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2016 JAN 28 P 2:01

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

U.S. DISTRICT COURT

N.D. OF ALABAMA

UNITED STATES OF AMERICA

v.

DAVID LEE ALLEN

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)

PLEA AGREEMENT

The United States and defendant DAVID LEE ALLEN (ALLEN), hereby acknowledge the following plea agreement in this case:

PLEA

The defendant agrees to plead guilty to COUNTS ONE AND TWO of the Information filed in the above numbered and captioned matter. In exchange, the United States agrees to the disposition specified below, subject to the conditions in paragraphs VII and VIII.

TERMS OF THE AGREEMENT

I. MAXIMUM PUNISHMENT

The defendant understands that the maximum statutory punishment that may be imposed for the crime of doing or causing to be done any act with respect to a drug if the act was done while the drug was held for sale after shipment of one or more of its components in interstate commerce, and the act resulted in the drug being adulterated, in violation of 21 U.S.C. § 331(k), as charged in COUNT ONE

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and COUNT TWO, is, for each count:

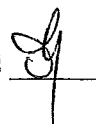
- A. Imprisonment for not more than one year;
- B. A fine of not more than \$250,000, or;
- C. Both (a and b);
- D. Supervised release of not more than one year; and
- E. Special Assessment Fee of \$25.

II. FACTUAL BASIS FOR PLEA

The defendant stipulates that the following facts are true and may be used to establish a factual basis for defendant's guilty plea and sentence.

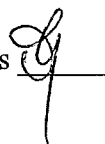
- A. Advanced Specialty Pharmacy, d/b/a Meds IV ("Meds IV"), was a compounding pharmacy located in Birmingham, Alabama. Meds IV compounded various drugs for human use, including an intravenous drug known as total parenteral nutrition ("TPN"). TPN was liquid nutrition administered intravenously to patients who could not or should not receive their nutrition through eating.
- B. ALLEN was the pharmacist-in-charge of Meds IV. He supervised all compounding at Meds IV and was specifically responsible for reviewing and approving TPN formulations. ALLEN was also responsible for filling the individual prescriptions Meds IV received for patient-specific TPN products.
- C. Prior to the end of 2010, Meds IV had been compounding TPN using, among other ingredients, a commercially available amino acid solution. Beginning in or around February of 2011, Meds IV began compounding its own amino acid solution, which it then mixed with other ingredients to form TPN.
- D. One or more of the components Meds IV used to compound its own amino acid solution was shipped to Meds IV from outside the state of Alabama.

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- E. The amino acid solution was prepared outside a laminar airflow workbench, and was kept unrefrigerated, in a room that was not sterile, in a large pot sitting on the floor, sometimes overnight, before it was sterilized and used.
- F. On or around February 25, 2011, Méds IV shipped TPN which had been compounded from its own amino acid solution ("Lot 2011-0255") to area hospitals.
- G. On March 1, 2011, Meds IV sent a sample of the TPN which contained amino acid solution from Lot 2011-0255 to an outside laboratory for sterility and endotoxin testing. By some time on March 8, 2011, Meds IV had been notified by the outside laboratory that two samples of TPN which contained amino acid solution from Lot 2011-0255 had tested positive for endotoxins. Meds IV discarded Lot 2011-0255 of amino acid solution, and compounded a new amino acid solution, Lot 2011-0288, using the new amino acid solution to continued compounding TPN. Patients at local hospitals continued receiving TPN which contained amino acid from the new batch.
- H. Meds IV was notified on March 14, 2011, by a hospital in the Birmingham area, that four patients receiving TPN had tested positive for *S. Marcescens*. The TPN was compounded and distributed by Meds IV. This notification was the first time Meds IV was informed of a link between its TPN and patients testing positive for *S. Marcescens*. On or about March 16, 2011, Meds IV began notifying some customers that compounding of TPN was suspended until further notice.
- I. Through his actions, defendant caused the TPN to become adulterated.

The defendant hereby stipulates that the facts stated above are substantially correct and that the Court can use these facts in calculating the defendant's sentence. The defendant further acknowledges that these facts do not constitute all of the evidence of each and every act that the defendant and/or any co-conspirators may have committed.

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DAVID LEE ALLEN

III. RECOMMENDED SENTENCE

Subject to the limitations in paragraph **VIII** regarding subsequent conduct and pursuant to Rule 11(c)(1)(B), Fed.R.Crim.P., the government will recommend the following disposition:


A. That the defendant be awarded an appropriate reduction in offense level for acceptance of responsibility.

B. That the defendant be remanded to the custody of the Bureau of Prisons and incarcerated for a term consistent with the advisory United States Sentencing Guideline range as that is determined by the court on the date that the sentence is pronounced.

C. That following the said term of imprisonment, the defendant be placed on supervised release for a period to be determined by the court, subject to the standard conditions of supervised release as set forth in U.S.S.G. § 5D1.3.

D. That the defendant be required to surrender any license to practice pharmacy held in any state as a condition of Supervised Release.

E. That the defendant be required to pay a fine in accordance with the sentencing guidelines, said amount due and owing as of the date sentence is pronounced, with any outstanding balance to be paid in full by the expiration of the term of supervised release.

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F. That the defendant be required to pay restitution in an amount to be determined by the court.

G. That the defendant pay a special assessment fee of \$25 per count of the Information, said amount due and owing as of the date sentence is pronounced.

IV. WAIVER OF RIGHT TO APPEAL AND POST-CONVICTION RELIEF

In consideration of the recommended disposition of this case, I, DAVID ALLEN, hereby waive and give up my right to appeal my conviction and/or sentence in this case, as well as any fines, restitution, and forfeiture orders that the Court might impose. Further, I waive and give up the right to challenge my conviction and/or sentence, any fines, restitution, forfeiture orders imposed or the manner in which my conviction and/or sentence, any fines, restitution, and forfeiture orders were determined in any post-conviction proceeding, including, but not limited to, a motion brought under 28 U.S.C. § 2255.

The defendant reserves the right to contest in an appeal or post-conviction proceeding any or all of the following:

A. Any sentence imposed in excess of the applicable statutory maximum sentence(s);

B. Any sentence imposed in excess of the guideline sentencing range determined by the Court at the time sentence is imposed; and,

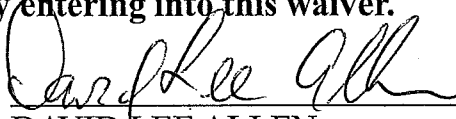
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C. Ineffective assistance of counsel.

The defendant acknowledges that before giving up these rights, the defendant discussed the Federal Sentencing Guidelines and their application to the defendant's case with the defendant's attorney, who explained them to the defendant's satisfaction. The defendant further acknowledges and understands that the government retains its right to appeal where authorized by statute.

I, DAVID LEE ALLEN, hereby place my signature on the line directly below to signify that I fully understand the foregoing paragraphs, and that I am knowingly and voluntarily entering into this waiver.


DAVID LEE ALLEN

V. UNITED STATES SENTENCING GUIDELINES

Defendant's counsel has explained to the defendant, that in light of the United States Supreme Court's decision in United States v. Booker, the federal sentencing guidelines are advisory in nature. Sentencing is in the Court's discretion and is no longer required to be within the guideline range. The defendant agrees that, pursuant to this agreement, the Court may use facts it finds by a preponderance of the evidence to reach an advisory guideline range, and defendant explicitly waives any right to have those facts found by a jury beyond a reasonable doubt.

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VI. AGREEMENT NOT BINDING ON COURT

The defendant fully and completely understands and agrees that it is the Court's duty to impose sentence upon the defendant and that any sentence recommended by the government is **NOT BINDING UPON THE COURT**, and that the Court is not required to accept the government's recommendation.

Further, the defendant understands that if the Court does not accept the government's recommendation, the defendant does not have the right to withdraw the guilty plea.

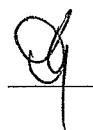
VII. VOIDING OF AGREEMENT

The defendant understands that should the defendant move the Court to accept the defendant's plea of guilty in accordance with, or pursuant to, the provisions of North Carolina v. Alford, 400 U.S. 25 (1970), or tender a plea of *nolo contendere* to the charges, this agreement will become NULL and VOID. In that event, the Government will not be bound by any of the terms, conditions, or recommendations, express or implied, which are contained herein.

VIII. SUBSEQUENT CONDUCT

The defendant understands that should the defendant violate any condition of pretrial release or violate any federal, state, or local law, or should the defendant say or do something that is inconsistent with acceptance of responsibility, the United States will no longer be bound by its obligation to

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A handwritten signature or set of initials, possibly 'GJ', written over a horizontal line.

make the recommendations set forth in paragraph III of the Agreement, but instead, may make any recommendation deemed appropriate by the United States Attorney in her sole discretion.

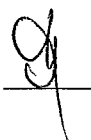
IX. OTHER DISTRICTS AND JURISDICTIONS

The defendant understands and agrees that this agreement **DOES NOT BIND** any other United States Attorney in any other district, or any other state or local authority.

X. COLLECTION OF FINANCIAL OBLIGATION

In order to facilitate the collection of financial obligations to be imposed in connection with this prosecution, the defendant agrees to fully disclose all assets in which the defendant has any interest or over which the defendant exercises control, directly or indirectly, including those held by a spouse, nominee or other third party. The defendant also will promptly submit a completed financial statement to the United States Attorney's Office, in a form that it provides and as it directs. The defendant also agrees that the defendant's financial statement and disclosures will be complete, accurate, and truthful. Finally, the defendant expressly authorizes the United States Attorney's Office to obtain a credit report on the defendant in order to evaluate the defendant's ability to satisfy any financial obligation imposed by the Court.

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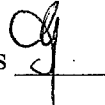


XI. AGREEMENT REGARDING RELEVANT CONDUCT AND RESTITUTION

As part of the defendant's plea agreement, the defendant admits to the above facts associated with the charges and relevant conduct for any other acts. The defendant understands and agrees that the relevant conduct contained in the factual basis will be used by the Court to determine the defendant's range of punishment under the advisory sentencing guidelines. The defendant admits that all of the crimes listed in the factual basis are part of the same acts, scheme, and course of conduct. This agreement is not meant, however, to prohibit the United States Probation Office or the Court from considering any other acts and factors which may constitute or relate to relevant conduct. Additionally, if this agreement contains any provisions providing for the dismissal of any counts, the defendant agrees to pay any appropriate restitution to each of the separate and proximate victims related to those counts should there be any.

XII. FORFEITURE, TAX, AND OTHER CIVIL/ADMINISTRATIVE PROCEEDINGS

Unless otherwise specified herein, the defendant understands and acknowledges that this agreement does not apply to or in any way limit any pending or prospective proceedings related to defendant's tax liabilities, if any, or to any other pending or prospective forfeiture or other civil or administrative proceedings, not otherwise addressed herein.

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Immigration Status

Defendant recognizes that pleading guilty may have consequences with respect to his immigration status if he is not a citizen of the United States. Under federal law, a broad range of crimes are removable offenses, including the offense(s) to which defendant is pleading guilty. Removal and other immigration consequences are the subject of a separate proceeding, however, and defendant understands that no one, including any attorney or the district court, can predict to a certainty the effect of conviction on immigration status. Defendant nevertheless affirms that he wants to plead guilty regardless of any immigration consequences that plea may entail, even if the consequence is automatic removal from the United States.

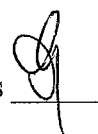
XIII. FORFEITURE OF LICENSE TO PRACTICE PHARMACY

The defendant agrees, as a condition of this agreement, to surrender any and all licenses to practice pharmacy, held in any States, within 14 days of the date of sentencing.

XIV. DEFENDANT'S UNDERSTANDING

I have read and understand the provisions of this agreement consisting of 12 pages. I have discussed the case and my constitutional and other rights with my lawyer. I am satisfied with my lawyer's representation in this case. I understand that by pleading guilty, I will be waiving and giving up my right to continue to

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plead not guilty, to a trial by jury, to the assistance of counsel at that trial, to confront, cross-examine, or compel the attendance of witnesses, to present evidence in my behalf, to maintain my privilege against self-incrimination, and to the presumption of innocence. I agree to enter my plea as indicated above on the terms and conditions set forth herein.

NO OTHER PROMISES OR REPRESENTATIONS HAVE BEEN MADE TO ME BY THE PROSECUTOR, OR BY ANYONE ELSE, NOR HAVE ANY THREATS BEEN MADE OR FORCE USED TO INDUCE ME TO PLEAD GUILTY.

I further state that I have not had any drugs, medication, or alcohol within the past 48 hours except as stated here:

X

I understand that this Plea Agreement will take effect and will be binding as to the Parties after all necessary signatures have been affixed hereto.

I have personally and voluntarily placed my initials on every page of this Agreement and have signed the signature line below to indicate that I have read, understand, and approve all of the provisions of this Agreement, both individually and as a total binding agreement.

1/28/16
DATE


David Lee Allen
DAVID LEE ALLEN

Defendant's Initials DL

XIV. COUNSEL'S ACKNOWLEDGMENT

I have discussed this case with my client in detail and have advised him of all rights and all possible defenses. He has conveyed to me that he understands this Agreement and consents to all its terms. I believe the plea and disposition set forth herein are appropriate under the facts of this case and are in accord with my best judgment. I concur in the entry of the plea on the terms and conditions set forth herein.

1-28-15
DATE



Michael C. Shores
Defense Counsel

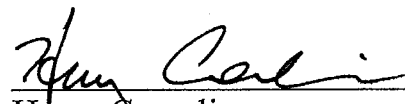
XV. GOVERNMENT'S ACKNOWLEDGMENT

I have reviewed this matter and this Agreement and concur that the plea and disposition set forth herein are appropriate and are in the interests of justice.

JOYCE WHITE VANCE
UNITED STATES ATTORNEY

BENJAMIN C. MIZER
PRINCIPAL DEPUTY ASSISTANT
ATTORNEY GENERAL

By:

 1/28/16

Henry Cornelius
Assistant U.S. Attorney

HEIDE L. HERRMANN / BY HC

Heide L. Herrmann
Trial Attorney 1/28/16

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