

FILED IN OPEN COURT  
06/27/2018  
TIMOTHY M. O'BRIEN, CLERK  
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DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA

Plaintiff,

v.

Case No. 17-40052-01-DDC

KATHLEEN STEGMAN

Defendant.

PLEA AGREEMENT PURSUANT TO FEDERAL RULE  
OF CRIMINAL PROCEDURE 11(c)(1)(C)

The United States of America, by and through Assistant United States Attorney Duston J. Slinkard, and Kathleen Stegman, the defendant, personally and with her counsel, Robin D. Fowler hereby enter into the following plea agreement pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure:

1. **Defendant's Guilty Plea.** The defendant agrees to plead guilty to Count 1 of the Information charging a violation of 21 U.S.C. § 331, that is, receiving in interstate commerce and causing the receipt in interstate commerce of a misbranded drug, that is, Dysport, and delivering and proffering for delivery for pay or otherwise the misbranded drug with the intent to defraud and mislead. By entering into this plea agreement, the defendant admits to knowingly committing the offense, and to being guilty of the offense. The defendant understands that the maximum sentence which may be imposed as to Count 1 of the Information to which she has agreed to plead guilty is not more than 3 years of imprisonment, a fine of up to the greater of \$250,000 or twice the gross gain or loss from the conduct in Count 1, 1 year of supervised release, and a \$100.00 mandatory special assessment. The defendant further agrees to forfeit \$73,000 to the United States, as agreed.

2. **Factual Basis for the Guilty Plea.** The parties agree the facts constituting the offense to which the defendant is pleading guilty are as follows:

The defendant was the owner and operator of Midwest Medical Aesthetics ("Midwest Medical"), a "medical spa," located at the time of its operation on Nall Avenue, in Leawood, Kansas, within the District of Kansas.

From at least in or about June 2011 through at least in or about November 2013, the defendant purchased approximately \$73,000 worth of foreign-sourced Dysport®, which is a prescription drug.

The Food and Drug Administration ("FDA") is the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA's responsibilities include regulating the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs and medical devices. The FDA carries out its responsibilities by enforcing the Food, Drugs, and Cosmetic Act ("FDCA") and other pertinent laws and regulations.

The FDCA defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "articles . . . intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. §321(g)(1)(B) and (C).

Prescription drugs are drugs that, because of their toxicity and other potential for harmful effects, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. 21 U.S.C. § 353(b)(1)(B).

The FDCA defines "label" as "a display of written, printed, or graphic matter upon the . . . immediate container of any article." 21 U.S.C. § 321(k).

The FDCA defines "labeling" as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

Under the FDCA, drugs are deemed to be "misbranded" unless their labeling bears adequate warnings. 21 U.S.C. § 352(f)(2). Drugs are also deemed to be misbranded unless their labeling bears adequate directions for use. 21 U.S.C. § 352(f)(1). Under regulations promulgated by the FDA, "adequate directions for use" is defined as directions under which a layman can safely use a drug or device for its intended uses. 21 C.F.R. §§ 201.5.

A prescription drug is also "misbranded" if its label does not bear the symbol "Rx only" at any time prior to dispensing. 21 U.S.C. § 353(b)(4)(A).

Drugs are also "misbranded" under the FDCA if any word, statement, or other information, required to appear on the drug's label or labeling, is not prominently placed thereon. 21 U.S.C. § 352(c). Under FDA regulations, a drug may be misbranded under section 352(c) unless "[a]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language . . . ." See 21 C.F.R. §§ 21 C.F.R. 201.15(c)(l).

Drugs approved for foreign markets will almost always be unapproved drugs under United States law, even if chemically identical to the U.S.-approved version. Foreign drugs may have different labeling (including different warnings, dosage recommendations, and indications for use) and may be manufactured in some place other than the location approved in the U.S. approval process.

In addition, foreign market versions of FDA-approved drugs will almost always be "misbranded" under the FDCA because: (1) their label does not bear the statement "Rx only" as required by 21 U.S.C. § 353(b)(4); and (2) they do not meet the exemption from the FDCA's requirement that the drug's labeling bear adequate directions for use. More specifically, the labeling approved by foreign regulatory authorities differs from the FDA-approved labeling that must accompany the product for the exemption in 21 C.F.R. § 201.100 to apply.

Foreign market versions of FDA-approved prescription drugs are outside of the supply chain regulated by the FDA for the purpose of protecting public safety and health. Consequently, foreign market versions of FDA-approved prescription drugs can be contaminated and/or sub-potent, especially, for example, if they are shipped without adherence to requisite temperature controls.

Abobotulinumtoxin A is the established name for the drug and biological product approved for sale in the United States as Dysport®. Dysport® is typically injected directly into patients, making the sterility and efficacy of this prescription drug important. According to the label for FDA-approved Dysport®, reconstituted Dysport® should be stored in a refrigerator at temperatures between 2° and 8° Celsius, and should be used within four hours of being reconstituted.

In January of 2013, FDA agents seized a quantity of Dysport® from the defendant's business, which was misbranded as its label was written entirely in Turkish. In addition, records provided by the defendant indicated that her business purchased approximately \$73,000 of Dysport® from the same supplier as provided the Dysport® with the Turkish labeling.

3. **Proposed Rule 11(c)(1)(C) Sentence.** The parties propose, as an appropriate disposition of the case:

- (a) one year plus one day of imprisonment on Count 1, to be served concurrently with the term of imprisonment imposed in Case No. 14-20109-01-JAR;

- (b) 1 year of supervised release, to be served concurrently with the term of supervised release imposed in Case No. 14-20109-01-JAR;
- (c) no fine;
- (d) the mandatory special assessment of \$100.00; and
- (e) forfeiture as described in paragraph 9.

The parties seek this binding plea agreement as an appropriate disposition of the case, because if the Court permits itself to be bound by the proposed sentence, it brings certainty to the sentencing process; it assures that the defendant and the government will benefit from the bargain they have struck; it serves the interests of justice; and it assures a sentence consistent with the sentencing factors of 18 U.S.C. § 3553(a). If the Court does not agree with the sentence, the defendant and United States may be restored to the positions they maintained prior to reaching this plea agreement. This plea agreement centers on the defendant's agreement to enter her guilty plea as soon as the Court's schedule permits, thereby preserving valuable Court, prosecution, defense, United States Probation Office, United States Marshals' Service and other law enforcement resources.

4. **Application of the Sentencing Guidelines.** The parties are of the belief that the proposed sentence does not offend the advisory sentencing guidelines. Because this proposed sentence is sought pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the parties are not requesting imposition of an advisory guideline sentence.

5. **Government's Agreements.** In return for the defendant's plea of guilty as set forth herein, the United States agrees to not file any additional charges against the defendant arising out of the investigation and facts forming the basis for the present Information.

6. **Consequences for Violating the Plea Agreement.** The United States' obligations under this plea agreement are contingent upon the defendant's continuing to manifest an

acceptance of responsibility. If the defendant denies or gives conflicting statements as to her involvement, falsely denies or frivolously contests relevant conduct the Court determines to be true, willfully obstructs or impedes the administration of justice, as defined by U.S.S.G. § 3C1.1 (or willfully attempts to do so), or has engaged in additional criminal conduct, the United States reserves the right to petition the Court for a hearing to determine if she has breached this plea agreement.

If the Court finds by a preponderance of the evidence that the defendant (1) has breached or violated this plea agreement; (2) has willfully obstructed or impeded the administration of justice, as defined by U.S.S.G. § 3C1.1 (or willfully attempted to do so); (3) has engaged in additional criminal conduct; or (4) has otherwise failed to adhere to this plea agreement's terms, this plea agreement will be deemed null and void, and the United States may pursue any additional charges arising from the criminal activity under investigation, as well as any charges for any perjury, false statement, or obstruction of justice that may have occurred.

If the Court finds the defendant has violated this plea agreement, she understands and agrees that all statements she made, any testimony she gave before a grand jury or any tribunal, or any leads from such statements or testimony, shall be admissible against her in any and all criminal proceedings. The defendant waives any rights which might be asserted under the United States Constitution, any statute, Federal Rule of Criminal Procedure 11(f), Federal Rule of Evidence 410, or any other federal rule that pertains to the admissibility of any statements she made subsequent to this plea agreement.

7. **Whether to Accept the Proposed Plea Agreement and Sentence is Up to the Court.** The Court has no obligation to accept the proposed plea agreement and sentence. It is solely within the Court's discretion whether to accept the proposed binding plea agreement as an appropriate disposition of the case.

8. **Withdrawal of Plea Permitted Only if the Court Does Not Accept the Plea Agreement and Proposed Sentence.** If the Court agrees to be bound by the proposed plea agreement and sentence, the parties shall be bound by all the terms of the proposed plea agreement and the defendant will not be permitted to withdraw her guilty plea. If the Court announces that it will NOT be bound by the proposed plea agreement, the parties agree that at that time either party may withdraw the proposed plea agreement, and if either does so, then all parties will be restored to the positions they were in prior to the entry of the defendant's plea. If neither party elects to withdraw the proposed plea agreement at the time the Court announces that it will not be bound, and before the Court proceeds with sentencing, then the parties shall be bound by all the terms of the proposed plea agreement and the defendant will not be permitted to withdraw her guilty plea.

9. **Forfeiture of Assets.** The defendant knowingly and voluntarily agrees and consents to the imposition of a forfeiture judgment against her in the amount of \$73,000, which sum represents the value of property subject to forfeiture. The defendant knowingly and voluntarily waives her right to a trial regarding forfeiture, and voluntarily waives all constitutional, legal and equitable defenses to the imposition of a forfeiture judgment. The defendant acknowledges and agrees that the imposition of a forfeiture judgment shall not be deemed an alteration of the defendant's sentence or this agreement, and shall not be treated as satisfaction of any fine, restitution, cost of imprisonment, or any other penalty the Court may impose upon her in addition to forfeiture. Additionally, the defendant agrees to the immediate entry of the Final Order of Forfeiture.

10. **Identification of Assets and Agreement Concerning Monetary Penalties (Restitution, Fines, Assessments) and Forfeiture.** The defendant agrees to cooperate fully with the United States Attorney's Office and specifically agrees as follows:

- (a) Defendant agrees to execute a financial statement provided by the United States Attorney's Office and to update the statement with any material changes within 30 days of any such change. Defendant further agrees to provide all supporting documentation, including, but not limited to, copies of federal tax returns. The defendant agrees to disclose all assets in which defendant has any interest or which defendant exercises control, directly or indirectly, including those held by a spouse, nominee, or other third party, as well as any transfer of assets that has taken place within six years preceding the entry of the judgment in this criminal case. Additionally, the defendant agrees to periodically execute an updated financial statement at the request of the United States Attorney's Office until such time the judgment debt is paid in full.
- (b) Defendant agrees to authorize the release of all financial information requested by the United States, including, but not limited to, executing authorization forms for the United States to obtain tax information, bank account records, credit history, and social security information. Defendant agrees the United States Attorney's Office may subpoena any records it deems relevant to conduct a full financial investigation. Defendant agrees to discuss or answer any questions by the United States relating to its financial investigation.
- (c) Defendant agrees to submit to an examination prior to and/or after sentencing, which may be taken under oath, and/or may include a polygraph examination.
- (d) Defendant agrees that any waivers, consents, or releases executed for the United States Probation Office for purposes of preparation of the Presentence Report may be provided to the United States Attorney's Office. All information defendant provided to the United States Probation Office or independently obtained by the United States Probation Office may be provided to the United States Attorney's Office.
- (e) Defendant agrees to notify the government if she disposes of any property which has a value greater than \$10,000.
- (f) Defendant agrees that whatever monetary penalties the Court imposes (including any fine, restitution, assessment, or forfeiture judgment), will be due and payable immediately and subject to immediate enforcement by the United States. Should the Court impose a schedule of payments, she agrees that the schedule of payments is a minimum schedule of payments and not the only method, nor a limitation on the methods, available to the United States to enforce the judgment. If defendant is incarcerated, defendant agrees to participate in the Bureau of Prisons' Inmate Financial Responsibility Program, regardless of whether the Court specifically directs participation or imposes a schedule of payments.
- (g) If defendant posted funds as security for defendant's appearance in this case, defendant authorizes the Court to release the funds to the Clerk of the United States District Court to be applied to the criminal monetary impositions at the time of sentencing.

- (h) Defendant waives any requirement for demand of payment on any restitution, fine, assessment, or forfeiture judgment entered by this Court.
- (i) Defendant agrees to notify the United States Attorney's Office within 30 days of any change of address or other contact information until the judgment debt is paid in full.
- (j) Defendant agrees the terms of this agreement shall be incorporated into the Judgment in a Criminal Case.
- (k) Defendant waives the administrative requirements of the Treasury Offset Program, including the requirement of default, and agrees to be immediately included in the Treasury Offset Program allowing federal benefits and payments to be offset and applied to the balance of criminal monetary penalties.
- (l) Defendant agrees that noncompliance with any of the terms set forth in this paragraph will result in a continuance of the sentencing hearing.

11. **Payment of Special Assessment.** The defendant understands that a mandatory special assessment of \$100.00 per count of conviction will be entered against her at the time of sentencing. The defendant agrees to deliver to the Clerk of the United States District Court payment in the appropriate amount no later than the day of sentencing. The defendant has the burden of establishing an inability to pay the required special assessment. The parties acknowledge that if the Court finds the defendant is without resources to pay the special assessment at the time of sentencing, the Court may allow payment during her period of incarceration.

12. **Waiver of Appeal and Collateral Attack.** The defendant knowingly and voluntarily waives any right to appeal or collaterally attack any matter in connection with this prosecution, her conviction, or the components of the sentence to be imposed herein, including the length and conditions of supervised release, as well as any sentence imposed upon a revocation of supervised release. The defendant is aware that 18 U.S.C. § 3742 affords her the right to appeal the conviction and sentence imposed. By entering into this agreement, the defendant knowingly



waives any right to appeal a sentence imposed in accordance with the sentence recommended by the parties under Rule 11(c)(1)(C). The defendant also waives any right to challenge her sentence, or the manner in which it was determined, or otherwise attempt to modify or change her sentence, in any collateral attack, including, but not limited to, a motion brought under 28 U.S.C. § 2255 (except as limited by *United States v. Cockerham*, 237 F.3d 1179, 1187 (10th Cir. 2001)), or a motion brought under Federal Rule of Civil Procedure 60(b). In other words, the defendant waives the right to appeal the sentence imposed in this case, except to the extent, if any, the Court imposes a sentence in excess of the sentence recommended by the parties under Rule 11(c)(1)(C). However, if the United States exercises its right to appeal the sentence imposed, as authorized by 18 U.S.C. § 3742(b), the defendant is released from this waiver and may appeal the sentence received, as authorized by 18 U.S.C. § 3742(a). Notwithstanding the foregoing waivers, the parties understand that the defendant in no way waives any subsequent claims with regards to ineffective assistance of counsel or prosecutorial misconduct.

13. **FOIA and Privacy Act Waiver.** The defendant waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552. The defendant further waives any rights conferred under the Privacy Act of 1974, 5 U.S.C. § 552a, to prevent or object to the disclosure of records or materials pertaining to this case.

14. **Waiver of Claim for Attorney's Fees.** The defendant waives all claims under the Hyde Amendment, 18 U.S.C. § 3006A, for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

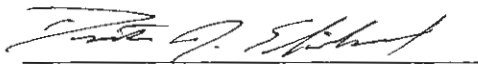
15. **Full Disclosure by United States.** The defendant understands the United States will provide to the Court and the United States Probation Office all information it deems relevant

to determining the appropriate sentence in this case. This may include information concerning her background, character, and conduct, including the entirety of her criminal activities. The defendant understands these disclosures are not limited to the count to which she is pleading guilty. The United States may respond to comments she or her attorney makes, or to positions she or her attorney takes, and to correct any misstatements or inaccuracies. The United States further reserves its right to make any recommendations it deems appropriate regarding the disposition of this case, subject only to any limitations set forth in this plea agreement. The defendant also has the right to provide information concerning the offense and to make recommendations to the Court and the United States Probation Office.

16. **Parties to the Agreement.** The defendant understands this plea agreement binds only her and the United States Attorney for the District of Kansas, and that it does not bind any other federal, state, or local prosecution authority.

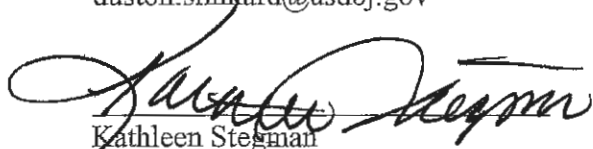
17. **No Other Agreements.** The defendant has had sufficient time to discuss this case, the evidence, and this plea agreement with her attorney and she is fully satisfied with the advice and representation her attorney provided. Further, the defendant acknowledges that she has read the plea agreement, understands it, and agrees it is true and accurate and not the result of any threats, duress or coercion. The defendant further understands that this plea agreement supersedes any and all other agreements or negotiations between the parties, and that this plea agreement embodies each and every term of the agreement between the parties.

18. The defendant acknowledges that she is entering into this plea agreement and is pleading guilty because she is guilty. She further acknowledges that she is entering her guilty plea freely, voluntarily, and knowingly.



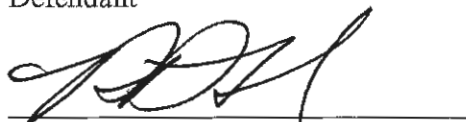
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Date: 6/20/2018



Kathleen Stegman  
Defendant

Date: 6/20/18



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