

U.S. DISTRICT COURT
N.D. OF N.Y.
FILED

APR 1 2009

LAWRENCE K. BAERMAN, CLERK

IN THE UNITED STATES DISTRICT COURT ALBANY
FOR THE NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

DOUGLAS M. HARGRAVE, MD,

Defendant.

Criminal Action No.

09-CR- 426

ANDREW T. BAXTER, United States Attorney for the Northern District of New York (by Thomas A. Capezza and Jason S. Hedges, appearing) and DOUGLAS M. HARGRAVE, MD (with Terence P. O'Connor, Esq., appearing) hereby enter into the following Plea Agreement regarding the disposition of a criminal charge against the Defendant:

1. **Defendant's Promises.** In return for the consideration described below, DOUGLAS M. HARGRAVE, MD ("HARGRAVE") agrees as follows:

a. The Defendant will enter a plea of guilty to a one-count Information charging HARGRAVE with misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2.

b. The Defendant consents to the entry of an order directing HARGRAVE to pay restitution in full to any person who would qualify as a victim of the conduct of THE PLASTIC SURGERY GROUP, LLP (hereinafter "TPSG") and its agents, as outlined in the Plea Agreement

between the United States and TPSG, under 18 U.S.C. § 3663 or § 3663A, whether or not such conduct is encompassed in the offense of conviction.

2. **Potential Penalties.** DOUGLAS M. HARGRAVE, MD understands that the potential penalties for misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2 are:

- a. **Maximum Term of Imprisonment:** 1 year. (21 U.S.C. § 333(a)(1))
- b. **Mandatory Minimum Term of Imprisonment:** none.
- c. **Supervised Release:** In addition to imposing any other penalty, the sentencing Court may require the Defendant to serve a term of supervised release of up to 1 year, to begin at the expiration of any term of imprisonment imposed upon a given defendant. 18 U.S.C. § 3583. Under some circumstances, the Court may also extend the term of supervised release, and it may modify, reduce, or enlarge the conditions of such release.
- d. **Maximum Fine:** \$100,000. (18 U.S.C. § 3571(b) (5)) In its discretion, the Court may impose an alternative fine of the greater of twice the pecuniary gain to the Defendant or loss to any victim resulting from the offense of conviction. (18 U.S.C. § 3571(d))
- e. **Mandatory Restitution:** The sentencing Court may order that the Defendant pay restitution to any victim of the offense of conviction. (18 U.S.C. §§ 3663 & 3664)
- f. **Forfeiture:** The sentence imposed by the Court may include an order of forfeiture.
- g. **Special Assessment:** The Defendant will be required to pay an assessment of \$25, which is due and payable at the time of sentencing. (18 U.S.C. § 3013) The Defendant

agrees to deliver a check or money order to the Clerk of the Court in the amount of \$25, payable to the U.S. District Court at the time of his sentencing.

h. Interest and Penalties: Interest and penalties may accrue, as a matter of law, on any unpaid financial obligation imposed as part of the Defendant's sentence, from as early as the date of sentencing.

i. Collateral Consequences: Conviction of a misdemeanor may result in collateral consequences.

3. Sentencing Factors. DOUGLAS M. HARGRAVE, MD understands that the sentence to be imposed upon HARGRAVE is within the discretion of the sentencing Court, subject to the statutory maximum penalties and the provisions of the Sentencing Reform Act and the United States Sentencing Guidelines promulgated thereunder, as modified by *United States v. Booker*, 543 U.S. 220 (2005). While the Court is not ultimately bound to impose a sentence within the applicable Sentencing Guidelines range, it must take into account the Sentencing Guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a). The United States Attorney's Office will ask the Court to apply the Guidelines in effect on the date of sentencing, pursuant to 18 U.S.C. § 3553(a)(4)(A)(ii) and U.S.S.G. § 1B1.11, even if the application of the Guidelines in effect at the time the defendant committed the offense would generate a lower sentencing range.

4. Elements of the Offense. DOUGLAS M. HARGRAVE, MD understands the following legal elements of the offense stated in misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2, and admits that those elements accurately describe HARGRAVE's criminal conduct:

a. The article is a drug;

- b. an act was done to the drug that resulted in the drug being misbranded; and
- c. while the drug was held for sale after shipment in interstate commerce.

See 21 U.S.C. § 331(k); United States v. Sullivan, 332 U.S. 689, 695 (1948); United States v. Gel Spice Co., 601 F. Supp. 1205, 1210 (E.D.N.Y. 1984).

- d. This is a “strict liability” offense that does not require proof of an intent to mislead or defraud.

5. **Factual Basis for the Plea.** DOUGLAS M. HARGRAVE, MD admits the following facts, which establish HARGRAVE’s guilt with respect to the offense of misbranding a drug, a “strict liability” offense under 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2:

- a. The FDA regulates the manufacture and distribution of drugs in the United States. The FDA also regulates the manufacture and distribution of “biological products,” which includes toxins used for the “prevention, treatment, or cure of a disease or condition of human beings.” Botulinum Toxin Type A, like many products, meets the definitions of both “drug” and “biological product,” and is thus regulated as both a drug and a biological product. There is only one Botulinum Toxin Type A product that has ever been approved by FDA; this product was first approved in 1989. In 1991, Allergan, Inc. (“Allergan”), purchased the rights to this product and began to market it under the name BOTOX®. Subsequently, Allergan received additional approvals to market BOTOX® for other indications. In April 2002, Allergan obtained a license from the FDA for a new drug and biological product called “BOTOX® Cosmetic” for use on humans to treat facial wrinkles.

b. Toxin Research International, Inc. ("TRI") is a company based in Arizona. TRI distributed a form of Botulinum Toxin Type A (hereafter "TRI-toxin"). The TRI-toxin had not been approved or licensed for use on humans by the FDA (nor has it ever been).

c. THE PLASTIC SURGERY GROUP, LLP ("TPSG") is a limited liability partnership whose members consisted of professional corporations organized under the laws of New York State. Defendant DOUGLAS M. HARGRAVE, MD, was the principal of one such professional corporation. The medical offices of TPSG are located in Albany, in the State and Northern District of New York.

d. TPSG provides a number of plastic surgery treatments to patients, including Botulinum Toxin Type A injections for the treatment of facial wrinkles. Beginning in or about January 2004, TPSG stopped purchasing BOTOX®/BOTOX® Cosmetic and began exclusively purchasing, for use in its practice, TRI-toxin, which was not approved by the FDA.

e. From approximately February 2004 to December 2004, defendant DOUGLAS M. HARGRAVE, MD, injected approximately twenty-five (25) patients seeking treatment for facial wrinkles with TRI-toxin. During this time period, the patients believed that they were being injected with FDA-approved BOTOX®/BOTOX® Cosmetic.

f. On or about March 12, 2004, in the Northern District of New York, defendant DOUGLAS M. HARGRAVE, MD, administered or caused the administration of a misbranded drug, namely, Botulinum Toxin Type A manufactured by Toxin Research International, Inc. in Arizona ("TRI-toxin"), while it was held for sale and after shipment in interstate commerce, in that defendant

DOUGLAS M. HARGRAVE, MD, in connection with the injection of a patient, offered the TRI-toxin for sale to a patient under the name of another drug, namely BOTOX®/ BOTOX® Cosmetic.

The Defendant understands that the sentencing Court may make factual findings with respect to any and all sentencing factors and issues, including those referenced in the United States Sentencing Guidelines, whether or not such factors or issues have been admitted by the Defendant or stipulated by the parties. In making those findings by a preponderance of the evidence, the Court may consider any reliable evidence, including hearsay. The Defendant agrees that HARGRAVE's sentence may be determined based upon such judicial fact-finding.

6. **Use of Defendant's Admissions.** The Defendant agrees that the statements made by HARGRAVE in signing this Agreement, including the factual admissions set forth above in paragraph 5, shall be admissible and useable against the Defendant by the United States in any subsequent criminal or civil proceeding, even if HARGRAVE fails to enter a guilty plea pursuant to this Agreement, or if such a guilty plea is later vacated or withdrawn. The Defendant waives any rights under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410, to the extent these rules are inconsistent with this paragraph or with this Agreement generally.

7. **Collection of Financial Obligations.** In order to facilitate the collection of financial obligations to be imposed in connection with this prosecution, the Defendant agrees fully to disclose all assets in which he has any interest or over which the Defendant exercises control, directly or indirectly, including those held by a spouse, nominee or other third party.

a. The Defendant will promptly submit a completed financial statement to the U.S. Attorney's Office, in a form it provides and as it directs. The Defendant promises that his financial statement and disclosures will be complete, accurate and truthful.

b. The Defendant expressly authorizes the U.S. Attorney's Office to obtain a credit report on HARGRAVE in order to evaluate the Defendant's ability to satisfy any financial obligation imposed by the Court.

8. **Government's Promises and Reservation of Rights.** In exchange for the plea of guilty to misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333, and 18 U.S.C. § 2 by DOUGLAS M. HARGRAVE, MD and HARGRAVE's continuing compliance with all of the terms of this Plea Agreement, the United States Attorney's Office for the Northern District of New York agrees as follows:

a. It will bring no further federal criminal charges against the Defendant relating to the conduct in the Northern District of New York, committed before the date of this Agreement, which is described as misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2 and the Defendant's admissions in paragraph 5, above, for so long as the guilty plea and sentence on misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2 remain in effect.

b. If the guilty plea to misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2 is later withdrawn or vacated, the charges dismissed or not prosecuted pursuant to subparagraph(s) 8a and 8b of this Agreement may be filed and prosecuted, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the filing of any such charges. The Defendant waives any defense or objection to the filing and prosecution of any such charges that are not time-barred by the applicable statute of limitations as of the date of this Agreement.

c. It reserves the right to recommend a specific sentence within the applicable Guidelines range determined by the Court.

d. The U.S. Attorney's Office reserves the right to advise the sentencing Court and the Probation Office of any information, in aggravation or mitigation of sentencing, whether or not encompassed within misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2.

9. **Stipulations.** The U.S. Attorney's Office and DOUGLAS M. HARGRAVE, MD agree to stipulate at sentencing to the statement(s) set forth in subparagraph a below, subject to the caveats set forth in the subparagraphs following:

a. **Stipulations**

i. The U.S. Attorney's Office will recommend a 2-level downward adjustment to the applicable Sentencing Guidelines range if, (A) through the time of sentencing, the Defendant clearly demonstrates "acceptance of responsibility" to the satisfaction of the Government for the offense [of conviction], as defined in U.S.S.G. § 3E1.1(a); and (B) the Government does not learn of new evidence of conduct committed by the Defendant, either before or after HARGRAVE's guilty plea, that constitutes "obstruction of justice," as defined in U.S.S.G. § 3C1.1.

b. Until the Probation Office has fully investigated the defendant's criminal history, it is not possible to predict with certainty the Defendant's Criminal History Category and, in some cases, HARGRAVE's total offense level.

c. It is understood that these stipulations cannot and do not bind the sentencing Court, which may make independent factual findings by a preponderance of the evidence and may reject any or all stipulations between the parties. The rejection of any or all stipulations by the Court will not be the basis for the withdrawal of a plea of guilty by the Defendant, and will not release either the U.S. Attorney's Office or the Defendant from any other portion of this Agreement, including any other stipulations agreed to herein.

d. No stipulation in this Agreement shall affect the parties' respective obligations to ensure that, to the extent possible, the Court has all information pertinent to its determination of an appropriate sentence. The parties may provide any such factual information to the Probation Office and/or to the Court, without limitation, before or after the completion of the Presentence Investigation Report, and agree that the submission of such information shall not be deemed "advocacy" in violation of any stipulation in this Agreement.

e. To the extent the stipulations above do not reflect agreement on any factor or issue potentially affecting the applicable advisory Sentencing Guidelines range, the Defendant and the U.S. Attorney's Office each expressly reserves the right to advocate if, and how, any such factor or issue would apply under the Sentencing Guidelines.

10. **Preliminary Sentencing Guidelines Estimates.** The Defendant understands that any estimate of the Defendant's total offense level, criminal history score, and/or Sentencing Guidelines range provided before sentencing is preliminary and is not binding on the parties to this Agreement, the Probation Office, or the Court.

11. **Remedies for Breach.** Should the U.S. Attorney's Office determine that the Defendant, after the date of this Plea Agreement, (i) has committed any further crime or violated any

condition of release or supervision imposed by the Court (whether or not charged) or (ii) has otherwise breached any condition of this Agreement, the U.S. Attorney's Office will have the right, in its sole discretion, to void this Agreement, in whole or in part. In the event of any such breach, the Defendant will not be permitted to withdraw the guilty plea under this Agreement, but will thereafter be subject to prosecution for any federal criminal violation of which the U.S. Attorney's Office has knowledge, including but not limited to charges that this Office has agreed to dismiss or has agreed not to prosecute.

a. The Defendant waives any defense or objection to the commencement of any such prosecution that is not time-barred by the applicable statute of limitations as of the date of this Agreement, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the commencement of any such prosecution.

b. Moreover, in connection with any such prosecution, any information, statement, or testimony provided by the Defendant, and all leads derived therefrom, may be used against HARGRAVE, without limitation.

c. In the event of any such breach by the Defendant, the U.S. Attorney's Office will have the right, in its sole discretion, to do the following, notwithstanding any contrary provision or stipulation in this Plea Agreement:

i. to advocate if, and how, any particular adjustment or specific offense characteristic affects the applicable Sentencing Guidelines range;

ii. to utilize any information, statement, or testimony provided by the Defendant in determining the applicable Sentencing Guidelines range, notwithstanding U.S.S.G. § 1B1.8;

iii. to recommend a specific sentence of imprisonment within or above the applicable Sentencing Guidelines range determined by the Court.

12. **Limitations on Agreement.** This Agreement is limited to the U.S. Attorney's Office for the Northern District of New York and cannot bind other federal, state or local prosecuting or administrative authorities. Furthermore, this Agreement does not prohibit the United States, any agency thereof, or any third party from initiating or prosecuting any civil or administrative proceedings directly or indirectly involving the Defendant, including, but not limited to, proceedings by the Internal Revenue Service relating to potential civil tax liability or proceedings relating to the forfeiture of assets.

13. **Agreement Not Binding on the Court.** The Court is neither a party to, nor bound by this Agreement. The Court may accept or reject this Plea Agreement or defer a decision until it has considered the Presentence Investigation Report prepared by the U.S. Probation Office.

a. If the Court rejects the provisions of this Agreement permitting the Defendant to plead guilty to 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1) and 18 U.S.C. § 2 in satisfaction of other charges, which provisions were negotiated pursuant to Fed. R. Crim. P. 11(c)(1)(A), the Court will afford the Defendant an opportunity to withdraw the plea of guilty prior to sentencing, pursuant to Fed. R. Crim. P. 11(c)(5) & (d).

b. The Court is not bound by any recommendation, stipulation, or request made by the parties, pursuant to Fed. R. Crim. P. 11(c)(1)(B), as to the appropriate sentence, and the Defendant may not withdraw the plea of guilty if the Court declines to follow any such recommendation, stipulation, or request. The U.S. Attorney's Office reserves the right to support and defend, in connection with any post-sentencing proceedings, any decision the Court may make with regard to the Defendant's sentence, whether or not such decision is consistent with this Office's recommendations, stipulations, or requests.

14. **Waiver of Defendant's Rights.** The Defendant acknowledges that he has read each of the provisions of the entire Plea Agreement with the assistance of counsel and understands its provisions. The Defendant further acknowledges that the plea is voluntary and did not result from any force, threat, or promises other than the promises in this Plea Agreement.

a. The Defendant understands the right to assistance of counsel at every stage of the proceeding and has discussed his constitutional and other rights with defense counsel. The Defendant understands that by entering a plea of guilty, HARGRAVE will be giving up the right (i) to be presumed innocent until proven guilty beyond a reasonable doubt; (ii) to plead not guilty; (iii) to trial by jury; (iv) to confront, cross-examine, and compel the attendance of witnesses at trial; (v) to present evidence in HARGRAVE's defense; and (vi) to remain silent and refuse to be a witness against HARGRAVE by asserting the privilege against self-incrimination.

b. The Defendant has been advised by defense counsel of the nature of the charges to which he is entering a guilty plea and the nature and range of the possible sentence. The Defendant understands the sentencing Court's obligation to consider the United States Sentencing Guidelines (as explained further above) and the Court's discretion to depart from those Guidelines

under some circumstances or otherwise to impose a reasonable sentence outside of the applicable Sentencing Guidelines range.

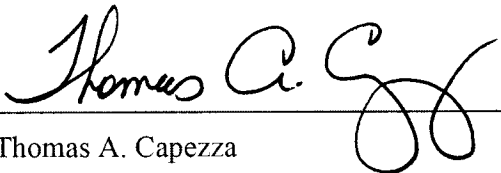
15. **Waiver of Appeal and Collateral Attack.** The Defendant acknowledges that, after consultation with defense counsel, he fully understands the extent of his rights to appeal, and/or to collaterally attack the conviction and sentence in this case. The Defendant waives any and all rights, including those conferred by 18 U.S.C. § 3742 and/or 28 U.S.C. § 2255, to appeal or collaterally attack his conviction and any sentence of imprisonment of 6 months or less, including any related issues with respect to the establishment of the advisory Sentencing Guidelines range or the reasonableness of the sentence imposed. The Defendant acknowledges that the number of months specified above is not a promise of any particular sentence and is not binding on the Court. The Defendant agrees that, should the sentence imposed exceed 6 months, this would not permit him to withdraw his guilty plea or to appeal or collaterally attack his conviction, but would merely allow the Defendant to appeal or collaterally attack the sentence imposed by the Court, to the extent permitted by 18 U.S.C. § 3742 and/or 28 U.S.C. § 2255.

16. **Memorialization of Agreement.** No promises, agreements or conditions other than those set forth in this Agreement will be effective unless memorialized in writing and signed by all parties or confirmed on the record before the Court. This Agreement, to become effective, must be

signed by all of the parties listed below.

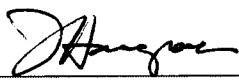
ANDREW T. BAXTER
United States Attorney
Northern District of New York

Dated: 8/11, 2009

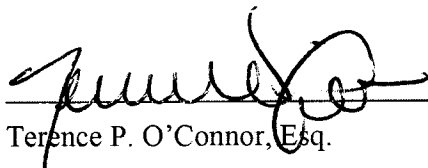
By: 
Thomas A. Capezza
Assistant U.S. Attorney
Bar Roll No.

Jason S. Hedges
Special Assistant U.S. Attorney

Dated: 7/28, 2009


DOUGLAS M. HARGRAVE, MD
Defendant

Dated: 7/28, 2009


Terence P. O'Connor, Esq.
Attorney for Defendant
Bar Roll No. 501073