

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS  
LAREDO DIVISION

U.S. MAGISTRATE COURT  
JSH - SDTX  
FILED  
DEC 20 2013 DF  
David J. Bradley, Clerk  
Laredo Division

UNITED STATES OF AMERICA

v.

EDUARDO MIRANDA

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§

CRIMINAL NO. L-13-1406

**PLEA AGREEMENT**

The United States of America, by and through Kenneth Magidson, United States Attorney for the Southern District of Texas, and the undersigned Assistant United States Attorney, and Defendant, Eduardo Miranda, and Defendant's counsel, pursuant to Rule 11(c)(1)(A) and 11(c)(1)(B) of the Federal Rules of Criminal Procedure, state that they have entered into an agreement, the terms and conditions of which are as follows:

**The Defendant's Agreement**

1. Defendant agrees to plead guilty to Count One of the Criminal Information. Count One charges Defendant with strict liability misdemeanor introduction and delivery for introduction into interstate commerce a drug product that was misbranded in violation of Title 21, United States Code, Sections 331(a), 352(f) and Title 18, United States Code, Section 2. Defendant is entering a guilty plea pursuant to the provision of Title 21, United States Code, Section 333(a)(1) which states that any person who violates a provision of section 331 shall be imprisoned for not more than one year. Defendant, by entering this plea, agrees that he is waiving any right to have the facts that the law makes essential to the punishment either charged in the Information or proven to a jury beyond a reasonable doubt.

**Punishment Range**

2. The statutory maximum penalty for each violation of Title 21, United States

Code, § 331(a) is a term of imprisonment of NOT MORE THAN ONE YEAR and a fine of not more than \$100,000. Title 21, United States Code, §333(a)(1) and Title 18, United States Code, § 3571. Additionally, Defendant may receive a term of supervised release after imprisonment of no more than one year. Title 18, United States Code, §§ 3559(a) and 3583(b). Defendant acknowledges and understands that if he should violate the conditions of any period of supervised release which may be imposed as part of his sentence, then Defendant may be imprisoned for the entire term of supervised release, without credit for time already served on the term of supervised release prior to such violation. Title 18, United States Code, §§ 3559(a) and 3583(e)(3). Defendant understands that he cannot have the imposition or execution of the sentence suspended, nor is he eligible for parole.

**Mandatory Special Assessment**

3. Pursuant to Title 18, United States Code, § 3013(a)(1)(A), immediately after sentencing, Defendant will pay to the Clerk of the United States District Court a special assessment in the amount of twenty-five dollars (\$25.00) per count of conviction. The payment will be by cashier's check or money order payable to the Clerk of the United States District Court, c/o District Clerk's Office, P.O. Box 61010, Houston, Texas 77208, Attention: Finance.

**Immigration Consequences**

4. Defendant understands if he is not a citizen of the United States, Defendant's plea of guilty will result in a criminal conviction that could lead to Defendant's subsequent deportation, removal and/or exclusion from the United States. This conviction could also lead to Defendant being permanently barred from legally entering the United States after being deported or removed. In addition, Defendant's attorney has advised Defendant of the potential immigration consequences that could come about as a result of Defendant's plea of guilty. After

understanding the potential immigration consequences of pleading guilty, Defendant still wishes to plead guilty as detailed in this plea agreement.

#### **Waiver of Appeal**

5. Defendant is aware that Title 28, United States Code, § 1291, and Title 18, United States Code, § 3742, afford a defendant the right to appeal the conviction and sentence imposed. Defendant knowingly and voluntarily waives the right to appeal the conviction and the sentence imposed, or the manner in which the sentence was determined. Additionally, Defendant is aware that Title 28, United States Code, § 2255, affords the right to contest or “collaterally attack” a conviction or sentence after the conviction or sentence has become final. Defendant knowingly and voluntarily waives the right to contest his conviction or sentence by means of any post-conviction proceeding.

6. In agreeing to these waivers, Defendant is aware that a sentence has not yet been determined by the Court. Defendant is also aware that any estimate of the possible sentencing range under the Sentencing Guidelines that he may have received from his counsel, the United States, or the Probation Office, is a prediction, not a promise, and such estimate **did not induce his guilty plea** and is binding on neither the United States, the Probation Office, nor the Court. The United States does not make any promise or representation concerning what sentence Defendant will receive. Defendant further understands and agrees that the Sentencing Guidelines are “effectively advisory” to the Court. *United States v. Booker*, 125 S.Ct. 738 (2005). Accordingly, Defendant understands that, although the Court must consult the Sentencing Guidelines and must take them into account when sentencing Defendant, the Court is not bound to follow the Sentencing Guidelines nor sentence Defendant within the calculated guideline range.

7. Defendant understands and agrees that each and all waivers contained in the Agreement are made in exchange for the concessions made by the United States in this Plea Agreement.

**The United States' Agreements**

8. The United States agrees to each of the following:

(a) If Defendant pleads guilty to Criminal Information and persists in that plea through sentencing, and if the Court accepts this Plea Agreement, at the time of sentencing, the United States agrees not to oppose Defendant's anticipated request to the Court and the United States Probation Office that he receive a two (2)- level downward adjustment under § 3E1.1(a) of the Sentencing Guidelines should Defendant accept responsibility as contemplated by the Sentencing Guidelines (U.S.S.G.); and

(b) If Defendant qualifies for an adjustment under U.S.S.G. § 3E1.1(a) and Defendant's offense level is 16 or greater, the United States may move for an additional one (1)-level downward adjustment based on the timeliness of the plea or the expeditious manner in which Defendant provided complete information regarding his role in the offense.

(c) the parties agree to jointly recommend to the court that USSE 2N2.1(a) Agreement Binding - Southern District of Texas Only is the appropriate sentencing guideline level.

9. The United States agrees that it will not further criminally prosecute Defendant in the Southern District of Texas for offenses arising from conduct charged in the Indictment. This Plea Agreement binds only the United States Attorney's Office for the Southern District of Texas and Defendant. It does not bind any other United States Attorney. The United States will bring this Plea Agreement and the full extent of Defendant's cooperation to the attention of other prosecuting offices if requested.

**United States' Non-Waiver of Appeal**

10. The United States reserves the right to carry out its responsibilities under the Sentencing Guidelines. Specifically, the United States reserves the right:

(a) to bring its version of the facts of this case, including its evidence file and any investigative files, to the attention of the Probation Office in connection with that

office's preparation of a presentence report;

- (b) to set forth or dispute sentencing factors or facts material to sentencing;
- (c) to seek resolution of such factors or facts in conference with Defendant's counsel and the Probation Office;
- (d) to file a pleading relating to these issues, in accordance with U.S.S.G. § 6A1.2 and Title 18, United States Code, § 3553(a); and
- (e) to appeal the sentence imposed or the manner in which it was determined.

#### **Sentence Determination**

11. Defendant is aware that the sentence will be imposed after consideration of the Sentencing Guidelines, which are only advisory, as well as the provisions of Title 18, United States Code, § 3553(a). Defendant nonetheless acknowledges and agrees that the Court has authority to impose any sentence up to and including the statutory maximum set for the offense(s) to which Defendant pleads guilty, and that the sentence to be imposed is within the sole discretion of the sentencing judge after the Court has consulted the applicable Sentencing Guidelines. Defendant understands and agrees the parties' positions regarding the application of the Sentencing Guidelines do not bind the Court, and that the sentence imposed is within the discretion of the sentencing judge. If the Court should impose any sentence up to the maximum established by statute, or should the Court order any or all of the sentences imposed to run consecutively, Defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this Plea Agreement.

### **Rights at Trial**

12. Defendant represents to the Court that he is satisfied that his attorney has rendered effective assistance. Defendant understands that by entering into this Agreement, he surrenders certain rights as provided in this Plea Agreement. Defendant understands that those rights include the following:

- (a) If Defendant persisted in a plea of not guilty to the charge, Defendant would have the right to a speedy jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if Defendant, the United States, and the Court all agree.
- (b) At a trial, the United States would be required to present witnesses and other evidence against Defendant. Defendant would have the opportunity to confront those witnesses and his attorney would be allowed to cross-examine them. In turn, Defendant could, but would not be required to, present witnesses and other evidence on his own behalf. If the witnesses for Defendant would not appear voluntarily, he could require their attendance through the subpoena power of the court.
- (c) At a trial, Defendant could rely on a privilege against self-incrimination and decline to testify, and no inference of guilt could be drawn from such refusal to testify. However, if Defendant desired to do so, he could testify on his own behalf.

### **Factual Basis for Guilty Plea**

13. Defendant is pleading guilty because he is guilty of the charge contained in the Criminal Information. If this case were to proceed to trial, the United States could prove each element of the offense beyond a reasonable doubt. The following facts, among others would be offered to establish Defendant's guilt:

Defendant EDUARDO MIRANDA, M.D., is an oncologist in Laredo, Texas. Defendant owns and operates his own medical practice, located at 2344 Laguna Del Mar Court, Suite 104, Laredo, Texas. Defendant was a sole practitioner who was in charge of his in-house pharmacy in his practice during the time period relevant to this Criminal Information, October 2007 through

January 2009.

On or about October 2007, Defendant began ordering five cancer drugs from a pharmacy called Quality Specialty Products (“QSP”). QSP was located in Canada. These drugs were not approved for distribution or use in the U.S. and were misbranded as (1) the labels did not bear the “Rx Only” language as required by the Food and Drug Administration (“FDA”); (2) the labels did not bear National Drug Code (“NDC”) numbers that FDA-approved versions bear; and (3) some of them had instructions/labeling in other languages, such as French, contrary to FDA-approved versions.

Most times, Defendant himself called QSP at a toll free “1-800” number to place orders for these drugs. On a few occasions, he directed a member of his staff to call and obtain the drugs. All the orders from QSP were charged to Defendant’s personal credit card. The drugs were always shipped from outside of the United States, from Canada or Europe.

Defendant ordered the following five different types of cancer drugs from QSP:

1. Kytril is an anti-nauseant and antiemetic agent, used for prevention of nausea and vomiting associated with cancer treatment. Kytril was first approved by the FDA in December 1993, and its most recent labeling revision was approved by the FDA in October 2009. The lot numbers of Kytril found in Defendant’s office indicated that these medications were meant for the Canadian market.
2. Taxotere is an antimiotic chemotherapy medication, used to treat certain types of breast, lung, prostate, stomach, and head and neck cancer. Taxotere was first approved by the FDA in May 1996, and the most recent labeling revision was approved by the FDA in June 2010. Taxotere seized from Defendant was found to have been manufactured in Great Britain.
3. Zometa is used to treat hypercalcemia of malignancy, a condition resulting in high calcium blood levels due to cancer, as well as multiple myeloma and breast, lung, and prostate cancer that have metastasized to the bone. It was first approved by the FDA in August 2001. Zometa found in Defendant’s office was manufactured in Great Britain.
4. Eloxatin is used to treat colon cancer. It was approved by the FDA in January 2005, and its most recent labeling revision was approved in March 2009. Batches of Eloxatin found

in Defendant's office were found to have been manufactured in Great Britain.

5. Gemzar is used to treat ovarian, breast, lung, and pancreatic cancer. It was approved by the FDA in May 1996 and the most recent labeling revision was approved in March 2010. Gemzar found in Defendant's office was manufactured in Great Britain.

On December 4, 2008, U.S. postal inspectors in Dallas, Texas, were conducting an investigation at the international mail facility when they came across a box from QSP in Canada addressed to Eduardo Miranda in Laredo, Texas. The box contained boxes of Kytril, and an accompanying invoice with a notation that the rest of the orders would be shipped separately.

On January 29, 2009, U.S. postal inspectors made a controlled delivery of four packages from QSP labeled medical supplies to Defendant's medical offices. Immediately afterwards, FDA executed a search warrant on Defendant's medical offices. Defendant agreed to answer agents' questions and admitted to having ordered these drugs from QSP and administering these non-FDA approved drugs to his patients. The total cost of drugs that Defendant ordered from QSP, based on invoices and credit card bills, was \$745,612.91.

While Defendant was purchasing these drugs from QSP, he also purchased small amounts of these drugs from an approved distributor in the U.S. The misbranded, non-FDA approved drugs and the FDA approved drugs were commingled in the pharmacy and administered to patients without distinction. Defendant then filed claims with Medicaid, Medicare and private insurance after administering non-FDA approved/misbranded drugs and was reimbursed as if he had been administering FDA-approved drugs to his patients. From October 2007 through January 2009, 91.53% of Kytril ordered by Defendant came from QSP; 83.74% of Zometa; 84.92% of Taxotere; 86.6% of Gemzar; and 92.59% of Eloxatin. The rest of drugs were FDA-approved drugs from an approved retailer/distributor in the U.S.

From October 25, 2007 through January 22, 2009, Defendant was reimbursed \$416,070.24 by Medicaid and \$274,477.00 by Medicare for administering these drugs to his patients, resulting in a total reimbursement of \$690,547.24. Defendant received reimbursement from Medicaid and Medicare for using misbranded and unapproved drugs for which he should not have gotten reimbursed. The amount of reimbursement that Defendant was not entitled to was \$361,959.31 by Medicaid and \$238,512.20 by Medicare.

From October 25, 2007, through January 26, 2009, Defendant was reimbursed \$451,915.20 by Blue Cross/Blue Shield of Texas for administering these five drugs to his patients. Defendant was not entitled to reimbursement of \$403,966.99 from Blue Cross/Blue Shield of Texas.

Defendant now judicially admits and confesses that beginning on or about October 2007 through January 28, 2009, he caused to be introduced and delivered for introduction into interstate commerce drugs that were misbranded and was reimbursed approximately \$1,004,438.50 for the administration of these non-FDA approved drugs.

#### **Breach of Plea Agreement**

14. If Defendant should fail in any way to fulfill completely all of the obligations under this Plea Agreement, the United States will be released from its obligations under the Plea Agreement, and Defendant's plea and sentence will stand. If at any time Defendant retains, conceals or disposes of assets in violation of this Plea Agreement, or if Defendant knowingly withholds evidence or is otherwise not completely truthful with the United States, then the United States may move the Court to set aside the guilty plea and reinstate prosecution. Any information and documents that have been disclosed by Defendant, whether prior to or subsequent to this Plea Agreement, and all leads derived therefrom, will be used against

Defendant in any prosecution.

**Restitution, Forfeiture, and Fines**

15. This Plea Agreement is being entered into by the United States on the basis of Defendant's express representation that he will make a full and complete disclosure of all assets over which he exercises direct or indirect control, or in which he has any financial interest. Defendant agrees not to dispose of any assets or take any action that would effect a transfer of property in which he has an interest, unless Defendant obtains the prior written permission of the United States.

16. Defendant agrees to make complete financial disclosure by truthfully executing a sworn financial statement (Form OBD-500) by the deadline set by the United States, or if no deadline is set, prior to sentencing. Defendant agrees to authorize the release of all financial information requested by the United States, including, but not limited to, executing authorization forms permitting the United States to obtain tax information, bank account records, credit histories, and social security information. Defendant agrees to discuss and answer any questions by the United States relating to Defendant's complete financial disclosure.

17. Defendant agrees to pay full restitution as a part of this Plea Agreement. As a part of this Plea Agreement, Defendant agrees to full restitution of \$361,959.31 to Medicaid, program operated by the State of Texas; \$238,512.20 to Medicare, an agency of the United States; and \$403,966.99 to Blue Cross/Blue Shield of Texas. Restitution shall be due and paid pursuant to a payment schedule approved by the Court.

18. Defendant agrees to take all steps necessary to pass clear title to forfeitable assets to the United States and to assist fully in the collection of restitution and fines, including, but not limited to, surrendering title, executing a warranty deed, signing a consent decree, stipulating to

facts regarding the transfer of title and the basis for the forfeiture, and signing any other documents necessary to effectuate such transfer. Defendant also agrees to direct any banks which have custody of his assets to deliver all funds and records of such assets to the United States.

19. Defendant understands that forfeiture, restitution, and fines are separate components of sentencing and are separate obligations.

#### **Fines**

20. Defendant understands that under the Sentencing Guidelines the Court is permitted to order Defendant to pay a fine that is sufficient to reimburse the government for the costs of any imprisonment or term of supervised release, if any. Defendant agrees that any fine imposed by the Court will be due and paid pursuant to a payment schedule approved by the Court, and Defendant will not attempt to avoid or delay payment. Defendant waives the right to challenge the fine in any manner, including by direct appeal or in a collateral proceeding.

#### **Complete Agreement**

21. This written Plea Agreement, consisting of 14 pages, including the attached addendum of Defendant and his attorney, constitutes the complete Plea Agreement between the United States, Defendant, and his counsel. No promises or representations have been made by the United States except as set forth in writing in this Plea Agreement. Defendant acknowledges that no threats have been made against him and that he is pleading guilty freely and voluntarily because he is guilty of the misdemeanor offense.

22. Any modification of this Plea Agreement must be in writing and signed by all parties.

Filed at \_\_\_\_\_, Texas, on 12/20, 2013.

  
\_\_\_\_\_  
EDUARDO MIRANDA  
Defendant

Subscribed and sworn to before me on 12/20, 2013.

DAVID J. BRADLEY, Clerk  
UNITED STATES DISTRICT CLERK

By:   
\_\_\_\_\_  
Deputy United States District Clerk

APPROVED:

KENNETH MAGIDSON  
United States Attorney

By:   
\_\_\_\_\_  
SONAH LEE  
Assistant United States Attorney  
Southern District of Texas

  
\_\_\_\_\_  
OSCAR O. PENA  
Attorney for Defendant

  
\_\_\_\_\_  
RAUL GUERRA  
Assistant United States Attorney  
Southern District of Texas