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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

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| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>vs.<br><br>MARK WRIGHT,<br><br>Defendant. | Case No.<br><br>STATEMENT BY DEFENDANT IN ADVANCE OF PLEA OF GUILTY AND PLEA AGREEMENT<br><br>Judge |

I hereby acknowledge and certify that I have been advised of and that I understand the following facts and rights, and that I have had the assistance of counsel in reviewing, explaining, and entering into this agreement:

1. As part of this agreement with the United States of America ("United States"), I intend to plead guilty to Counts 1 and 2 of the Misdemeanor Information. My attorney has explained the nature of the charges against me, and I have had an opportunity to discuss the nature of the charges with my attorney. I understand the charges and what the United States is required to prove in order to convict me.

The elements of Count 1. 21 U.S.C. §§ 331(a), 333(a)(1) (Introduction of Misbranded Medical Devices into Interstate Commerce) are:

First: The product, as specified in the Misdemeanor Information was a medical device as defined at 21 U.S.C. § 321(h);

Second: The medical device was misbranded under 21 U.S.C. § 352(o) because the notification required by 21 U.S.C. 360(k) had not been filed with the U.S. Food and Drug Administration at least 90 days before the device was introduced into interstate commerce; and

Third: The defendant introduced, delivered for introduction, or caused the introduction or delivery for introduction of the misbranded device into interstate commerce.

The elements of Count 2, 21 U.S.C. §§ 331(a), 333(a)(1) (Introduction of Adulterated Medical Devices into Interstate Commerce) are:

First: The product, as specified in the Misdemeanor Information was a medical device as defined at 21 U.S.C. § 321(h);

Second: The medical device was adulterated under 21 U.S.C. § 351(f) because it was required to have an approved application for premarket approval in effect but it did not have one in effect; and

Third: The defendant introduced, delivered for introduction, or caused the introduction or delivery for introduction of the adulterated medical device into interstate commerce.

2. I know that the maximum possible penalty provided by law for Counts 1 and 2 of the Misdemeanor Information, a violation of 21 U.S.C. § 331(a) is a term of imprisonment of up to 1 year, a fine of up to $200,000, or twice the gross gain to the defendant, or twice the gross loss stemming from the offense, whichever is greatest, a term of supervised release of up to 1 year, and any applicable forfeiture. I understand that if I violate a term or condition of supervised release, I can be returned to prison for the length of time provided in 18 U.S.C. § 3583(e)(3).

a. Additionally, I know the Court is required to impose an assessment in the amount of $25 for each offense of conviction, pursuant to 18 U.S.C. § 3013(A)(iii).

b. I understand that, if I am not a United States citizen, I may be removed from the United States, denied citizenship, and denied admission to the United States in the future.

3. I know that the sentencing procedures in this case and the ultimate sentence will be determined pursuant to 18 U.S.C. § 3553(a), and that the Court must consider, but is not bound by, the United States Sentencing Guidelines, in determining my sentence. I have discussed these procedures with my attorney. I also know that the final calculation of my sentence by the Court may differ from any calculation the United States, my attorney, or I may have made, and I will not be able to withdraw my plea if this occurs.

4. I know that I can be represented by an attorney at every stage of the proceeding, and I know that if I cannot afford an attorney, one will be appointed to represent me.

5. I know that I have a right to plead "Not Guilty" or maintain my earlier plea of "Not Guilty" and can have a trial on the charges against me.

6. I know that I have a right to a trial by jury, and I know that if I stand trial by a jury:

a. I have a right to the assistance of counsel at every stage of the proceeding.

b. I have a right to see and observe the witnesses who testify against me.

c. My attorney can cross-examine all witnesses who testify against me.

d. I can call witnesses to testify at trial, and I can obtain subpoenas to require the attendance and testimony of those witnesses. If I cannot afford to pay for the appearance of a witness and mileage fees, the United States will pay them.

e. I cannot be forced to incriminate myself, and I do not have to testify at any trial.

f. If I do not want to testify, the jury will be told that no inference adverse to me may be drawn from my election not to testify.

g. The United States must prove each and every element of the offense charged against me beyond a reasonable doubt.

h. It requires a unanimous verdict of a jury to convict me.

i. If I were to be convicted, I could appeal, and if I could not afford to appeal, the United States would pay the costs of the appeal, including the services of appointed counsel.

7. If I plead guilty, I will not have a trial of any kind.

8. I know that 18 U.S.C. § 3742(a) sets forth the circumstances under which I may appeal my sentence. However, fully understanding my right to appeal my sentence, and in consideration of the concessions and/or commitments made by the United States in this plea agreement, I knowingly, voluntarily and expressly waive my right to appeal as set forth in paragraph 12 below.

9. I know that 18 U.S.C. § 3742(b) sets forth the circumstances under which the United States may appeal my sentence.

10. I know that under a plea of guilty the judge may ask me questions under oath about the offense. The questions, if asked on the record and in the presence of counsel, must be answered truthfully and, if I give false answers, I can be prosecuted for perjury.

11. I stipulate and agree that the following facts accurately describe my conduct. These facts provide a basis for the Court to accept my guilty plea:

At all times relevant to the Information, the Defendant, Mark Wright ("Wright"), was a resident of Scottsdale, Arizona. Defendant Wright was the Chief Executive Officer ("CEO") of

Dolor Technologies, LLC. ("Dolor"), a medical device company, from on or about July 15, 2013, until he ceased employment with Dolor on July 31, 2017. Dolor was engaged in the medical device business throughout the United States, including the District of Utah. Dolor developed, manufactured, marketed, sold, and distributed a medical device that was called the SphenoCath and that was Dolor's only product. Dolor shipped the SphenoCath in interstate commerce, and the SphenoCath was ultimately delivered to health care providers throughout the United States.

The SphenoCath was a medical device, as defined in 21 U.S.C. § 321(h)(1). The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et. seq.*, prohibited the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a device that was adulterated or misbranded. 21 U.S.C. § 331(a). A device was adulterated if it was required to have an approved premarket application ("PMA approval") but did not have one in effect. 21 U.S.C. § 351(f)(1)(B). A device was misbranded if, among other things, the manufacturer failed to provide the U.S. Food and Drug Administration ("FDA") with premarket notification pursuant to FDCA section 510(k), at least ninety days prior to introducing the device into interstate commerce ("section 510(k) clearance"). 21 U.S.C. § 352(o). A manufacturer could avoid the PMA approval and section 510(k) clearance requirements if the device qualified for an exemption.

In or around February 2013, Dolor began selling and distributing the SphenoCath device within and throughout the United States. In his capacity as Dolor's CEO, Wright directed and participated personally in marketing the SphenoCath. Wright, among other things, provided marketing materials to and communicated directly with purchasers and potential purchasers of the SphenoCath.

Wright and Dolor intended that the SphenoCath be used to treat migraine headaches by administering sphenopalatine ganglion ("SPG") nerve blocks, and Wright and Dolor marketed the SphenoCath for this intended use. A nerve block was the interruption of signals traveling along a nerve generally caused by applying an anesthetic, such as lidocaine, to the nerve endings. The SPG was a bundle of nerves located behind the bony structure of the nose. The SphenoCath was a catheter with a specially-curved tip capable of reaching—and administering anesthetic to—the SPG nerve.

In its initial required registration with FDA, Dolor listed the SphenoCath as a "class I exempt" device, meaning that the SphenoCath was claimed to be exempt from the PMA-approval and 510(k)-clearance requirements as an "[e]ar, nose, and throat drug administration device" under 21 C.F.R. § 874.5220. That regulation identified exempt devices as those that were "intended specifically to administer medicinal substances to treat ear, nose, and throat disorders" and gave as examples "powder blowers," "droppers, ear wicks, manual nebulizer pumps, and nasal inhalers." In fact, the SphenoCath failed to qualify for the exemption under 21 C.F.R. § 874.5220 because Wright and Dolor intended that the SphenoCath treat a neurological disorder—migraine headaches—and not an ENT disorder, and because Wright and Dolor intended that the SphenoCath target a neurological site—the SPG nerve—and not the ear, nose, or throat.

On or about April 17, 2014, Dolor, through its counsel, submitted an "informal request for product classification and jurisdictional assignment" to the U.S. Food and Drug

Administration (FDA). Dolor's informal request, as supplemented on April 25, 2014, asked the FDA's Office of Combination Products whether the SphenoCath device could be cleared for the "trans[-]nasal administration of local anesthetic into the region of the sphenopalatine fossa, the ethmoidal crest and the vidian (or petrosal) canal to perform neuro-modulation [nerve block] of the sphenopalatine ganglia, pterygopalatine ganglia and the maxillary branch of the trigeminal ganglia." This was not a notification pursuant to the section 510(k) clearance process, but rather was Dolor's exploration of, among other things, whether the SphenoCath would require further study in order to receive section 510(k) clearance.

On or about June 13, 2014, FDA's Office of Combination Products informed Dolor that, "[a]fter review of the information, we are unable to provide a definitive answer to your question regarding classification of your product . . . . [W]e recommend that you contact CDRH [FDA Center for Devices and Radiological Health] to proceed with investigational studies regarding the proposed product." Neither Wright nor Dolor responded to FDA concerning its recommendation of "proceed[ing] with investigational studies." Neither Wright nor Dolor ever submitted a section 510(k) clearance notification to FDA for the SphenoCath, and neither Wright nor Dolor ever sought or obtained PMA approval for the SphenoCath.

Instead, Wright and Dolor continued to market the SphenoCath with the intention that it be used to treat migraine headaches by administering SPG nerve blocks. For example, Dolor's website described the SphenoCath as a "revolutionary" device that "delivers anesthetic through the nasal cavity, effectively delivering an SPG block for migraine pain." Wright and Dolor also distributed marketing materials, intended for health care providers, that included claims such as "The SphenoCath Solution" for "The Pain Management Problem" of "episodic & chronic migraine and cluster headaches." As part of marketing efforts, Wright and Dolor provided unsolicited directions to health care providers on how to fill the SphenoCath with lidocaine and/or other anesthesia drugs, insert the SphenoCath into the nose, angle the curved tip towards the nasal cavity, and flood the nasal cavity with a specific drug which would reach the SPG nerve and trigger the nerve block.

12. The only terms and conditions pertaining to this plea agreement between me and the United States are as follows:

a. **Guilty Plea.** I will plead guilty to Counts 1 and 2 of the Misdemeanor Information.

b. **Relevant Conduct.** I understand and agree that the Presentence Report may include descriptions of conduct I engaged in which either was not charged against me, will not be pleaded to by me, or both. I understand and agree that the Court may take these facts into consideration in sentencing.

c. **Acceptance of Responsibility**. The United States agrees to recommend that my offense level under the U.S. Sentencing Guidelines be decreased by two levels for acceptance of responsibility pursuant to Sentencing Guideline § 3E1.1(a) if, in the opinion of the United States, I clearly demonstrate acceptance of responsibility for my offenses, up to and including at the time of sentencing, as set forth in § 3E1.1 of the Sentencing Guidelines. In addition, the United States agrees to move for an additional one-level reduction in the offense level, in accordance

with Sentencing Guideline § 3E1.1(b), if I qualify for a two-level reduction under § 3E1.1(a) and the offense level is 16 or greater prior to receiving the two-level reduction.

d. **Fine.** I will pay a criminal fine of five thousand dollars ($5,000.00) to the United States. I agree that the amount of this penalty is appropriate given the facts and circumstances of this case and that the amount of this fine is within the range recommended by the U.S. Sentencing Guidelines.

e. **Enjoinment.** I agree not to contest that any term of supervised release will include, but not be limited to, a ban against, directly or indirectly, as proprietor, contractor, consultant, or employee, working or providing services for any company engaged in the manufacturing, importing, marketing, or distribution, or selling of any drug or medical device (as defined by 21 U.S.C. § 321(g), (h)).

f. **Appeal Waiver.**

(1) Fully understanding my limited right to appeal my sentence, as explained above in paragraph 8, and in consideration of the concessions and/or commitments made by the United States in this plea agreement, I knowingly, voluntarily, and expressly waive my right to appeal any sentence imposed upon me, and the manner in which the sentence is determined, on any of the grounds set forth in 18 U.S.C. § 3742 or on any ground whatever, except I do not waive my right to appeal (1) a sentence above the maximum penalty provided in the statute of conviction as set forth in paragraph 2 above; and (2) a sentence above the high-end of the guideline range as determined by the district court at sentencing, or, in the event that no such determination is made by the district court, a sentence above the high-end of the guideline range as set forth in the final presentence report.

(2) I also knowingly, voluntarily, and expressly waive my right to challenge my sentence, and the manner in which the sentence is determined, in any collateral review motion, writ or other procedure, including but not limited to a motion brought under 28 U.S.C. § 2255, except on the issue of ineffective assistance of counsel.

(3) I understand that this waiver of my appeal and collateral review rights concerning my sentence shall not affect the United States' right to appeal my sentence pursuant to18 U.S.C. § 3742(b). However, I understand that the United States agrees that if it appeals my sentence, I am released from my waiver.

(4) I further understand and agree that the word "sentence" appearing throughout this waiver provision is being used broadly and applies to all aspects of the Court's sentencing authority, including, but not limited to: (1) sentencing determinations; (2) the imposition of imprisonment, fines, supervised release, probation, and any specific terms and conditions thereof; and (3) any orders of restitution.

g. **Rule 410 Waiver.** If the Court finds that I failed to fulfill my obligations under this plea agreement, or if I withdraw my plea of guilty, I agree that this agreement, my statements pursuant to this agreement, or any leads derived therefrom, shall be admissible at any trial, hearing, or other proceeding.

h. **Presentence Report and Financial Information.** I agree to provide truthful and complete information, including financial information, as requested by the probation office for the preparation of my presentence report and for determination of the conditions of my supervised release. I also consent to allowing the United States Attorney's Office to run a credit check on me. I consent to being placed on the Treasury Offset Program and State Finder.

13. I understand and agree that this plea agreement is solely between me and the United States Attorney for the District of Utah and does not bind any other federal, state, or local prosecuting, administrative, or regulatory authorities.

14. I understand that I have a right to ask the Court any questions I wish to ask concerning my rights about these proceedings and the plea.

* * * *

I make the following representations to the Court:

1. I am 67 years of age. My education consists of college graduate. I can [can/cannot] read and understand English.

2. This Statement in Advance contains all terms of the agreements between me and the United States; if there are exceptions, the Court will be specifically advised, on the record, at the time of my guilty plea of the additional terms. I understand the United States and I cannot have terms of this plea agreement that are not disclosed to the Court.

3. No one has made threats, promises, or representations to me that have caused me to plead guilty, other than the provisions set forth in this agreement.

4. Neither my attorney nor the United States has promised me that I would receive probation or any other form of leniency because of my plea.

5. I have discussed this case and this plea with my lawyer as much as I wish, and I have no additional questions.

6. I am satisfied with my lawyer.

7. My decision to enter this plea was made after full and careful thought; with the advice of counsel; and with a full understanding of my rights, the facts and circumstances of the case and the consequences of the plea. I was not under the influence of any drugs, medication, or intoxicants when I made the decision to enter the plea, and I am not now under the influence of any drugs, medication, or intoxicants.

8. I have no mental reservations concerning the plea.

9. I understand and agree to all of the above. I know that I am free to change or delete anything contained in this statement. I do not wish to make changes to this agreement because I agree with the terms and all of the statements are correct.

DATED this 14th day of May, 2023

Mark Wright
Defendant

I certify that I have discussed this plea agreement with the defendant, that I have fully explained his rights to him, and that I have assisted him in completing this written agreement. I believe that he is knowingly and voluntarily entering the plea with full knowledge of his legal rights and that there is a factual basis for the plea.

DATED this 25th day of May, 2023.

BRENNAN H. MOSS
Attorney for Defendant

I represent that all terms of the plea agreement between the defendant and the United States have been, or will be at the plea hearing, disclosed to the Court, and there are no undisclosed agreements between the defendant and the United States.

DATED this 2nd day of June, 2023.

TRINA A. HIGGINS
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JACOB J. STRAIN
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