, the practice could substantially increase its profit on each drug claim.

(2) Executed or Attempted to Execute the Scheme or Artifice to Defraud:

The second element that must be proven is that, not only did Posey devise a scheme or artifice to defraud, but that she actually executed or attempted to execute the scheme. The unit of prosecution under the health care fraud statute, 18 U.S.C. § 1347, that is, the execution or attempted execution of the fraudulent scheme, has generally been interpreted as the individual false claim to a health care benefit program. *United States v. Hickman*, 331 F.3d 439, 447 (5th Cir. 2003). Here, Posey is charged with causing to be submitted forty-five separate false claims for six patients to Medicare and BlueCross BlueShield of Tennessee in 2011 and 2012 seeking reimbursement for the approved drug Avastin when the unapproved drug Altuzan was provided.

(3) Acted with Intent to Defraud:

The final element needed to establish health care fraud is that Posey acted with the intent to defraud. "Direct proof" of one's specific wrongful intent is "rarely available" but willfulness may be inferred from circumstantial evidence of fraudulent intent. *United States v. Marabelles*, 724 F.2d 1374, 1379-80 (9th Cir.1984); *see also United States v. Tucker*, 133 F.3d 1208, 1218 (9th Cir. 1998). The Sixth Circuit has applied this reasoning to a section 1347 conviction, explaining that "[i]ntent can be inferred from efforts to conceal the unlawful activity, from misrepresentations, from proof of knowledge and from profits." *United States v. Davis*, 490 F.3d 541, 549 (6th Cir. 2007) (internal quotation marks and citation omitted). All those factors are present in this case.

Posey's intent can be inferred from her efforts to conceal the unlawful activity and accompanying misrepresentations. For example, Posey lied to FDA and FBI agents during the

investigation. Finally, intent can be inferred from Posey's efforts to conceal the unapproved Altuzan by shipping the unapproved drugs back to the United Kingdom after learning of FDA's investigation of McLeod Cancer and Blood Center in Johnson City.

False Statements (18 U.S.C. § 1001(a)(2))

In Counts 82 and 83, Posey is charged with knowingly and willfully making false, fraudulent and fictitious material statements and representations to Special Agent Robert West of the FDA Office of Criminal Investigation. Both of the false statements made by Posey were in response to questions regarding whether the practice was purchasing or using foreign or foreign labeled drugs. While Posey certainly had a Fifth Amendment right to not answer Agent West's questions, Posey's knowing and willful misrepresentations to Agent West fall squarely within the conduct prohibited by 18 U.S.C. § 1001(a)(2). *See United States v. Steele*, 933 F.2d 1313, 1320 (6th Cir. 1991)(en banc). Furthermore, the questions were posed during the course of a criminal investigation by the FDA; thus, as recognized by the Supreme Court in *United States v. Rodgers*, 466 U.S. 475 (1984), the false statements to the federal agent violate the false statements statute.

In order to find Posey guilty of violating 18 U.S.C. § 1001(a)(a), the prosecution must prove the following elements: (a) that the defendant made a statement or representation; (b) that the statement was false, fictitious or fraudulent; (c) that the statement or representation was material; (d) that the defendant acted knowingly and willfully; and (e) that the statement pertained to a matter within the jurisdiction of the executive branch of the United States government. *See United States v. Geisen*, 612 F.3d 471, 489 (6th Cir. 2010).

Posey made verbal statements and representations to Special Agent West in response to his questions posed to Posey. In addition to making the statement, the prosecution must also

show that it was false, fictitious or fraudulent. According to the Sixth Circuit Pattern Instructions for section 1001(a)(2), a statement is false or fictitious if it was untrue when it was made, and the defendant knew it was untrue at that time. A statement is fraudulent if it was untrue when it was made, the defendant knew it was untrue at that time and the defendant intended to deceive. In this case, Posey's statements were false and fictitious as well as fraudulent. Posey specifically denied buying or using foreign drugs or foreign labeled drugs at the practice. At the time Posey made these statements, she had been purchasing foreign drugs from Clinical Care for roughly three years. Posey's obvious goal in lying to Agent West was to deceive Special Agent West and thwart the investigation. As a result, not only are the statements false and fictitious, but because they were made with the intent to deceive, they are also fraudulent.

In determining whether the statement was material, the Sixth Circuit has defined a material statement as one that has the natural tendency to influence or is capable of influencing a decision of the governmental entity. *See United States v. White*, 270 F.3d 356, 365 (6th Cir. 2001). In this case, the FDA was investigating the importation and use of unapproved foreign drugs in the United States. Telling an FDA investigator that you did not import or use foreign drugs clearly could influence a decision by FDA regarding the investigation. In addition, the fact that the statement was made directly to an FDA agent conducting an investigation further proves that the statements were made knowingly and willfully. An act is done knowingly and willfully if it is done voluntarily and intentionally, and not because of mistake or some other reason. In this case, not only did Posey voluntarily make the statements in response to Agent West's questions, she intentionally gave the answers she did in order to try and avoid discovery of her misconduct.

The final element, that the statement occurred within the jurisdiction of the executive branch, is straightforward. A matter is within the jurisdiction of the executive branch of the United States government if the executive branch has the power to exercise authority in that matter. The Sixth Circuit has explained that, "[w]hen [a] federal agency has power to exercise its authority, even if the federal agency does not have complete control over the matter, the matter is within the agency's jurisdiction." *United States v. Grenier*, 513 F.3d 632, 638 (6th Cir. 2008) (internal citations omitted).

FDA is an "agency" of the United States within the Department of Health and Human Services. As noted earlier, FDA is charged with enforcement of the FDCA, to include prohibitions on misbranded drugs. It is the job of the President (and his appointed heads of federal departments and agencies) to implement and enforce the laws written by Congress. In this case, the executive branch, through the FDA, was enforcing the FDCA, which regulates all aspects of food, drugs and cosmetics in this country. That the FDA had the power to exercise its authority regarding the importation of unapproved drugs brought into this country is beyond debate. As a result, Posey's statements involved a matter occurring within the jurisdiction of the executive branch.

Evidentiary Issues:

In addition to the legal arguments above, the government expects issues to arise at trial in regards to several evidentiary issues. Each of these anticipated issues is discussed more fully below.

Character Evidence

Under Rule 404(a)(1) of the Federal Rules of Evidence, a defendant may offer evidence of a pertinent trait of his or her character for the purpose of proving that he or she acted in conformity therewith on a particular occasion. That is, the defendant may present evidence of pertinent good character traits to suggest to the jury that a person of his or her good character would not commit the offense with which he or she is charged. *Michelson v. United States*, 335 U.S. 469 (1948); *United States v. Cylkouski*, 556 F. 2d 799 (6th Cir. 1977).

However, character testimony is admissible only when relevant to a particular issue, and witnesses may testify only about the character trait relevant to that issue. "The word 'pertinent' is read as synonymous with 'relevant.'" *United States v. Angelini*, 678 F.2d 380, 381 (1st Cir. 1982). Because Dr. Sen is not charged with an offense involving intent, knowledge, or willfulness, proof of his character is simply irrelevant and inadmissible. *See United States v. Hall*, 653 F.2d 1002, 1005-06 (5th Cir. 1981) (generally, the test for relevance in a criminal case is based upon the elements of the offenses charged and the relevant defenses raised to defeat criminal liability).

Similarly, evidence concerning Dr. Sen's qualifications and reputation as a physician is irrelevant to a violation of 21 U.S.C. § 331(a). As noted earlier, the Supreme Court has stated that the only defense which may be raised is that the defendant was powerless to prevent the violation. *Park*, 421 U.S. at 673.

Claims of Drug Equivalence

The Court should prohibit any arguments by the defendants that the unapproved and misbranded drugs obtained through Clinical Care contained the same or similar active ingredients as FDA-approved drugs. There would be no legal relevance to that contention. FDA does not approve active ingredients; FDA approves finished pharmaceutical products, to include

the active ingredients, inactive ingredients, manufacturing process, packaging, labels, labeling and product inserts. Unapproved drugs are not exempt from the FDA-approval requirement simply because other drug companies followed federal law and obtained FDA approval for their products. *See United States v. Genendo Pharmaceutical*, 485 F.3d 958, 960 (7th Cir. 2007) ("Before a drug is introduced into interstate commerce, a drug manufacturer must obtain FDA approval (specific to each drug and each manufacturer) of the manufacturing process, labeling, and packaging of the drug."); *see also United States v. Generix Drug Corp.*, 460 U.S. 453, 459 (1983) ("The term 'drug' is plainly intended throughout the Act to include entire drug products, complete with active and inactive ingredients"); *In re Canadian Import Antitrust Litigation*, 470 F.3d 785, 790 (8th Cir. 2006) (holding that drugs approved for use in foreign markets are unapproved and misbranded under U.S. law, despite being chemically identical to FDA-approved equivalents).

In the instant case, Dr. Charles Lee will testify that the drugs obtained by ETHOIM from Clinical Care were not approved by the FDA. The Court should not allow the defendants to bootstrap the unapproved drugs to FDA-approved drugs. To permit the defendants to offer such evidence or argue this theory to the jury invites the jury to disregard and nullify the law. *See United States v. Krzyske*, 836 F.2d 1013, 1021 (6th Cir. 1988)(defendant had no right to instruction on jury nullification; "A jury's 'right' to reach any verdict it wishes does not, however, infringe on the duty of the court to instruct the jury only as to the correct law applicable to the particular case.") *See also United States v. Hill*, 2010 WL 4604033, *2 (W.D.Ky.,Nov. 2, 2010), aff'd, 483 Fed.Appx. 195 (6th Cir. 2012) (granting government motion to prohibit defense from arguing jury nullification). Concomitant with the obligation to instruct

the jury as to the correct law is the Court's obligation to admit only relevant and material evidence.

Business Records

As shown below, the invoices, packing slips and electronic mail between Clinical Care and ETHOIM were records kept in the usual course of those entities' business activities and as such are admissible under Rule 803(6), Federal Rules of Evidence.

Rule 803(6) of the Federal Rules of Evidence permits the admission of hearsay contained in a "memorandum, report, record, or data compilation, in any form, of acts, events, conditions, opinions, or diagnoses" where the following conditions are met: (1) it must be "made at or near the time," (2) it must be "by, or from information transmitted by, a person with knowledge," (3) it must be, "kept in the course of a regularly conducted business activity," and (4) it must have been "the regular practice of that business activity to make the memorandum, report, record, or data compilation." These conditions must be shown by the testimony of a custodian or some other qualified witness or by a certification that complies with Rule 902(11) or other rule or statute permitting certification. The term "business" includes "business, institution, association, profession, occupation, and calling of every kind, whether or not conducted for profit."

An invoice received at the time of purchase is a business record. *United States v. Hines*, 564 F. 2d 925, 928 (10th Cir. 1977). Similarly, delivery invoices in the possession of a manufacturer but prepared by a common carrier are business records. *United States v. Pfeiffer*, 539 F. 2d 668 (8th Cir. 1976). *See also United States v. Stavroff*, 149 F.3d 478, 484-85 (6th Cir. 1998) (discussing the application of the business records exception to the hearsay rule). Similarly, a printout of selected data is admissible as a business record even if it was produced in response to a subpoena. Where the underlying records in the electronic database met the criteria

for business records, any printout is also a business record. *United States v. Nixon*, 694 F.3d 623, 634-35 (6th Cir. 2012). A drug companies' computer-generated records of drug purchases are properly admitted as business records. *United States v. Moon*, 513 F.3d 527, 543-45 (6th Cir. 2008). Nor does the person authenticating the records have to be the custodian or person who created the records; an investigative agent or other person may establish the necessary foundation for admission if the witness has knowledge of the procedures under which the records were created. *United States v. Hathaway*, 798 F.2d 902, 906 (6th Cir. 1986). *See also United States v. Seelig*, 622 F.2d 207, 214 (6th Cir. 1980) (where DEA agent asked pharmacist for records required to be kept for sales of Schedule V drugs, agent's testimony that the exhibits were the records turned over by the pharmacist-defendant provided an adequate foundation to satisfy business records exception).

Email message may be business records under Rule 803(6), although the mere retention of email messages does not necessarily make them business records. *See United States v. Cone*, 714 F.3d 197, 219 (4th Cir. 2013)(emails back to defendants from customers complaining that products were "fake" or "counterfeit" in prosecution for importing equipment with counterfeit marks were not "business record" but were admissible to prove defendants were on notice of complaints that articles were counterfeit; district court erred in failing to give limiting instruction). *See also Espedito Realty, LLC v. National Fire Ins. Co. of Hartford,* 935 F.Supp.2d 319, 325 (D. Mass. 2013)(emails found to be business records). Email messages sent and received in connection with orders and delivery of goods or services and retained by a business to memorialize those transactions can be business records under Rule 803(6). *DirecTV, Inc. v. Murray*, 307 F.Supp.2d 764, 772-73 (D.S.C. 2004). Here, Ms. Posey regularly sent to and received email from a Clinical Care sales representative email messages concerning the ordering

and delivery of the drugs, and, as such, the email messages are a records of a regularly conducted business activity. In any event, the email messages the government will seek to introduce will not be introduced to prove that the factual averments contained therein are true but to prove that Ms. Posey was placed on notice of certain matters, such as drugs being held up in Customs (placing her on notice that the drugs were being imported) and that drugs were not FDA-approved. Admission for such non-hearsay purposes is proper. *See Cone, supra*.

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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2013, a copy of the foregoing Response was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's electronic filing system.

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