IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **MICHAEL SCHLUETER,** **THOMAS VARIOLA, and** **THE OKLAHOMA MALE CLINIC,** **Defendants.**	**Case No. CR-12-199-R**

DEFENDANT MICHAEL SCHLUETER'S SENTENCING MEMORANDUM

Pursuant to 18 U.S.C. §3553(a) and *United States v. Booker*, 12 S.Ct. 738 (2005), Defendant Michael Schlueter ("Mr. Schlueter") submits the following Sentencing Memorandum requesting a sentence that does not involve a term of imprisonment. Mr. Schlueter respectfully submits this information and factors to aid this Court in determining what type and length of sentence is sufficient, but not greater than necessary, to comply with the statutory directives set forth in 18 U.S.C. §3553.

BRIEF STATEMENT OF RELEVANT FACTS

Mr. Schlueter along with co-defendant Thomas Variola owned and operated the Oklahoma Male Clinic ("OMC") from October 3, 2011 until February 22, 2012. The OMC provided treatment for weight loss, and male erectile dysfunction. On August 29, 2012, a two-count information was filed in this Court. Only Count 1 of the Information specifically alleged that Mr. Schlueter committed a crime. The crime he was alleged to

have committed was a misdemeanor charge of misbranding, which is a strict liability offense.

Count 2 of the Information, alleged that OMC acted with an intent to defraud and mislead under the misbranding provision of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "FDCA"). On October 25, 2012, Mr. Schlueter pled guilty to the misdemeanor charge of misbranding, solely as a responsible corporate officer. As such, no specific intent to misbrand or to defraud was admitted to by Mr. Schlueter, as the count of conviction is a strict liability offense. *See United States v. Dotterwich*, 320 U.S. 277 (1943); 21 U.S.C.A. § 333(a)(1). Rather, pursuant to his plea agreement, Mr. Schlueter pled guilty to being a corporate officer who was responsible for a company "dispensing prescription drugs that were misbranded within the meaning of 21 U.S.C. §§352(f)(1) and 353(b)(1) while they were held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§33(k).)

A Pre-Sentence Investigation Report ("PSR") has calculated the advisory guideline range to be 30 to 37 months for this strict liability misdemeanor. However, the maximum sentence for the offense is only 12 months. As such, the PSR recommends that Mr. Schlueter receive the maximum punishment allowed under the law, one year. This guideline calculation was derived in large part on the cross reference to § 2B1.1(b)(1), which relates to crimes involving fraud. As explained above, Mr. Schlueter has not pled guilty to committing a fraud . To use this section of the guidelines the Government must prove other relevant conduct, *i.e.* fraud, was committed by Mr. Schlueter and that will require a showing of specific intent. Moreover the Government

will also have to prove the loss that is alleged within the PSR, which based on the Government's discovery, it does not appear it can do to any reasonable degree of certainty. Mr. Schlueter asserts that the guideline calculation set forth in the PSR results in greater than necessary sentence which does not comply with the statutory directives set forth in 18 U.S.C. §3553.

ARGUMENT AND AUTHORITIES

As established in *United States v. Booker*, 125 S. Ct. 738, 756 (2005), this Court, instead of being bound by the Sentencing Guidelines, is only required to "consider Guidelines ranges, . . . but it permits the court to tailor the sentence in light of other statutory concerns as well." *Booker* at 757. Accordingly, *Booker* requires that the sentencing court treat the guidelines as just one of a number of sentencing factors set forth in 18 U.S.C. §3553(a). Once the Guidelines range is properly computed, a district court "may not presume that the Guidelines range is reasonable." *Gall v. United States*, 128 S.Ct. 586, 596-97 (2007); Rather, sentencing courts have a duty to subject the defendant's sentence to the thorough adversarial testing contemplated by federal sentencing procedure. The sentencing judge must consider every convicted person as an individual and every case as a unique study in the human failings that sometimes mitigate, sometimes magnify, the crime and the appropriate punishment. *Gall v. United States*, 128 S. Ct. 586 (2007).

After all, the primary goal of 18 U.S.C. §3553(a) is for sentencing courts to impose a sentence sufficient, but not greater than necessary, to comply with the purposes

set forth in paragraph 2 of this Section. Those purposes identified in Section 3553(a)(2) are as follows:

> (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;
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> (B) to afford adequate deterrence to criminal conduct;
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> (C) to protect the public from further crimes of the defendant; and,
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> (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

Further, in determining the minimally sufficient sentence, Section 3553(a) further directs sentencing courts to consider the following factors:

> 1) the nature and circumstances of the offense and the history and characteristics of the defendant;
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> 2) the kinds of sentences available;
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> 3) the kinds of sentences and the sentencing range established for the offense level;
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> 4) any pertinent policy statement;
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> 5) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and,
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> 6) the need to provide restitution to any victims of the offense;

Moreover, 18 U.S.C. §3661 provides that no limitation shall be placed on the information concerning the background, character and conduct of the defendant upon which a court of

the United States may receive and consider for the purpose of imposing an appropriate sentence.

I. RELEVANT STATUTORY SENTENCING FACTORS APPLIED TO THIS CASE.

A. THE NATURE AND CIRCUMSTANCES OF THE OFFENSE

The Count of conviction relates to a strict liability misdemeanor charge of being a corporate officer who was responsible for a company "dispensing prescription drugs that were misbranded within the meaning of 21 U.S.C. §§352(f)(1) and 353(b)(1) while they were held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§33(k).) It is the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. (the "FDCA") which provides the statutory basis for this crime. Violations under the FDCA fall into three broad categories: (1) misbranding; (2) adulteration; and (3) lack of "new drug" approval. *See* 21 U.S.C. §§ 331, 355, and 401. A list of acts prohibited as "misbranding" are generally listed throughout § 331. Section 333 sets forth the penalties for misbranding. The misdemeanor violations are strict liability offenses and the felony convictions require (i) a previous conviction for an FDCA violation or (ii) that the defendant have acted with the "intent to defraud or mislead." *See United States v. Dotterwich*, 320 U.S. 277 (1943). Consequently, a felony conviction pursuant to section 333(a)(2) "requires knowledge of the misbranding and proof of specific intent to mislead or defraud connected to the misbranding violation." *United States v. Mitcheltree*, 940 F.2d 1329, 1351 (10th Cir. 1991).

Misbranding is commonly associated with inadequate or misleading labeling. *See*

id. § 352. Under the FDCA, not only is such labeling unlawful, the delivery of a "misbranded" item into interstate commerce and the receipt of a "misbranded" item after it has passed through interstate commerce are also unlawful. *Id*. § 331(a)-(c). Prescription drugs are generally exempt from these labeling requirements, but are nevertheless "misbranded" if dispensed or held for sale without the "prescription of a practitioner licensed by state law to administer such drug." *Id*. §§ 331(k), 353(b)(1), (b)(2) and (f)(1)(C); see also *United States v. Arlen*, 947 F.2d 139, 141 n.2 (5th Cir. 1991) ("Any prescription drug that is dispensed without a prescription is deemed 'misbranded' as a matter of law."); *Unites States v. Smith*, 573 F.3d 639 (8th Cir. 2009); United States v. Bradshaw, 840 F.2d 871, 872 n.2 (11th Cir. 1988).

There is no evidence that Mr. Schlueter had the specific intent to commit the crime of misbranding[1]. He has pled guilty to the misdemeanor charge of misbranding , solely as responsible corporate officers. 21 U.S.C.A. 333(a)(1). Accordingly, USSG 2N2.1, is the guideline that is applicable to violations of statutes and regulations dealing with any food, drug, biological product, device, cosmetic, agricultural product, or consumer product. It provides:

> (a) Base Offense Level: 6
> (b) Specific Offense Characteristic
> (1) If the defendant was convicted under 21 U.S.C. §331 after sustaining a prior conviction under 21 U.S.C. §331, increase by 4 levels.
> (c) Cross References

[1] In the Petition to Enter Plea of Guilty, the only admission was that "Employees misbranded drugs with the intent to defraud and or mislead." *See* Doc #19, ¶ 49. Accordingly, for the cross reference of fraud to be applicable, the Government must show that Mr. Schlueter had specific knowledge of the fact the drugs were misbranded.

> If the offense involved **fraud, apply §2B.1 (Theft, Property Destruction, and Fraud).**

Id. (emphasis added). It is under §2B.1(c) that the twelve (12) level increase to the base offense level of 6, is derived. Consequently, as the count of conviction does not involve any personal knowledge by Mr. Schlueter that he acted with the specific intent to defraud, for this twelve level enhancement to apply, the Government must prove through other relevant conduct by a preponderance of the evidence that Mr. Schlueter committed fraud. However, the evidence in this case falls short of being able to meet this burden.

In "The Offense Conduct" section of the PSR, the allegations of misconduct mostly relate to possible medical malpractice, and high pressure sales. Those issues include giving stronger medications when oral medications would have worked, salesmen wearing labs coats, keeping a patient's license and insurance card until after the visit, and not conducting labs prior to giving testosterone injections. At most the allegations include violations of licensure board regulations and/or evidence malpractice. They do not show an intent to defraud the patients about the effect or FDA approval of the drugs.

Further, even if these allegations are proven, there is no evidence Mr. Schlueter had specific intent to mislead in connection with the drugs. An intent to mislead or defraud is an essential element of the federal charge of misbranding, and the person must have the specific intent to mislead regarding whether the drugs are misbranded. *See U.S. v. Industrial Laboratories* Co., 456 F.2d 908, 910-911 (10th Cir 1972) ("We must hold that it was essential that the jury be told that under § 333(b) intent to mislead or defraud was an essential ingredient. The jury should have been further instructed that an act is

done willfully if done voluntarily and intentionally, and with specific intent to do something the law forbids, that is to say, with bad purpose either to disobey or to disregard the law."); *See*, *U.S. v. Hiland*, 909 F.2d 1114, 1128 (8th Cir. 1990) (knowledge of the essential nature of the alleged fraud is a specific intent requirement under § 333(a)(2)). S*ee also*, *U.S. v. Watkins*, 278 F.3d 961, 965-966 (9th Cir. 2002) (finding that proof of materiality was required for increased liability for a felony under the FDCA). In other words, there must be a specific intent to defraud or mislead and specific knowledge the drug was misbranded. Under the facts of this case, there is no evidence Mr. Schlueter knew the drugs being shipped from Florida to Oklahoma, and compounded on sight would have been "misbranded" under the FDCA.

After all, the OMC employed several medical professionals: (1) Dr. William J. Logue, employed from October 2011 until February 6, 2012, (2) Dr. George Petry, employed from February 1, 2012 until the close of OMC, and (3) Frank Buerger, PA, employed from February 6, 2012 until the close, (4) a nurse practitioner, (5) a basic EMT, and (6) a medical assistant. These medical professionals have an independent duty to their patients, and their licensing boards which would be much higher than any duty they may have had to their employer.

Moreover, the law provides that the FDA never has had authority to regulate the practice of medicine. This means that physicians may use legally marketed drugs or devices in any way that they believe, in their professional judgment, will best serve their patients (this does not violate the FDCA). *See, e.g., Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc*., 93 F.3d 511, 514 n. 33 (8th Cir.1996); *Bristol-Myers Squibb*

Co. v. Shalala, 91 F.3d 1493, 1496 (D.C.Cir.1996); *Ortho Pharm. Corp. v. Cosprophar, Inc*., 32 F.3d 690, 692 (2d Cir.1994); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir.1989); *United States v. An Article of Device … Diapulse*, 768 F.2d 826, 832 (7th Cir.1985); *Schlessing v. United States*, 239 F.2d 885, 886 (9th Cir.1956); *United States v. Evers*, 453 F.Supp. 1141, 1149-50 (M.D.Ala.1978), aff'd, 643 F.2d 1043, 1052-53 (5th Cir.1981); *FTC v. Simeon Management Corp*., 391 F.Supp. 697, 706 (N.D.Cal.1975), aff'd, 532 F.2d 708 (9th Cir.1976); *Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla.1990); *Jones v. Petland Orlando Store*, 622 So.2d 1114, 1115 (Fla.Dist.Ct.App. 1993); *Haynes v. Baton Rouge Gen. Hosp*., 298 So.2d 149, 153 (La.Ct.App.1974), *writ denied*, 302 So.2d 33 (La.1974); *U.S. v. Evers*, 453 F.Supp. 1141, 1148-1149 (D.C.Ala.,1978) (holding that the physician was not misbranding the drug for prescribing it for its off-label use). As such, as long as the drug is approved by the FDA for some purpose, a physician may prescribe it for any purpose without running afoul of the misbranding statute.

Further, as noted within the PSR the OMC was inspected by the Oklahoma State Board of Medical Licensure ("OSBML") in November of 2012. Following this investigation the OSBML investigator confirmed that testosterone was being administered without the proper labs. Additionally, it determined that OMC was storing testosterone without proper labeling or storage requirements. "The OBMLS determined that OMC was receiving prescriptions from Westchase Compounding Pharmacy, LLC, located in Tampa, Florida." See PSR, ¶ 9. After the inspection, OMC was not shut down, but was allowed to continue to operate with a few requirements not relating to

misbranding. Clearly the State's investigation provides a basis for the owners of OMC to in good faith believe their operations were legal under the law. The State allowed it to remain in business for months and never advised them that their conduct was considered misbranding under any law. As a result, there clearly is no intent to defraud or mislead as to the drugs at issue. As such, probation is appropriate under the facts of this case.

(a) <u>The "Loss" Calculation Cannot be Shown by a Preponderance of the Evidence.</u>

As set forth above. Mr. Schlueter asserts that the 12 level enhancement of fraud should not apply to him as he lacks the requisite intent. However, assuming *arguendo* there is sufficient evidence of intent to defraud, the twelve (12) level range is only applicable if the Government is successful in establishing by the preponderance of the evidence that $396,556.75 loss was received as a result of the sale of a misbranded drug. If the Government fails to prove this loss by a preponderance of the evidence than the range of punishment under the applicable advisory guideline range is 0 to 6 months. Originally, the probation officer calculated the loss at $793.113.50. This calculation was apparently based on all revenue received from OMC's entire operation. However, no analysis was conducted which linked this sum directly to the misbranded drugs in question nor did it account for the other services that the OMC performed. For example, the OMC did provide services related to weight loss. There was no deduction from the loss calculation for these legitimate services. Moreover, despite the objection to the PSR on this basis, still no analysis was provided for how the loss tied directly to the misbranding. Rather, following the objection, the loss was simply reduced in half in

order to be "conservative." This calculation with no connection to the actual loss is clearly improper and cannot be proven by a preponderance of evidence.

(b) <u>There is No Evidence to Support the 4 Level Enhancement.</u>

In Mr. Schlueter's PSR, the following is stated:

> The defendant was co-owner of OMC. He was present in Oklahoma City and was involved in the opening of OMC. Further, the defendant was involved in the sale of at least two other male clinics owned by himself and Variola. Therefore, the defendant was an organizer or leader of a criminal activity that involved five or more participants or was otherwise extensive; therefore, four levels are added. USSG §3B1.1(a).

This enhancement is wholly inapplicable to the nature and extent of this crime. As set forth above, Mr. Schlueter has only pled guilty to a strict liability misdemeanor. As such, the count of conviction cannot be the basis for this enhancement. Further, in order to apply the adjustment under USSG §3B1.1(a), the Government must show more than just a part ownership of OMC. As set forth in *U.S. v. Aptt*, 354 F.3d 1269, 1285 (10th Cir. 2004):

> To qualify for an adjustment under [Guideline 3B1.1], the defendant must have been the organizer, leader, manager, or supervisor of one or more other participants." U.S.S.G. § 3B1.1, cmt. n. 2 (emphasis added). (Here, as before, a "participant" is someone who is criminally responsible for the offense. See id., cmt. n. 1.) In fraudulent operations like this one, the emphasized language will often be crucial, because employees who are unaware of the **operation's fraudulent nature are not criminally responsible participants**; **as a result, managing or supervising their activities does not qualify a defendant for the enhancement. (emphasis added).**

A district court must first make the determination that a participant is criminally responsible for a commission of an offense before utilizing the enhancement. *U.S. v. Maloof*, 205 F.3d 819, 830 (5th Cir. 2000). ""A finding that other persons 'knew what was going on' is not a finding that these persons were criminally responsible for commission of an offense." *Id.*, quoting, *United States v. Mann*, 161 F.3d 840, 867 (5th Cir.1998)(*citing United States v. D'Angelo*, 598 F.2d 1002, 1003 (5th Cir.1979)), cert. denied, 119 S.Ct. 1766 (1999). Although a conviction is not necessary, the participant must have participated knowingly in some part of the criminal activity. *U.S. v. Boutte*, 13 F.3d 855, 860 (5th Cir.1994). As set forth above, the evidence is lacking that Mr. Schlueter has the specific intent to commit the crime of misbranding and his ownership of the OMC interests is insufficient to warrant the four level enhancement.

Furthermore, USSG §3B1.1(a) generally requires proof of five or more participants for its application or evidence that the crime was otherwise extensive. Based upon the investigation of the FDA, there are not five people that would be criminally responsible for the offense. There has been insufficient evidence presented that the employees of the clinic knew what they were doing was a crime. Moreover, the OMC was open for less than 5 months. It cannot be said to have been "otherwise extensive." *U.S. v. Hernandez-Mejia*, 2008 WL 5978897, 7-8 (D.N.M. 2008) ("The [Sentencing] Commission's intent is that this adjustment should increase with both the size of the organization and the degree of the defendant's responsibility.")..

(c) <u>The Characteristics of the Offender</u>

Mr. Schlueter is a dedicated married man with two adult children. As a result of this action, he is unemployed as all of his clinics were shutdown at the request of the Government. He has no criminal convictions, and in this case pled guilty without requiring the Government to present this case to the Grand Jury. Further, as set forth in detail in the PSR, Mr. Schlueter has medical conditions which require daily medications and doctor supervision.

B. THE KINDS OF SENTENCES AVAILABLE AND THE SENTENCING RANGE ESTABLISHED BY THE SENTENCING COMMISSION

Section 3561 of Title 18 does not prohibit probation in this instance. It states:

> (a) In general.--A defendant who has been found guilty of an offense may be sentenced to a term of probation unless--
>
> (1) the offense is a Class A or Class B felony and the defendant is an individual;
>
> (2) the offense is an offense for which probation has been expressly precluded; or
>
> (3) the defendant is sentenced at the same time to a term of imprisonment for the same or a different offense that is not a petty offense.
>
> …

None of the prohibitions in Section 3561 are applicable in this case. In fact, imprisonment under the circumstances would be highly unusual. *U.S. v. Purdue Frederick Co., Inc*., 495 F.Supp.2d 569, 576 (W.D.Va. 2007) (Case involving a misdemeanor conviction under the FDCA, the Court stated: The plea agreements provide for no incarceration for the individual defendants. The Government points out that a sentence of incarceration under the federal sentencing guidelines would be **unusual**

based on the facts of the case."). This is a strict liability offense which has no victim. The Supreme Court upheld the constitutionality of strict liability crimes "**in part, because their associated penalties 'commonly are relatively small, and conviction does no grave damage to an offender's reputation**.'" Placing Mr. Schlueter in prison for pleading guilty to a strict liability offense would be severely harsh.

C. PERTINENT POLICY CONSIDERATIONS.

Under 18 U.S.C. § 3661, "no limitation shall be placed on the information concerning the background, character, and conduct of [the defendant] which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence" (emphasis added). Mr. Schlueter identifies the following as factors the Court may consider in determining what type and length of sentence is sufficient, but not greater than necessary, to comply with the statutory directives set forth in 18 U.S.C. § 3553(a):

> (1) there is no victim;
>
> (2) if the drugs were prescribed by a physician to a patient with erectile dysfunction, the drugs would not have been considered misbranded,
>
> (3) there were medical professionals hired and employed by OMC,
>
> (4) Mr. Schlueter was not active in the day to day operations,
>
> (5) the drugs are effective in treating erectile dysfunction,
>
> (6) he is a family man and any incarceration would be detrimental to his family,
>
> (7) there is no evidence he knew the drugs being provided were misbranded,

(8) all of the clinics owned and operated by Mr. Schlueter have been shutdown, and

(9) he has taken responsibility for his crime.

The nature and circumstances of this offense and his role in the offense, taken in its entirety, sufficiently warrant a sentence of probation.

The Guidelines, as calculated in the PSR, suggest a term of imprisonment of 12 months.[2] While Schlueter is now aware of the OMC's violation of the law, he respectfully submits that the suggested term of imprisonment as calculated under the Guidelines is too severe and far exceeds what is necessary to satisfy the directives set forth in 18 U.S.C. §3553. Under 18 U.S.C. § 3661, "*no limitation* shall be placed on the information concerning the background, character, and conduct of [the defendant] which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence" (emphasis added). All of the factors discussed herein demonstrate that imprisonment would not be appropriate under the circumstances.

CONCLUSION

Any sentence which includes imprisonment in this case would be inappropriate. The "loss" significantly over-represents the seriousness of the strict liability crime. Further, his personal history and characteristics clearly establish that the term of imprisonment as calculated under the Sentencing Guidelines is too severe and far exceeds what is necessary to satisfy the directives set forth in 18 U.S.C. §3553.

[2] As set forth in the Addendum to the Presentence Investigation Report, Mr. Schlueter objects to this Guideline calculation as it incorrectly applies a larger figure to the Loss Table, and it applies a four level adjustment for Mr. Schlueter's role in the operation of the Oklahoma Male Clinic.

Respectfully submitted,

s/Seth A. Day

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CERTIFICATE OF SERVICE

By my signature below, I certify that I electronically transmitted foregoing Entry of Appearance to the Clerk of Court using the ECF System to the following attorney of record on this 13th day of March, 2013.

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s/Seth A. Day
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