U.S. Department of Justice

Rachael S. Rollins
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

March 13, 2023

Paul W. Shaw, Esq.
One Federal Street, 20th Floor
Boston, MA 02110
pshaw@verrill-law.com

Re: United States v. Greater Boston Behavioral Health LLC

Dear Mr. Shaw:

The United States Attorney for the District of Massachusetts ("the U.S. Attorney") and your client, Greater Boston Behavioral Health LLC ("Defendant"), agree as follows, pursuant to Federal Rule of Criminal Procedure ("Rule") 11(c)(1)(C):

1. Change of Plea

At the earliest practicable date, Defendant will waive Indictment and plead guilty to count 1 of the criminal Information attached to this Plea Agreement as Exhibit A charging it with Receipt of Misbranded Drugs in Interstate Commerce, in violation of 21 U.S.C. §§ 331(c), 333(a)(1). Defendant admits that Defendant committed the crime charged in the Information and is in fact guilty of the offense. Defendant agrees to the accuracy of the statement of facts attached to this Plea Agreement as Exhibit B.

2. Penalties

Defendant faces the following maximum penalties:

a) A fine of $250,000 or twice the gross gain or loss resulting from the offense, whichever is greater. *See* 18 U.S.C § 3571(c), (d). The gross gain resulting from the offense is $1,929,464. Therefore, the maximum fine is $3,858,928;

b) A term of probation of not more than 5 years. *See* 18 U.S.C. § 3561(c)(2);

c) A mandatory special assessment of $125. *See* 18 US.C. § 3013;

d) Restitution to victims of the offense, if any; and

e) Forfeiture to the extent charged in the Information.

3. Rule 11(c)(1)(C) Plea

In accordance with Rule 11(c)(1)(C), if the Court accepts this Plea Agreement, the Court must include the agreed disposition in the judgment. If the Court rejects any part of this Plea Agreement, the U.S. Attorney may void the agreement and/or Defendant may withdraw from it. Defendant may not withdraw Defendant's plea for any other reason.

Should the U.S. Attorney void the agreement and/or Defendant moves to withdraw Defendant's guilty plea, Defendant agrees to waive any defenses based upon statute of limitations, the constitutional protection against pre-indictment delay, and the Speedy Trial Act for all charges that could have been brought as of the date of this Plea Agreement.

Defendant may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Defendant immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Defendant understands that the decision whether to proceed immediately with the sentencing proceeding following the plea hearing, and to do so without a Presentence Report, is exclusively that of the United States District Court.

4. Sentencing Guidelines

The parties agree jointly to take the following positions at sentencing regarding the United States Sentencing Guidelines ("USSG" or "Guidelines"). The parties also agree that, while the fine provisions of the Guidelines do not apply to organizational defendants for misdemeanor violations of the Federal Food, Drug, and Cosmetic Act, *see* USSG § 8C2.1, the following is consonant with the Guidelines and takes into account Defendant's conduct under 18 U.S.C. §§ 3553 and 3572 and USSG § 8C2.10:

a) The base fine is $1,929,464, because this was the reasonably estimated pecuniary gain from the offense;

b) Pursuant to USSC § 8C2.5, the culpability score is three, determined as follows:

i. The base culpability score is five pursuant to USSG § 8C2.5(a);

ii. Defendant's culpability score is increased by one, because the organization had 10 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense (USSG § 8C2.5(b)(5));

iii. Defendant's culpability score is decreased by three because the organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct (USSG § 8C2.5(g))

c) Pursuant to USSG § 8C2.6, the multiplier range associated with a culpability score of three is 0.6 to 1.2.

d) Thus, pursuant to USSG § 8C2.7, the Guidelines fine range is $1,157,678.40 to $2,315,356.80.

e) Disgorgement pursuant to USSG § 8C2.9 is not necessary.

The United States may, at its sole option, be released from its commitments under this Plea Agreement, including, but not limited to, its agreement that Paragraph 5 constitutes the appropriate disposition of this case, if at any time between Defendant's execution of this Plea Agreement and sentencing, Defendant:

a) Fails to complete a factual basis for the plea;

b) Fails to truthfully admit Defendant's conduct in the offense of conviction;

c) Falsely denies, or frivolously contests, relevant conduct for which Defendant is accountable under USSG § 1B1.3;

d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Defendant is accountable under USSG § 1B1.3;

e) Engages in acts that form a basis for finding that Defendant has obstructed or impeded the administration of justice under USSG § 3C1.1;

f) Commits a crime; or

g) Attempts to withdraw Defendant's guilty plea.

Nothing in this Plea Agreement affects the U.S. Attorney's obligation to provide the Court and the U.S. Probation Office with accurate and complete information regarding this case.

5. Agreed Disposition

The parties agree on the following sentence:

a) A monetary penalty in the amount of $2,587,142, consisting of:

i. A criminal fine in the amount of $657,678 to be paid according to the

following schedule:

1. $219,226 to be paid not later than three months after entry of judgment;
2. $219,226 to be paid not later than June 1, 2024; and
3. $219,226 to be paid not later than June 1, 2025; and

ii. Forfeiture in the amount of $1,929,464, to be paid according to the following schedule:

1. $643,155 to be paid not later than three months after entry of judgment;
2. $643,155 to be paid not later than June 1, 2024; and
3. $643,154 to be paid not later than June 1, 2025.

b) A mandatory special assessment in the amount of $125, payable to the Clerk of the Court on or before the date of sentencing;

c) and probation for a term of three years.

In the event that Defendant does not comply with the above payment schedule, the full amount of the fine and forfeiture money judgment shall be due and payable immediately, and the United States may use all lawful remedies to collect the full amount of the fine and forfeiture money judgment that remain outstanding, including, but not limited to, seizing and/or forfeiting substitute assets and garnishing funds, as allowed by law, without further notice to Defendant.

6. Waiver of Appellate Rights and Challenges to Conviction or Sentence

Defendant has the right to challenge Defendant's conviction and sentence on "direct appeal." This means that Defendant has the right to ask a higher court (the "appeals court") to look at what happened in this case and, if the appeals court finds that the trial court or the parties made certain mistakes, overturn Defendant's conviction or sentence. Also, in some instances, Defendant has the right to file a separate civil lawsuit claiming that serious mistakes were made in this case and that Defendant's conviction or sentence should be overturned.

Defendant understands that Defendant has these rights, but now agrees to give them up. Specifically, Defendant agrees that:

a) Defendant will not challenge Defendant's conviction on direct appeal or in any other proceeding, including in a separate civil lawsuit; and

b) Defendant will not challenge Defendant's sentence, including any court orders related to forfeiture, restitution, fines or supervised release, on direct appeal or in any other proceeding, including in a separate civil lawsuit.

The U.S. Attorney agrees not to appeal the imposition of the sentence agreed to by the parties in paragraph 5.

Defendant understands that, by agreeing to the above, Defendant is agreeing that Defendant's conviction and sentence will be final when the Court issues a written judgment after the sentencing hearing in this case. That is, after the Court issues a written judgment, Defendant will lose the right to appeal or otherwise challenge Defendant's conviction and sentence regardless of whether Defendant later changes Defendant's mind or finds new information that would have led Defendant not to agree to give up these rights in the first place.

Defendant is agreeing to give up these rights in exchange for concessions the U.S. Attorney is making in this Agreement.

The parties agree that, despite giving up these rights, Defendant keeps the right to later claim that Defendant's lawyer rendered ineffective assistance of counsel, or that the prosecutor or a member of law enforcement involved in the case engaged in misconduct serious enough to entitle Defendant to have Defendant's conviction or sentence overturned.

7. Forfeiture

Defendant understands that the Court will, upon acceptance of Defendant's guilty plea, enter an order of forfeiture as part of Defendant's sentence, and that the order of forfeiture may include assets directly traceable to Defendant's offense, assets used to facilitate Defendant's offense, substitute assets and/or a money judgment equal to the value of the property derived from, or otherwise involved in, the offense.

The assets to be forfeited specifically include, without limitation, the following:

a. $1,929,464, to be entered in the form of an Order of Forfeiture (Money Judgment).

Defendant admits that $1,929,464 is subject to forfeiture on the grounds that it is equal to the amount of proceeds Defendant derived from the offense. Defendant agrees to pay the forfeiture money judgment as follows:

i. $643,155 to be paid not later than three months after entry of judgment;
ii. $643,155 to be paid not later than June 1, 2024; and
iii. $643,154 to be paid not later than June 1, 2025.

Defendant acknowledges and agrees that the amount of the forfeiture money judgment represents proceeds the Defendant obtained (directly or indirectly), and/or facilitating property and/or property involved in, the crimes to which Defendant is pleading guilty and that, due at least in part to the acts or omissions of Defendant, the proceeds or property have been transferred to, or deposited with, a third party, spent, cannot be located upon exercise of due diligence, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other

property which cannot be divided without difficulty. Accordingly, Defendant agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Defendant up to the value of the now missing directly forfeitable assets.

Defendant agrees to consent to the entry of an order of forfeiture for such property and waives the requirements of Federal Rules of Criminal Procedure 11(b)(1)(J), 32.2, and 43(a) regarding notice of the forfeiture in the charging instrument, advice regarding the forfeiture at the change-of-plea hearing, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Defendant understands and agrees that forfeiture shall not satisfy or affect any fine, lien, penalty, restitution, cost of imprisonment, tax liability or any other debt owed to the United States.

If the U.S. Attorney requests, Defendant shall deliver to the U.S. Attorney within 30 days after signing this Plea Agreement a sworn financial statement disclosing all assets in which Defendant currently has any interest and all assets over which Defendant has exercised control, or has had any legal or beneficial interest. Defendant further agrees to be deposed with respect to Defendant's assets at the request of the U.S. Attorney. Defendant agrees that the United States Department of Probation may share any financial information about the Defendant with the United States Attorney's Office.

Defendant also agrees to waive all constitutional, legal, and equitable challenges (including direct appeal, habeas corpus, or any other means) to any forfeiture carried out in accordance with this Plea Agreement.

Defendant hereby waives and releases any claims Defendant may have to any vehicles, currency, or other personal property seized by the United States, or seized by any state or local law enforcement agency and turned over to the United States, during the investigation and prosecution of this case, and consents to the forfeiture of all such assets.

8. Civil Liability

This Plea Agreement does not affect any civil liability, including any tax liability, Defendant has incurred or may later incur due to Defendant's criminal conduct and guilty plea to the charges specified in Paragraph 1 of this Agreement.

9. Breach of Plea Agreement

Defendant understands that if Defendant breaches any provision of this Agreement, violates any condition of Defendant's pre-trial release or commits any crime following Defendant's execution of this Plea Agreement, Defendant cannot rely upon such conduct to withdraw Defendant's guilty plea. Defendant's conduct, however, would give the U.S. Attorney the right to be released from his commitments under this Agreement, to pursue any charges that were, or are to be, dismissed under this Agreement, and to use against Defendant any of Defendant's statements, and any information or materials Defendant provided to the government during investigation or prosecution of Defendant's case—even if the parties had entered any earlier

during investigation or prosecution of Defendant's case—even if the parties had entered any earlier written or oral agreements or understandings about this issue.

Defendant also understands that if Defendant breaches any provision of this Agreement or engages in any of the aforementioned conduct, Defendant thereby waives any defenses based on the statute of limitations, constitutional protections against pre-indictment delay, and the Speedy Trial Act, that Defendant otherwise may have had to any charges based on conduct occurring before the date of this Agreement.

10. Who is Bound by Plea Agreement

This Agreement is only between Defendant and the U.S. Attorney for the District of Massachusetts. It does not bind the Attorney General of the United States or any other federal, state, or local prosecuting authorities.

11. Modifications to Plea Agreement

This Agreement can be modified or supplemented only in a written memorandum signed by both parties, or through proceedings in open court.

* * *

If this letter accurately reflects the agreement between the United States and your client, Greater Boston Behavioral Health LLC, please have the authorized representative of Greater Boston Behavioral Health LLC sign the attached Corporate Acknowledgment of Plea Agreement, and please sign the certification. Return the original of the Corporate Acknowledgment of Plea Agreement to Assistant United States Attorney Christopher Looney.

Sincerely,

RACHAEL S. ROLLINS
United States Attorney

By: _____
Kelly Lawrence
Chief, Health Care Fraud Unit
Patrick Callahan
Deputy Chief, Health Care Fraud Unit

_____
Christopher Looney
Assistant U.S. Attorney

CORPORATE ACKNOWLEDGMENT OF PLEA AGREEMENT

The Sole Member and the Shareholders of the Sole Member of Greater Boston Behavioral Health LLC have authorized me to execute this Plea Agreement on behalf of Greater Boston Behavioral Health LLC and to take all such actions as may be necessary to effectuate this Plea Agreement. The Shareholders have read this Plea Agreement and all attached exhibits—including the Criminal Information—in their entirety and has discussed them fully in consultation with their counsel. The Shareholders acknowledge that this Plea Agreement and attached exhibits fully set forth Greater Boston Behavioral Health LLC's agreement with the U.S. Attorney for the District of Massachusetts as it relates to the charges in the Criminal Information. The Shareholders additionally state that no additional promises or representations have been made to the Shareholders or to Greater Boston Behavioral Health LLC by the United States Attorney's Office, and no United States government official has made any unwritten promises or representations to Greater Boston Behavioral Health LLC in connection with its guilty plea. Greater Boston Behavioral Health LLC has received no prior offers to resolve this case.

Greater Boston Behavioral Health LLC
Defendant
By: Elliot M. Weinstein
Authorized Representative

Date: 4/11/23

Paul Shaw
Attorney for Defendant

Date: 04/11/2023

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	Criminal No.
v.	)	Violation:
GREATER BOSTON BEHAVIORAL HEALTH LLC,	)	Count One: Receipt of Misbranded Drugs in Interstate Commerce (21 U.S.C. §§ 331(c), 333(a)(1))
Defendant.	)	Forfeiture Allegation: (18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

INFORMATION

The United States Attorney charges that, at all times relevant to this information:

The Defendant

1. Greater Boston Behavioral Health LLC ("GBBH"), was a Massachusetts corporation providing medical services to patients, including treatment for chronic pain and migraines.

The Federal Food, Drug, and Cosmetic Act

2. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, regulated, among other things, the importation, manufacture, labeling, and distribution of drugs. The FDCA gave the United States Food and Drug Administration ("FDA") the authority to further regulate the importation, manufacture, labeling, and distribution of drugs to protect the health and safety of the American public.

3. Under the FDCA, the term "drug" was defined in relevant part as: (1) any article intended for use in the cure, mitigation, treatment, or prevention of disease in humans; or (2) any

article other than food intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1)(B) and (C).

4. The FDCA defined a "new drug" as, with limited exceptions, any drug that was not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended or suggested in its labeling. See 21 U.S.C. § 321(p).

5. The FDCA defined "label" to include a display of written, printed, or graphic matter upon the immediate container of a drug. 21 U.S.C. § 321(k). The FDCA defined "labeling" to include all labels as well as other written, printed, or graphic matter upon a drug, or any of its containers or wrappers, or otherwise accompanying such drug. 21 U.S.C. § 321(m).

6. Unless there was in effect with the FDA a new drug application ("NDA") or an abbreviated new drug application ("ANDA"), a new drug was unapproved and could not lawfully enter into interstate commerce. *See* 21 U.S.C. §§ 355(a); 331(d).

7. A biological product that was a "new drug" was not required to have an approved NDA or ANDA if it was the subject of an FDA-approved Biologics License Application ("BLA"). *See* 42 U.S.C. § 262(j).

8. NDAs, ANDAs, and BLAs described how the product was manufactured, its components, and what was stated on the label and in the labeling. As part of the process, FDA must have approved the manufacturing process, and label set forth in the application. *See* 21 U.S.C. § 355(b)(1); 42 U.S.C. § 262(a). The approval process addressed, among other things, the elements of the distribution, such as the methods used in, and the facilities and controls used for, the product's manufacturing, processing, and packing; and the proposed label. *See* 21 U.S.C. § 355(b)(1)(A)-(F); 42 U.S.C. § 262(a)(2)(C); *see also* 21 C.F.R. § 601.2(a). The approval

process required, among other things, that a manufacturer provide the proposed text of the label for the product. *See* 21 C.F.R. §§ 314.50(c)(2)(i), (e)(ii), and (l)(1)(i), and 601.2(a). Approval granted to a particular manufacturer for a particular product to be imported into and distributed in the United States did not constitute approval of any drug or biological product—even one with the same chemical composition—with a label that differed in any way from the label in the FDA-approved application.

9. Some of the drugs regulated under the FDCA were "prescription drugs." "Prescription drugs" were those drugs which, because of their toxicity or other potential harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required by FDA to be administered under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A) and (B).

10. The FDCA prohibited the receipt in interstate commerce of any drug that was misbranded and the delivery or proffered delivery of such drug for pay or otherwise, or the causing thereof. 21 U.S.C. § 331(c).

11. A drug was misbranded if it was a "prescription drug" and at any time prior to dispensing the label of the drug failed to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A).

12. A drug was also misbranded if its labeling did not bear adequate directions for its use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions adequate for a "layman" to use the "drug safely and for the purpose for which it was intended." 21 C.F.R. § 201.5. Prescription drugs, by definition, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or were required by FDA to be

administered under the professional supervision of a practitioner licensed by law to administer such drugs, and were therefore misbranded unless they qualified for an exemption.

13. A prescription drug was exempt from 21 U.S.C. § 352(f)(1) only if *all* of the listed conditions were met, including that: (1) the label bore the statement "Rx only"; (2) the label bore adequate information for its use, including any relevant hazards, side effects, and precautions under which medical practitioners could use the drug safely and was the labeling authorized by the FDA-approved new drug application. 21 C.F.R. §§ 201.100(b)(1), (c).

Botox® and Botox® Cosmetic

14. In 1989, FDA approved a BLA for Botox®, the brand name of a drug manufactured by Allergan, Inc.,[1] for the treatment of crossed eyes and spasm of the eyelids. Botox® was made up of the Botulinum Type A toxin, which was produced by the bacteria, Clostridium botulinum. The Type A toxin was a highly potent and potentially dangerous toxin, and could cause the disease botulism when present in human beings in a sufficient amount.

15. In 2002, FDA approved a supplement to Allergan's Botox BLA for the temporary improvement in the appearance of glabellar lines, commonly referred to as wrinkles. Under this FDA approval, Allergan's Type A toxin product was marketed and labeled for this supplemental usage as "Botox® Cosmetic." FDA's approvals for Botox® and Botox® Cosmetic limited them to use under the supervision of a licensed practitioner and required that their labels bear the symbol "Rx only."

16. On July 31, 2009, FDA approved several revisions to the labeling for Botox and Botox Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black box warning") under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of Botox and

[1] In May 2020, subsequent to the conduct identified herein, Allergan was acquired by AbbVie, Inc.

Botox Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that the different botulinum toxin products were not interchangeable because the units used to measure the products were different.

17. In 2010, the FDA approved Botox for treatment of chronic migraines in adults.

GBBH's Purchase and Use of Foreign Unapproved Botox

18. Beginning in 2012, GBBH sought out sources from which it could purchase Botox® ("Botox") that was manufactured, packaged, and labeled for sale in the United Kingdom and other foreign countries ("foreign Botox"). From in or about 2012 through in or about June 2019, GBBH purchased foreign Botox from a number of different sources.

19. The label of the foreign Botox purchased by GBBH differed from the FDA-approved label for Botox and Botox Cosmetic and lacked the designation "Rx Only" as required by the FDCA for prescription drugs. The label also typically did not include the FDA-required "black-box warning" concerning potential side-effects of Botox.

20. GBBH purchased foreign Botox at prices significantly below the price that Allergan and its authorized distributors charged for Botox and Botox Cosmetic that was manufactured and labeled for sale in the United States.

21. Doctors at GBBH used the foreign Botox to treat patients suffering from migraine headaches and did not disclose to these patients that they purchased the drug from foreign sources or that it was not labeled for distribution in the United States.

Count One
Receipt of Misbranded Drugs
(21 U.S.C. §§ 331(c); 333(a)(1))

22. The allegations set forth in Paragraphs 1 – 20 of this Information are incorporated and re-alleged as if set forth in full herein.

23. From in or around September 2012 through in or around June 2019, in the District of Massachusetts, defendant,

Greater Boston Behavioral Health LLC

received and caused the receipt of prescription drugs – specifically, foreign Botox – in interstate commerce that were misbranded within the meaning of: (i) 21 U.S.C. § 352(f)(1) in that their labeling failed to bear adequate directions for use, and (ii) 21 U.S.C. § 353(b)(4)(A) in that their labels failed to bear the symbol "Rx only," and delivered and proffered delivery of such misbranded drugs for pay and otherwise.

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1).

FORFEITURE ALLEGATION
(18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

24. Upon conviction of a violation of 21 U.S.C. §§ 33l(c), 333(a)(l), as set forth in Count One,

Greater Boston Behavioral Health LLC

the defendant herein, shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds traceable to the commission of the offense and all right, title, and interest in any prescription drug that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce, pursuant to 18 U.S.C. § 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c). The property to be forfeited includes, but is not limited to, the following:

a. $1,929,464, to be entered in the form of a forfeiture money judgment.

25. If any of the property described above as being subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of this Court;

d. has been substantially diminished in value; or has been commingled with other property that cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property described in paragraph 24.

All pursuant to 18 U.S.C. § 982(a)(7), 28 U.S.C § 2461(c), and 21 U.S.C. §§ 334 and 853(p).

Respectfully submitted,

RACHAEL S. ROLLINS
United States Attorney

By: */s/ Christopher Looney*
CHRISTOPHER R. LOONEY
Assistant U.S. Attorney

Date: March 13, 2023

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
v.	)	Count One: Receipt of Misbranded Drugs in Interstate Commerce (21 U.S.C. §§ 331(c), 333(a)(1))
GREATER BOSTON BEHAVIORAL HEALTH LLC,	)	
Defendant.	)	Forfeiture Allegation: (18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

AGREED-TO STATEMENT OF FACTS

Greater Boston Behavioral Health LLC ("GBBH") agrees to the accuracy of the following statement of facts:

The Defendant

1. GBBH was a Massachusetts corporation providing medical services to patients, including treatment for chronic pain and migraines.

Botox® and Botox® Cosmetic

2. Botox® and Botox® Cosmetic were brand names of drugs manufactured by Allergan, Inc.,[1] which, respectively, have been approved by the United States Food and Drug Administration ("FDA") for the treatment of crossed eyes and spasm of the eyelids, and for the temporary improvement in the appearance of glabellar lines, commonly referred to as wrinkles. FDA's approvals for Botox® and Botox® Cosmetic limited them to use under the supervision of a licensed practitioner and required that their labels bear the symbol "Rx only."

3. In 2009, FDA approved several revisions to the labeling for Botox and Botox Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black

[1] Allergan was acquired by AbbVie, Inc. in a transaction completed in May 2020.

box warning") cautioning that the effects of Botox and Botox Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that the different botulinum toxin products are not interchangeable because the units used to measure the products are different.

GBBH's Purchase and Use of Foreign Unapproved Botox

4. Beginning in 2012, GBBH sought out sources from which it could purchase Botox® that was manufactured, packaged, and labeled for sale in the United Kingdom and other foreign countries ("foreign Botox"). From 2012 through June 2019, GBBH purchased foreign Botox from a number of different sources.

5. The label of the foreign Botox purchased by GBBH differed from the FDA-approved label for Botox® and Botox® Cosmetic and lacked the designation "Rx Only" as required by the FDCA for prescription drugs. The label also typically did not include the FDA-required "black-box warning" concerning potential side-effects of Botox.

6. GBBH purchased foreign Botox at prices significantly below the price that Allergan and its authorized distributors charged for Botox® and Botox® Cosmetic that was manufactured and labeled for sale in the United States.

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7. Doctors at GBBH used the foreign Botox to treat patients suffering from migraine headaches and did not disclose to these patients that they purchased the drug from foreign sources or that it was not labeled for distribution in the United States.

Greater Boston Behavioral Health LLC
Defendant
By: Elliot M. Weinstein
Authorized Representative

Date: 4/13/23

Paul Shaw
Attorney for Defendant

Date: 4/13/2023