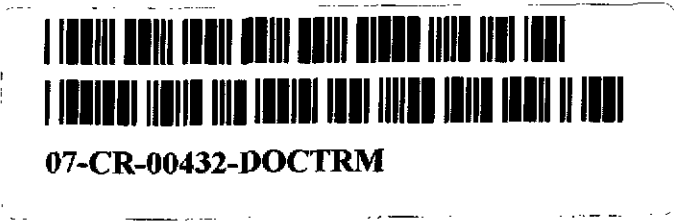


The Honorable Richard A. Jones



UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA,
Plaintiff,
v.
DONALD BRANDT,
Defendant.

NO. CR 07-432 RAJ
PLEA AGREEMENT

The United States of America, by and through Jeffrey C. Sullivan, United States Attorney for the Western District of Washington, and Susan Loitz and James M. Lord, Assistant United States Attorneys for said District, Defendant, DONALD BRANDT, and Defendant's attorney, Mark Mestel, enter into the following Agreement, pursuant to Federal Rule of Criminal Procedure 11(c):

1. Waiver of Indictment. Defendant, having been advised of the right to be charged by Indictment, agrees to waive that right and enter a plea of guilty to the charge brought by the United States Attorney in an Information.

2. The Charges. Defendant, having been advised of the right to have this matter tried before a jury, agrees to waive that right and enter pleas of guilty to the following misdemeanor charge contained in the Information: Causing the Introduction into Interstate Commerce of an Adulterated Medical Device, as charged in Count 1, in

1 violation of Title 21, United States Code, Section 331(a) and Title 18, United States Code,
2 Section 2.

3 By entering this plea of guilty, Defendant hereby waives all objections to the form
4 of the charging document. Defendant further understands that before entering Defendant's
5 plea of guilty, Defendant will be placed under oath. Any statement given by Defendant
6 under oath may be used by the United States in a prosecution for perjury or false
7 statement.

8 3. Elements of the Offense.

9 The elements of the offense of Causing the Introduction of an Adulterated
10 Medical Device into Interstate Commerce, as charged in Count 1, in violation of Title 21,
11 United States Code, Section 331(a), and Title 18, United States Code,
12 Section 2, are as follows:

13 First, the defendant caused a "medical device" as that term is defined in
14 Title 21, United States Code, Section 321(h) to be introduced into interstate commerce, or
15 aided and abetted the introduction of a medical device into interstate commerce; and

16 Second, the medical device when so introduced into interstate commerce
17 was "adulterated" as that term is defined in Title 21, United States Code, Section 351.

18 4. The Penalties. Defendant understands that the statutory penalties for the
19 offense charged in the Information, i.e., Causing the Introduction Into Interstate
20 Commerce of an Adulterated Medical Device as charged in Count 1, is as follows:

21 imprisonment for up to one (1) year, a fine of up to One Hundred Thousand dollars
22 (\$100,000.00), a period of supervision following release from prison of up to one (1)
23 year, and a Twenty-five dollar (\$25.00) special assessment. If Defendant receives a
24 sentence of probation, the probationary period could be up to five (5) years. Defendant
25 agrees that the special assessment shall be paid at or before the time of sentencing.

26 Defendant understands that supervised release is a period of time following
27 imprisonment during which Defendant will be subject to certain restrictions and
28 requirements. Defendant further understands that if supervised release is imposed and

1 Defendant violates one or more of its conditions, Defendant could be returned to prison for
2 all or part of the term of supervised release that was originally imposed. This could result
3 in Defendant serving a total term of imprisonment greater than the statutory maximum
4 stated above.

5 Defendant understands that in addition to any term of imprisonment and/or fine that
6 is imposed, the Court may order Defendant to pay restitution to any victim of the offense,
7 as required by law.

8 Defendant agrees that any monetary penalty the Court imposes, including the
9 special assessment, fine, costs or restitution, is due and payable immediately, and further
10 agrees to submit a completed Financial Statement of Debtor form as requested by the
11 United States Attorney's Office.

12 5. Rights Waived by Pleading Guilty. Defendant understands that by pleading
13 guilty, Defendant knowingly and voluntarily waives the following rights:

- 14 a. The right to plead not guilty and to persist in a plea of not guilty;
- 15 b. The right to a speedy and public trial before a jury of Defendant's
16 peers;
- 17 c. The right to the effective assistance of counsel at trial, including, if
18 Defendant could not afford an attorney, the right to have the Court appoint one for
19 Defendant;
- 20 d. The right to be presumed innocent until guilt has been established
21 beyond a reasonable doubt at trial;
- 22 e. The right to confront and cross-examine witnesses against Defendant
23 at trial;
- 24 f. The right to compel or subpoena witnesses to appear on Defendant's
25 behalf at trial;
- 26 g. The right to testify or to remain silent at trial, at which trial such
27 silence could not be used against Defendant; and
- 28 h. The right to appeal a finding of guilt or any pretrial rulings.

1 6. United States Sentencing Guidelines. Defendant understands and
2 acknowledges that, at sentencing, the Court must consider the sentencing range calculated
3 under the United States Sentencing Guidelines, together with the other factors set forth in
4 Title 18, United States Code, Section 3553(a), including: (1) the nature and circumstances
5 of the offenses; (2) the history and characteristics of the defendant; (3) the need for the
6 sentence to reflect the seriousness of the offense, to promote respect for the law, and to
7 provide just punishment for the offense; (4) the need for the sentence to afford adequate
8 deterrence to criminal conduct; (5) the need for the sentence to protect the public from
9 further crimes of the defendant; (6) the need to provide the defendant with educational and
10 vocational training, medical care, or other correctional treatment in the most effective
11 manner; (7) the kinds of sentences available; (8) the need to provide restitution to victims;
12 and (9) the need to avoid unwarranted sentence disparity among defendants involved in
13 similar conduct who have similar records. Accordingly, Defendant understands and
14 acknowledges that:

15 a. The Court will determine Defendant's applicable Sentencing
16 Guidelines range at the time of sentencing;

17 b. After consideration of the Sentencing Guidelines and the factors in
18 18 U.S.C. 3553(a), the Court may impose any sentence authorized by law, up to the
19 maximum term authorized by law;

20 c. The Court is not bound by any recommendation regarding the
21 sentence to be imposed, or by any calculation or estimation of the Sentencing Guidelines
22 range offered by the parties or the United States Probation Department, or by any
23 stipulations or agreements between the parties in this Plea Agreement; and

24 d. Defendant may not withdraw a guilty plea solely because of the
25 sentence imposed by the Court.

26 7. Sentencing Guideline Provisions.

27 **Base Offense Level:** The Defendant and the United States agree that the
28 applicable Base Offense level under the Sentencing Guidelines is 6.

1 **Other Guideline Issues:** The parties reserve the right to argue for or
2 against the applicability of other Sentencing Guideline provisions, including, for example,
3 USSG § 3A1.1(b)(1) and (2) with respect to vulnerable victims.

4 The United States will not ask for an evidentiary hearing in conjunction with
5 sentencing, unless either Donald Brandt or Sharon Brandt dispute any of the facts set
6 forth in the Presentence Report. In the event of such dispute, the parties agree that the
7 United States may call an agent from the FDA to present factual testimony and pertinent
8 exhibits.

9 The United States agrees that it will not ask for an order of restitution.

10 8. **Fine.** The Defendant shall cooperate with the Probation Office and the
11 United States Attorney's Office in providing financial disclosure so that the court will
12 have the necessary information to determine the Defendant's ability to pay a fine.

13 9. **Ultimate Sentence.** Defendant acknowledges that no one has promised or
14 guaranteed what sentence the Court will impose.

15 10. **Forfeiture of Medical Devices.** Defendant shall forfeit to the Food and Drug
16 Administration the following devices:

17 a. Three BK Precision 21.5 MHZ Multi-Function Arbitrary Wave Form
18 Generators, Model 4070, serial numbers 36701010007, 36701010004, 36709000018;

19 b. Two BK Precision Multi-Function Arbitrary Wave Form Generators,
20 Model 3011B, serial numbers 147-15108 and 147-15107;

21 c. One Electro-Acuscope, Model 70, serial number AP85P04305; and

22 d. One Vibe Machine, Model JD, serial number 23.

23 11. **Statement of Facts.** The parties agree on the following facts. Defendant
24 admits he is guilty of the charged offenses.

25 At all times relevant to the charges in the Information and to this Plea Agreement
26 the following was true and correct:

27 A. DONALD BRANDT and his wife Sharon Brandt operated a clinic on
28 Blodgett Road in Mt. Vernon, Washington, within the Western District of Washington.
The purpose of the business was to provide treatments and to sell supplements. Neither
DONALD BRANDT nor Sharon Brandt were licensed by Washington State as medical
practitioners.

1 B. The Food and Drug Administration (hereafter "FDA") regulates, among
2 other things, medical devices. Title 21, United States Code, Section 321(h) defines a
3 medical device, in pertinent part, as an instrument, apparatus, implement, machine,
4 contrivance, implant, in vitro reagent, or other similar or related article, including any
5 component, part, or accessory, which is intended for use in the diagnosis of disease or
6 other conditions, or in the cure, treatment, or prevention of a disease, in man or in animals,
7 or intended to affect the structure or any function of the body of man or other animals.

8 C. The introduction into interstate commerce and the receipt through interstate
9 commerce of a device that is adulterated is prohibited.

10 D. The device known as the Vibe Machine was adulterated as that term is
11 defined in Title 21, United States Code, Section 351(f)(1) in that it was a Class III device
12 lacking the required pre-market approval.

13 E. On or about December 29, 2004, DONALD BRANDT and Sharon Brandt
14 ordered a Vibe Machine from a business called The Vibe Machine Company in Greeley,
15 Colorado.

16 F. On or about January 3, 2005, DONALD BRANDT caused a Vibe Machine
17 to be sent from Greeley, Colorado via UPS to BRANDTS' address on Blodgett Road in
18 Mt. Vernon, WA.

19 G. On or about January 4, 2005, the BRANDTS received into their "clinic" on
20 Blodgett Road in Mt. Vernon, Washington, a Vibe Machine.

21 **13. Interdependence of Plea Agreements**

22 The parties agree that this Plea Agreement shall be conditioned upon the Court's
23 acceptance of the Plea Agreement in the matter of his wife, co-defendant, Sharon Brandt.
24 Defendant understands, therefore, that this Agreement is part of a package plea agreement
25 with the United States, to wit: if either Defendant or Sharon Brandt does not enter into,
26 and plead guilty pursuant to the respective Plea Agreement, or if either Defendant or
27 Sharon Brandt subsequently seeks to withdraw from the guilty plea, then the United States
28 will withdraw from both Plea Agreements and will seek and pursue the charges in the
Superseding Indictment, CR 07-432 RAJ.

14. **Non-Prosecution of Additional Offenses.** As part of this Plea Agreement,
the United States Attorney's Office for the Western District of Washington agrees to move
to dismiss the Superseding Indictment, CR 07-432 RAJ, issued on returned on January 16,
2008, and agrees not to prosecute Defendant for any additional offenses known to it as of
the time of this Agreement that are based upon evidence in its possession at this time, or
that arise out of the conduct giving rise to this investigation. In this regard, Defendant

1 recognizes the United States has agreed not to prosecute all of the criminal charges the
2 evidence establishes were committed by Defendant solely because of the promises made
3 by Defendant in this Agreement. Defendant agrees, however, that for purposes of
4 preparing the Presentence Report, the United States Attorney's Office will provide the
5 United States Probation Office with evidence of all conduct committed by Defendant.

6 Defendant agrees that any charges to be dismissed before or at the time of
7 sentencing were substantially justified in light of the evidence available to the
8 United States, were not vexatious, frivolous or taken in bad faith, and do not provide
9 Defendant with a basis for any future claims under the "Hyde Amendment," Pub.L. No.
10 105-119 (1997).

11 15. Acceptance of Responsibility. The United States acknowledges that if
12 Defendant qualifies for an acceptance of responsibility adjustment pursuant to
13 USSG § 3E1.1(a), Defendant's total offense level should be decreased by two (2) levels
14 pursuant to USSG §§ 3E1.1(a).

15 16. Breach, Waiver, and Post-Plea Conduct. Defendant agrees that if Defendant
16 breaches this Plea Agreement, the United States may withdraw from this Plea Agreement
17 and Defendant may be prosecuted for all offenses for which the United States has
18 evidence. Defendant agrees not to oppose any steps taken by the United States to nullify
19 this Plea Agreement, including the filing of a motion to withdraw from the Plea
20 Agreement. Defendant also agrees that if Defendant is in breach of this Plea Agreement,
21 Defendant has waived any objection to the reinstatement of any charges in the Indictment
22 that were previously dismissed or any additional charges that had not been prosecuted.

23 Defendant further understands that if, after the date of this Agreement, Defendant
24 should engage in illegal conduct, or conduct that is in violation of Defendant's conditions
25 of release (examples of which include, but are not limited to: obstruction of justice, failure
26 to appear for a court proceeding, criminal conduct while pending sentencing, and false
27 statements to law enforcement agents, the Pretrial Services Officer, Probation Officer or
28 Court), the United States is free under this Agreement to file additional charges against

1 Defendant or to seek a sentence that takes such conduct into consideration. Such a
2 sentence could include a sentencing enhancement under the United States Sentencing
3 Guidelines or an upward departure from the applicable sentencing guidelines range.

4 17. Waiver of Appeal As part of this Plea Agreement and on the condition that
5 the Court imposes a custodial sentence that is within or below the Sentencing Guidelines
6 range (or the statutory mandatory minimum, if greater than the Guidelines range) that is
7 determined by the Court at the time of sentencing, Defendant waives to the full extent of
8 the law:

- 9 a. any right conferred by Title 18, United States Code, Section 3742 to appeal
10 the sentence, including any restitution order imposed; and
11 b. any right to bring a collateral attack against the conviction and sentence,
12 including any restitution order imposed, except as it may relate to the
13 effectiveness of legal representation

14 Furthermore, this waiver does not preclude Defendant from bringing an appropriate
15 motion, pursuant to 28 U.S.C. 2241, to address the conditions of her confinement or the
16 decisions of the Bureau of Prisons regarding the execution of her sentence.

17 If Defendant breaches this Plea Agreement at any time by appealing or collaterally
18 attacking (except as to effectiveness of legal representation) the conviction or sentence in
19 any way, the United States may prosecute Defendant for any counts, including those with
20 mandatory minimum sentences, that were not charged pursuant to this Plea Agreement.

21 18. Voluntariness of Plea. Defendant agrees that Defendant has entered into this
22 Plea Agreement freely and voluntarily, and that no threats or promises, other than the
23 promises contained in this Plea Agreement, were made to induce Defendant to enter these
24 pleas of guilty.


25 19. Statute of Limitations. In the event this Agreement is not accepted by the
26 Court for any reason, or Defendant has breached any of the terms of this Plea Agreement,
27 the statute of limitations shall be deemed to have been tolled from the date of the Plea
28 Agreement to: (1) 30 days following the date of non-acceptance of the Plea Agreement by

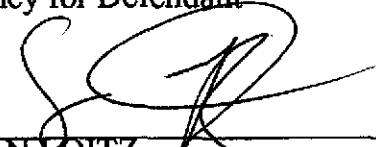
1 the Court; or (2) 30 days following the date on which a breach of the Plea Agreement by
2 Defendant is discovered by the United States Attorney's Office.

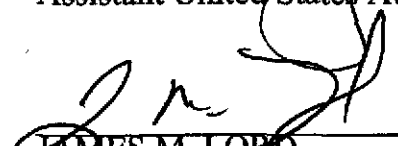
3 20. Completeness of Agreement. The United States and Defendant
4 acknowledge that these terms constitute the entire Plea Agreement between the parties.
5 This Agreement binds only the United States Attorney's Office for the Western District of
6 Washington. It does not bind any other United States Attorney's Office or any other office
7 or agency of the United States, or any state or local prosecutor.

8 Dated this day of May, 2008.

9
10 
11 DONALD BRANDT *of dc*
12 Defendant

13 
14 MARK MESTEL
15 Attorney for Defendant

16 
17 SUSAN EOITZ
18 Assistant United States Attorney

19 
20 JAMES M. LORD
21 Assistant United States Attorney