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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

UNITED STATES OF AMERICA,

Plaintiff,

vs.

TEMP RAY PATTERSON, MD,

Defendant.

Case No. 4:19-cr-248-BLW

RULE 11 PLEA AGREEMENT

I. GUILTY PLEA

A. Summary of Terms. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(B), the defendant, the attorney for the defendant, and the government¹ agree that the defendant will waive indictment and plead guilty to count One of the Information, which charges the defendant with Receipt and Delivery of Misbranded Devices, a felony violation of 21 U.S.C. §§ 331(c) and 333(a)(2).

This plea is voluntary and did not result from force, threats, or promises, other than any promise made in this agreement. Upon acceptance of the defendant's guilty plea(s), and the defendant's full compliance with the other terms of this agreement, the government, under Federal Rules of Criminal Procedure 11(c)(1)(B), will recommend a sentence within the agreed upon, applicable sentencing guideline range. Under Federal Rule of Criminal Procedure 11(c)(1)(A), the government agrees to not bring any additional criminal charges against the defendant based on conduct or allegations presently known to the Government.

B. Oath. The defendant will be placed under oath at the plea hearing. The government may use any statement that the defendant makes under oath against the defendant in a prosecution for perjury or false statement.

II. WAIVER OF CONSTITUTIONAL RIGHTS AT TRIAL

The defendant waives the following rights by pleading guilty pursuant to this agreement: 1) the right to plead not guilty to the offense(s) charged against the defendant and to persist in that plea; 2) the right to a trial by jury, at which the defendant would be presumed innocent and the burden would be on the government to prove the defendant's guilt beyond a reasonable doubt; 3) the right to have the jury agree unanimously that the defendant was guilty of the offense; 4) the

¹ The word "Government" in this Agreement refers to the United States Attorney for the District of Idaho.

right, at trial, to confront and cross-examine adverse witnesses; 5) the right to present evidence and to compel the attendance of witnesses; and 6) the right not to testify or present evidence without having that held against the defendant. If the court accepts the defendant's guilty plea, there will be no trial.

III. NATURE OF THE CHARGES

A. Elements of the Crime. The elements of the crime of Receipt and Delivery of Misbranded Devices, a felony violation of 21 U.S.C. §§ 331(c) and 333(a)(2), as charged in count One, are as follows:

1. The defendant received devices, as defined in 21 U.S.C. § 321(h) (breast implants), in interstate commerce;
2. Those devices were misbranded in one or more ways;
3. The defendant delivered or proffered the delivery of those misbranded devices for pay or otherwise; and
4. The defendant did and caused these acts with the intent to mislead.

B. Factual Basis. If this matter were to proceed to trial, the government and the defendant agree that the following facts would be proven beyond a reasonable doubt:

From on or about March 2014 through April 2015, in the District of Idaho, the defendant knowingly received and implanted in patients nine pairs of misbranded breast implants that were not approved by the Food and Drug Administration ("FDA"). The breast implants were shipped to the defendant in interstate commerce from China to Idaho. Breast implants were Class III medical devices under the Food, Drug and Cosmetic Act ("FDCA"). As such, they require an approved premarket approval application ("PMA") before they can be marketed or they must meet one of the listed exceptions. *See* 21 C.F.R. § 814.1. The breast implants the defendant

received did not have a PMA and did not meet a listed exception. The nine pairs of breast implants were misbranded devices.

The FDCA required the labeling for devices to contain adequate directions for use. 21 U.S.C. § 352(f). “Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended.” 21 C.F.R. § 801.5. It was impossible to write adequate directions for use for the breast implants the defendant received because they are Class III prescription devices and such devices can, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner. FDA-approved devices with their approved labeling are exempt from having adequate directions for use by a layperson under specific circumstances. 21 C.F.R. § 801.109. But unapproved prescription devices that do not meet all the conditions for an exemption from the requirement of having adequate directions for use are by law per se misbranded. Therefore, the breast implants received by the defendant were not approved by the FDA and were misbranded because, among other things, they did not have adequate directions for use. The defendant knew the breast implants were not FDA approved.

The defendant delivered and proffered for delivery the misbranded devices with the intent to mislead. The defendant provided his breast augmentation patients with labeling for FDA-approved breast implants including brochures, handouts, pre-operative worksheets, and sample sizers. The provided labeling misled his patients into believing that they would receive FDA-approved implants, when they did not. For example, on or about February 27, 2015, the defendant implanted one of the misbranded pairs of breast implants he received from China in patient C.S. Prior to the augmentation surgery and afterwards, the defendant provided C.S. with labeling for FDA-approved implants, telling her that she received a certain brand of FDA-approved implants. To support this, the defendant sent C.S. emails with pictures of the boxes and serial numbers of FDA-approved implants, falsely claiming that was what he implanted in her

body. In addition, the defendant changed C.S.'s medical records to show that she received a different size implant than was actually used. The defendant changed the size to match the sizing of the FDA-approved implants he told C.S. he used. The defendant acted with the intent to mislead C.S. to believe she received FDA-approved breast implants, when she did not.

The defendant charged the nine patients a total of \$34,875 for the breast augmentation surgeries he performed.

IV. SENTENCING FACTORS

A. Penalties. A violation of 21 U.S.C. §§ 331(c) and 333(a)(2), and 18 U.S.C. § 2, as charged in count One, is punishable by:

1. a term of imprisonment of 3 years;
2. a term of supervised release of not more than 1 year;
3. a term of probation up to 5 years; and
4. a maximum fine of \$250,000, and a special assessment of \$100.

B. Supervised Release. The court may impose a period of supervised release. No agreement exists as to the length of supervised release.

The law permits the combined prison time and term of supervised release to exceed the maximum term of incarceration for the crime(s) to which the defendant is pleading guilty. Violation of any condition of supervised release may result in further penalties and/or prosecution.

C. Fines and Costs. The court may impose a fine. No agreement exists as to the amount of the fine. The court may also order the defendant to pay the costs of imprisonment, probation, and supervised release.

D. Special Assessment. The defendant will pay the special assessment before sentencing and will furnish a receipt at sentencing. Payment will be made to:

The United States District Court, Clerk's Office
Federal Building and United States Courthouse
550 West Fort Street, Fourth Floor
Boise, Idaho 83724.

E. Restitution. In addition to any forfeiture, fine, or costs imposed, the defendant agrees to pay restitution equal to the loss caused to any uncompensated victim. The parties agree the restitution obligation in this case is equal to \$8,200, which represents the amount owed to A.U. and which the defendant agrees to pay at or prior to his plea hearing. The defendant agrees that all monetary penalties imposed by the court, including restitution, will be due immediately and subject to immediate enforcement by the government. The defendant agrees that any payment schedule or plan set by the court is merely a minimum schedule of payments and neither the only method, nor a limitation on the methods, available to the government to enforce the judgment, unless the court specifically states otherwise. The defendant is aware that voluntary payment of restitution prior to adjudication of guilt is a factor in considering whether the defendant has accepted responsibility under the United States sentencing guidelines ("USSG") §3E1.1. The defendant agrees to deliver a certified check or money order to the clerk of the court in the amount of \$8,200, payable to the "Clerk, U.S. District Court," to be deposited into the court registry until the date of sentencing and, thereafter, to be applied to satisfy (wholly or partially depending on the amount of the judgment) fines, costs, assessments, and restitution, pursuant to the judgment of the court.

V. ABANDONMENT AND WAIVER REGARDING SEIZED PROPERTY

For any property not forfeited, the Defendant abandons, releases, and waives any interest, now or in the future, to property seized or otherwise obtained by the government or law enforcement in this case unless specific exceptions are noted in this Agreement. Such property will be disposed of, destroyed, sold, forfeited, or transferred, in the government's sole discretion. Such disposition shall not constitute satisfaction of any assessment, fine, restitution, forfeiture,

cost of imprisonment, or any other penalty that this Court may impose. This includes property seized from the defendant's home and office in accordance with a search warrant executed on July 19, 2016, including, but not limited to:

- a. Breast implants, sizers, labeling, and promotional materials;
- b. Expired medical products;
- c. Dermapen devices, needles, and vials;
- d. Counterfeit and/or foreign-unapproved drugs or medical devices.

VI. UNITED STATES SENTENCING GUIDELINES

A. Application of Sentencing Guidelines. The court must consider the USSG in determining an appropriate sentence under 18 U.S.C. § 3553. The defendant agrees that the court may consider "relevant conduct" in determining a sentence pursuant to USSG § 1B1.3.

The court is not a party to this agreement. The agreement does not bind the court's determination of the USSG range. The court will identify the factors that will determine the sentencing range under the USSG. While the court may take the defendant's cooperation, if any, and the recommendations of the parties into account, the court has complete discretion to impose any lawful sentence, including the maximum sentence possible.

Recognizing that the court is not bound by this agreement, the parties agree to the recommendations and requests set forth below.

B. Sentencing Guidelines Recommendations and Requests.

1. **Government's Statements at Sentencing.** The government reserves the right to fully allocute at sentencing regarding any sentencing recommendation and to rely on any

information in support of its recommendation regardless of whether the information is contained in the plea agreement or the presentence report.

2. **Acceptance of Responsibility.** If the defendant clearly accepts responsibility for the offense, the defendant will be entitled to a reduction of two levels in the combined adjusted offense level, under USSG § 3E1.1(a). The government will move for an additional one-level reduction in the combined offense level under § 3E1.1(b) if the following conditions are met: (1) the defendant qualifies for a decrease under § 3E1.1(a); (2) the offense is level 16 or greater; and (3) the defendant has timely notified authorities of the defendant's intention to enter a plea of guilty, thereby permitting the government to avoid preparing for trial and permitting the court to allocate its resources efficiently. If, before sentence is imposed, the defendant fails to meet the criteria set out in USSG § 3E1.1, or acts in a manner inconsistent with acceptance of responsibility, the government will withdraw or decline to make such a recommendation.

3. **Amount of Loss.** The parties agree that the amount of loss is \$34,875.

4. **Downward Departure or Variance Request by Defendant.** Unless otherwise specified in this paragraph, the defendant will not seek a variance under 18 U.S.C. § 3553(a), without first notifying the Government of the defendant's intent to seek a variance and the defendant's reasons and basis therefor, such notice to be provided not less than 21 days before the date set for sentencing. As set forth below in Section B.5, the defendant will not seek a guideline-based departure.

5. **Stipulated Offense Level Calculations.** Provided that the defendant pleads guilty and accepts responsibility as described herein, the government agrees that the following sentencing calculation under the United States Sentencing Guidelines applies and agrees to recommend a sentence within this guideline calculation.

- a. The base offense level is six (6) pursuant to USSG § 2B1.1(a)(2);
- b. A four (4) level increase is appropriate, per USSG § 2B1.1(b)(1) for the loss amount;
- c. A two (2) level increase is appropriate, per USSG § 3B1.3 for abuse of a position of trust;
- d. A two (2) level decrease is appropriate, per USSG § 3E1.1(a) for acceptance of responsibility;
- e. The total adjusted offense level is ten (10).

The defendant agrees with the above-stated guideline calculation and further agrees not to move for, or argue for, any other guideline-based departure to reduce the offense level from the above-stated guideline calculation, unless the District Court's guideline range is greater than the above-stated guideline calculation. The defendant is free to argue for a non-guideline based variance pursuant to the factors in 18 U.S.C. § 3553. The parties recognize that the pre-sentence investigator and the Court are not bound by this guideline calculation.

VII. WAIVER OF RIGHT TO DIRECT APPEAL AND TO COLLATERAL ATTACK UNDER 28 U.S.C. § 2255

A. **Waiver:** In exchange for this agreement, and except as provided in subparagraph B, the defendant waives any right to appeal or collaterally attack the entry of plea, the conviction, the entry of judgment, and the sentence, including forfeiture and restitution. The waiver of the challenge to the conviction includes challenges to the constitutionality of any statute of conviction and arguments that the admitted conduct does not fall within any statute of conviction.

The defendant acknowledges that this waiver shall result in the dismissal of any direct appeal or collateral attack the defendant might file seeking to challenge the plea, conviction or sentence in this case. Further, the filing of such an appeal or collateral attack will breach this

agreement and will allow the government to withdraw from the agreement and take other remedial action.

If the defendant believes the government has not fulfilled its obligations under this agreement, the defendant will object at the time of sentencing; further objections are waived.

B. Exceptions:

1. **Direct Appeal:** Notwithstanding subparagraph A, the defendant shall retain the right to file one direct appeal if one of the following unusual circumstances occurs:
 - a. the sentence imposed by the court exceeds the statutory maximum;
 - b. the court arrived at an advisory USSG range by applying an upward departure under chapter 5K of the USSG; or
 - c. the court exercised its discretion under 18 U.S.C. § 3553(a) to impose a sentence that exceeds the advisory USSG range as determined by the court.

The defendant understands that the above circumstances occur rarely and that in most cases this agreement completely waives all appellate rights.

2. **Motion Under 28 U.S.C. § 2255:** Notwithstanding subparagraph A, the defendant shall retain the right to file a 28 U.S.C. § 2255 motion alleging ineffective assistance of counsel.

VIII. PROVIDING INFORMATION FOR THE PRESENTENCE REPORT

The defendant agrees to provide material financial and other information requested by a representative of the United States probation office for use in preparing a presentence report. Failure to execute releases and provide information for the presentence report violates this agreement and relieves the government of its obligations in this agreement. Such failure and response by the government will not, however, constitute grounds for withdrawing the plea of guilty unless the government so requests. Providing materially false information will subject the defendant to additional penalties, including an enhancement under USSG § 3C1.1.

IX. DISCLOSING FINANCIAL INFORMATION

The defendant agrees to disclose all of the defendant's assets and sources of income to the government, including all assets over which the defendant exercises or exercised direct or indirect control, or in which the defendant has had any financial interest. The defendant also agrees to cooperate in obtaining any records relating to ownership of assets when sought by the government. The defendant agrees truthfully to complete a personal financial statement within fourteen days from the date the defendant signs this agreement. If the government provides a financial statement to be completed, the defendant agrees to complete the financial statement truthfully and accurately within fourteen days from the date the defendant signs this agreement or the date the financial statement is provided to the defendant or counsel, whichever is later. The defendant agrees to provide updates with any material changes in circumstances, as described in 18 U.S.C. § 3664(k) within seven days of the event giving rise to the changed circumstances. The failure timely and accurately to complete, sign, and update the financial statements as required herein, may constitute failure to accept responsibility under USSG § 3E1.1, as well as other things.

The defendant authorizes the government: (a) to obtain a credit report on the defendant; (b) to inspect and copy all financial documents and information held by the United States probation office; and (c) to obtain financial records related to the defendant.

Before sentencing, defendant agrees not to dissipate any assets without the consent of both the government's financial litigation unit and the asset forfeiture unit. If any assets are sold, any sale proceeds received from sale of assets will be deposited with the clerk and, upon sentencing, paid toward any monetary penalties due as ordered in the judgment.

X. NO RIGHT TO WITHDRAW PLEA

The defendant understands that the court may not follow the recommendations or requests made by the parties at the time of sentencing. The defendant cannot withdraw from this agreement or the guilty plea, regardless of the court's actions.

XI. CONSEQUENCES OF VIOLATING AGREEMENT

A. **Government's Options.** If the defendant fails to keep any promise in this agreement or commits a new crime, the government is relieved of any obligation: 1) to make a sentencing recommendation consistent with the terms promised in this agreement; and 2) not to prosecute the defendant on other charges, including charges not pursued due to this agreement. Such charges may be brought without prior notice. In addition, if the government determines after sentence is imposed that the defendant's breach of the agreement warrants further prosecution, the government may choose between letting the conviction(s) under this agreement stand or vacating such conviction(s) so that such charge(s) may be re-prosecuted. If the government determines that a breach warrants prosecution before sentencing, it may withdraw from the agreement in its entirety.

The government's election to pursue any of the above options cannot be a basis for the defendant to withdraw the guilty plea(s) made pursuant to this agreement.

B. **Defendant's Waiver of Rights.** If the defendant fails to keep any promise made in this agreement, the defendant gives up the right not to be placed twice in jeopardy for the offense(s) to which the defendant entered a plea of guilty or which were dismissed under this agreement. In addition, for any charge that is brought as a result of the defendant's failure to keep this agreement, the defendant gives up: (1) any right under the Constitution and laws of the United States to be charged or tried in a more speedy manner; and (2) the right to be charged within the applicable statute of limitations period if the statute of limitations has expired.

Furthermore, if the defendant does not enter an acceptable plea, the government will move to continue the trial now set to allow the government adequate time to prepare. The defendant agrees not to contest such a continuance, and agrees that the resulting delay would be excludable time under 18 U.S.C. § 3161(h).

XII. MISCELLANEOUS

A. **No Other Terms.** This agreement is the complete understanding between the parties, and no other promises have been made by the government to the defendant or to the attorney for the defendant. This agreement does not prevent any governmental agency from pursuing civil or administrative actions against the defendant or any property. Unless an exception to this paragraph is explicitly set forth elsewhere in this document, this agreement does not bind or obligate governmental entities other than that specified as the government in this agreement (i.e., the United States Attorney's Office for the District of Idaho). The government will bring the defendant's cooperation and pleas to the attention of other prosecuting authorities at the request of the defendant or defense counsel.

B. **Plea Agreement Acceptance Deadline.** This plea offer is explicitly conditioned on the defendant's notification of acceptance of this agreement no later than 5:00 p.m. on August 9, 2019.

C. **Risk of Removal from the United States.** The defendant recognizes that pleading guilty may have consequences with respect to the defendant's immigration status if the defendant is not a citizen of the United States. Under federal law, a broad range of crimes are removable offenses, including the offense to which the defendant is pleading guilty. Removal and other immigration consequences are the subject of a separate proceeding, however. While arguments may be made in such a proceeding, it is virtually certain that defendant will be

removed from the United States. The defendant nevertheless affirms that the defendant wants to plead guilty.

XIII. UNITED STATES' APPROVAL

I have reviewed this matter and the agreement. This agreement constitutes a formal plea offer from the government. Any oral discussions with the defendant and defense counsel about a plea do not constitute a plea offer. Any written offer or agreement made before this agreement is no longer a valid offer by the government and is rescinded. I agree on behalf of the United States that the terms and conditions set forth above are appropriate and are in the best interests of justice.

BART M. DAVIS
UNITED STATES ATTORNEY
By:



DARCI WARD CRANE
Assistant United States Attorney



Date

XIV. ACCEPTANCE BY DEFENDANT AND COUNSEL

I have read and carefully reviewed every part of this agreement with my attorney. I understand the agreement and its effect upon my potential sentence. Furthermore, I have discussed all of my rights with my attorney and I understand those rights. No other promises or inducements have been made to me, directly or indirectly, by any agent of the government, including any Assistant United States Attorney, concerning the plea to be entered in this case. I understand that this agreement constitutes a formal plea offer from the government. Any oral discussions between the government and me or my counsel about a plea do not constitute a plea offer. Any written offer or agreement made before this agreement is no longer a valid offer by the government and is rescinded. In addition, no one has threatened or coerced me to do, or to refrain from doing, anything in connection with this case, including enter a guilty plea. I understand that,

if I am not a citizen or naturalized citizen of the United States, by pleading guilty in this case it is virtually certain that I will be removed from the United States. I am satisfied with my attorney's advice and representation in this case.




TEMP RAY PATTERSON, MD
Defendant

8/7/2019

Date

I have read this agreement and have discussed the contents of the agreement with my client. The agreement accurately sets forth the entirety of the agreement. I have conveyed all written offers from the government to the defendant pursuant to *Missouri v. Frye*, 132 S. Ct. 1399, 1408-09 (2012). I understand that this agreement constitutes a formal plea offer from the government. Any oral discussions between the government and me or my client about a plea do not constitute a plea offer. Any written offer or agreement made before this agreement is no longer a valid offer by the government and is rescinded. I have discussed with my client the fact that if my client is not a citizen or naturalized citizen of the United States, by pleading guilty in this case, it is virtually certain that my client will be removed from the United States. I concur in my client's decision to plead guilty as set forth above.



SCOTT MCKAY
Attorney for the defendant

8/8/2019

Date