

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES of AMERICA

v.

MEREDITH RIGDON LENTZ

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Case No. 3:05-00046

JUDGE ~~XXXXXXXX~~ Brown

PETITION TO ENTER A PLEA OF GUILTY

I, M. Rigdon Lentz, respectfully represent to the court as follows:

(1) My true full name is Meredith Rigdon Lentz. I was born February 2, 1945, and completed 20 years of formal education

(2) My attorney is Hal Hardin.

(3) I have received a copy of the information before being called upon to plead and have read and discussed it with my lawyer, and believe and feel that I understand every accusation made against me in the information.

(4) I have told my lawyer the facts and surrounding circumstances concerning the matters mentioned in the indictment/information and believe and feel that my lawyer knows enough about my case to render me effective assistance. My lawyer has counseled and advised with me as to the nature and cause of every accusation against me. We have thoroughly discussed the government's case against me and my potential defenses to the government's case. My lawyer has explained to me each element of the crime charged and how the government would offer to prove these elements beyond a reasonable doubt.

(5) I understand that the statutory penalty is accurately stated in the presentence report.

I have been advised that I will be sentenced under the sentencing provisions of the Comprehensive Crime Control Act of 1984, pursuant to guidelines established by the United States Sentencing Commission. I also understand that the Judge shall impose a sentence within the guideline range unless the court finds, and states on the record, any mitigating or aggravating circumstances that were not adequately taken into consideration by the Sentencing Commission in formulating the guidelines. I also understand that, if the court fails to follow the guidelines or improperly applies the guidelines, I have a right to a review of my sentence by the United States Court of Appeals for the Sixth Circuit. I estimate the guideline range to be as shown in the presentence report. I realize that my guideline range will be calculated by the United States Probation Officer who prepared the presentence report in my case, subject to challenge by either me

or the government with the final guideline calculation based upon the factual and legal findings of the court.

(6) I understand that I can plead "NOT GUILTY" to any or all offenses charged against me, and continue to plead "NOT GUILTY", and that if I choose to plead not guilty, the Constitution guarantees me (a) the right to a speedy and public trial by jury; (b) the right not to testify and no implication of guilt would arise by my failure to do so; (c) the right to be presumed innocent until such time, if ever, that the government proves my guilt beyond a reasonable doubt to the satisfaction of a court and jury; (d) the right to see and hear all the witnesses and to cross-examine any witness who may testify against me; (e) the right to use the power and process of the court to compel the production of any evidence, including the attendance of any witnesses, in my favor, and to testify in my own behalf if I choose to do so; (f) the right to have the assistance of counsel in my defense at all stages of the proceedings; and, (g) if I am convicted at such trial I have the right to appeal with a lawyer to assist me and the appeal will not cost me any money if I am indigent. I understand that if the court accepts my plea that there will be no jury trial and that I will be convicted of the count(s) to which I plead just as if a jury found me guilty of the charge(s) following a trial and that the court may impose sentence upon me within the limits set forth in the plea agreement stated in paragraph (10) herein.

(7) No officer or agent of any branch of government (federal, state or local), nor any other person, has told me what sentence I will receive. If there are any agreements between myself and my lawyer and the prosecution concerning my plea they are fully set forth in paragraph (10) below. I understand that even with a plea agreement, no person can bind the Judge to give any particular sentence in my case and that, if the Judge decides to reject the plea agreement set forth in paragraph (10) below, I will be offered the opportunity to withdraw my plea and plead not guilty, if I desire, unless the government has only agreed to recommend a sentence to the court [Rule 11(e) (1) (B) of the Federal Rules of Criminal Procedure]. I hope to receive probation or some form of leniency but I am prepared to accept any punishment permitted by law which the judge may see fit to impose. I understand that if the judge decides to make a recommendation about where I should serve any incarceration, the recommendation is not a promise or a guarantee, but only a recommendation and is not binding on the Bureau of Prisons which will make the final decision (after I am sentenced) about where I might be incarcerated.

(8) My lawyer has done all that anyone could do as counsel and assist me, and I understand the proceedings in this case against me. My lawyer has done all the investigation and research in this case that I have asked him to do and I am satisfied with his representation at this point.

(9) Fully understanding my rights to plead "NOT GUILTY" and fully understanding the consequence of my plea of guilty, I wish to plead "GUILTY" and respectfully request the court to accept my plea as follows:

Guilty to the information

(10) This plea is a result of a plea agreement between my lawyer and the prosecution under the provisions of Rule 11 of the Federal Rules of Criminal Procedure. The plea agreement is as follows:

(See attached)

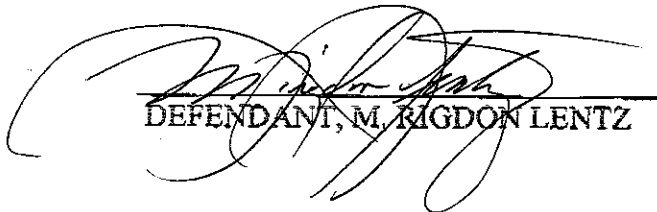
(11) I offer my plea of "GUILTY" freely and voluntarily and of my own accord; also my lawyer has explained to me, and I feel and believe I understand, the statements set forth in the indictment/information, and in this petition, and in the "Certificate of Counsel" which is attached to this petition.

(12) I am not under the influence of either drugs or alcohol

(13) I pray that the court enter my plea of "GUILTY" as set forth in paragraph (9) of this petition, in reliance upon my statements made in this petition.

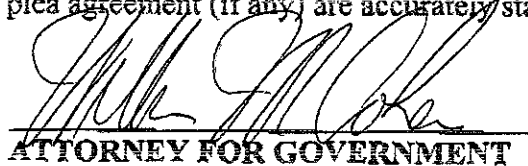
(14) Recognizing that the court may reserve acceptance of this plea pending the receipt of the presentence report, I hereby waive the provisions of Rule 32 Fed R. Crim. P. to the extent that such provisions conflict with 18 U.S.C. §3552(d), and agree that the presentence report may be disclosed to the United States Attorney, my counsel and myself, prior to the sentencing hearing.

Signed by me in open court under the penalties of perjury in the presence of my lawyer, this 6 day of January, 2006.


DEFENDANT, M. RIGDON LENTZ

ACKNOWLEDGMENT OF GOVERNMENT ATTORNEY

The maximum punishment, plea and plea agreement (if any) are accurately stated above

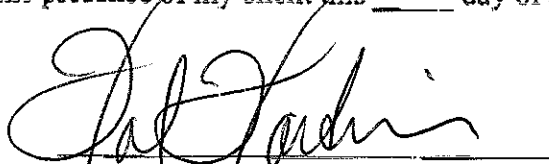

ATTORNEY FOR GOVERNMENT

CERTIFICATE OF COUNSEL

The undersigned, as attorney and counselor for M. Rigdon Lentz hereby certifies as follows:

- (1) I have read and fully explained to Dr. Lentz all the accusations against him in this case;
- (2) To the best of my knowledge and belief each statement set forth in the foregoing petition is in all respects accurate and true;
- (3) In my opinion the plea of "GUILTY" as offered by my client in paragraph (9) of the foregoing petition, is voluntarily and understandingly made; and I recommend to the court that the plea of "GUILTY" be accepted and entered as requested in paragraph (9) of the foregoing petition.

SIGNED by me in open court in the presence of my client this ____ day of January, 2006.



Hal Hardin (#003101)
Attorney for Defendant
218 Third Avenue North
Nashville, TN 37201
615/369-3377

ORDER

Good cause appearing therefore from the foregoing petition of the foregoing named defendant and the certificate of counsel and for all proceedings heretofore had in this case, it is **ORDERED** that the petition be granted and the defendant's plea of "GUILTY" be accepted and entered as prayed in the petition and as recommended in the certificate of counsel.

DONE in open court this 6 day of January, 2006.



UNITED STATES DISTRICT JUDGE
Magistrate

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA)
)
)
 v.) No 3:05-00046
) Judge Haynes
)
 MEREDITH RIGDON LENTZ)

PLEA AGREEMENT

The United States of America, through James K. Vines, United States Attorney for the Middle District of Tennessee, and William M. Cohen, Assistant United States Attorney, the defendant, Meredith Rigdon Lentz, and the defendant's counsel, Hal D. Hardin, pursuant to Rule 11(C)(1)(B) of the Federal Rules of Criminal Procedure, have entered into an agreement, the terms and conditions of which are as follows:

Charge in This Case

1. Defendant acknowledges that he has been charged in the Superseding Information in this case with failing to prepare and maintain records required by the Secretary of the Department of Health and Human Services concerning Dr. Lentz's Metastatic Colorectal Cancer Feasibility Study, in violation of Title 21, United States Code, Sections 331(e) and 333(a)(1).

2. Defendant has read the charge against him contained in the Superseding Information, and that charge has been fully explained to him by his attorney. Defendant fully understands the nature and elements of the crime with which he has been charged.

Charge to Which Defendant is Pleading Guilty

3. By this Plea Agreement, defendant agrees to enter a voluntary plea of guilty to the Superseding Information, charging him with failing to prepare and maintain records. After sentence has been imposed on the Superseding Information to which defendant pleads guilty as agreed herein, the government will move to dismiss the Indictment.

Penalties

4. The parties understand and agree that the offense to which defendant will enter a plea of guilty carries the following maximum terms of imprisonment and fines: One year incarceration, one year of supervised release, a \$100,000 fine, and a \$25.00 special assessment.

Acknowledgments and Waivers Regarding Plea of Guilty

Nature of Plea Agreement

5. This Plea Agreement is entirely voluntary and represents the entire agreement between the United States Attorney and defendant regarding defendant's criminal liability in case no. 3:05-00046.

6. Defendant understands that by pleading guilty he surrenders certain rights, including the following:

(1) If defendant persisted in a plea of not guilty to the charge against him, he would have the right to a public and speedy trial. The trial could be either a jury trial or a trial by the judge sitting without a jury. The defendant has a right to a jury trial. However, in order that the trial be conducted by the judge sitting without a jury, the defendant, the government, and the judge all must agree that the trial be conducted by the judge without a jury.

(2) If the trial is a jury trial, the jury would be composed of twelve laypersons selected at random. Defendant and his attorney would have a say in who the jurors would be by removing prospective jurors for cause when actual bias or other disqualification is shown, or without cause by exercising so-called peremptory challenges. The jury would have to agree unanimously before it could return a verdict of either guilty or not guilty. The jury would be instructed that defendant is presumed innocent; that the government bears the burden of proving defendant guilty of the charge(s) beyond a reasonable doubt; that it could not convict defendant on the charge(s) in the indictment unless, after hearing all the evidence, it was persuaded of defendant's guilt beyond a reasonable doubt; and that it must consider each count of the indictment against defendant separately.

(3) If the trial is held by the judge without a jury, the judge would find the facts and determine, after hearing all the evidence, whether or not the judge was persuaded of defendant's guilt beyond a reasonable doubt.

(4) At a trial, whether by a jury or a judge, the government would be required to present its witnesses and other evidence against defendant. Defendant would be able to confront those government witnesses and his attorney would be able to cross-examine them. In turn, defendant could 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.

(5) At a trial, defendant would have a privilege against self-incrimination so that he could decline to testify, and no inference of guilt could be drawn from his refusal to testify. If defendant desired to do so, he could testify on his own behalf.

7. Defendant understands that by pleading guilty he is waiving all the rights set forth in the prior paragraph. Defendant's attorney has explained those rights to him, and the consequences of his waiver of those rights. Defendant further understands he is waiving all appellate issues that might have been available if he had exercised his right to trial.

8. The parties have no reason to believe that the defendant suffers from any mental health or physical problems that would affect his competency to plead guilty.

Factual Basis

9. Defendant will plead guilty because he is in fact guilty of the charge contained in the information. In pleading guilty, defendant admits the following facts and that those facts establish his guilt beyond a reasonable doubt:

Meredith Rigdon Lentz was a physician who practiced in Nashville, Tennessee, and treated cancer patients. Dr. Lentz applied to the Food and Drug Administration for approval to conduct a feasibility study of the effectiveness and safety of treating certain cancer patients with an investigational device, to wit, an apheresis machine. On December 30, 1997, Dr. Lentz obtained conditional approval from FDA to treat metastatic colorectal cancer patients with the apheresis device. Pursuant to statute and the Code of Federal Regulations, the FDA approval required Dr. Lentz to submit a clinical status report to FDA within six months after enrolling a patient into the feasibility study.

On January 20, 1998, patient W.H. was enrolled into the colorectal feasibility study. Dr. Lentz was thus required to submit a report to FDA on the clinical status of W.H. on or about July 20, 1998. However, Dr. Lentz did not do so, and did not submit a status report until February 1999.

This statement of facts is provided solely to assist the Court in determining whether a factual basis exists for defendant's plea of guilty. The statement of facts does not contain each and every fact known to the defendant and to the United States concerning the defendant's and/or others' involvement in the offense conduct and other matters.

Sentencing Guidelines Calculations

10. The parties understand that the Court will take account of the United States Sentencing Guidelines (hereinafter "U.S.S.G."), together with other sentencing goals, and will consider the U.S.S.G. recommended sentencing range in imposing defendant's sentence. The parties agree that the U.S.S.G. to be considered in this case are those effective November 1, 2004.

11. For purposes of determining the U.S.S.G. recommended sentencing range, the United States and the defendant agree on the following points:

(1) **Offense Level Calculations.**

1. The base offense level for the count of conviction is six, pursuant to U.S.S.G. § 2N2.1;
2. Two points will be added under Section 3B1.3 for abuse of position of trust.
- iii. Assuming defendant clearly demonstrates acceptance of responsibility, to the satisfaction of the government, through his allocution and subsequent conduct prior to the imposition of sentence, a 2-level reduction will be warranted, pursuant to U.S.S.G. § 3E1.1(a).

(2) **Criminal History Category.** Based upon the information now known to the government (including representations by the defense), the defendant has no criminal history points.

(3) **Anticipated Sentencing Range.** Therefore, based on the facts now known to the government, the anticipated offense level is Six, which, combined with the anticipated Criminal History Category of I, would result in an anticipated recommended sentencing range of 0-6 months imprisonment (**the “Anticipated Guidelines Range”**) and a fine range of \$500 to \$5,000. The Court also may impose an additional fine amount to cover all or part of the costs of any term of incarceration, supervised release, or probation ordered, as provided in U.S.S.G. § 5E1.2(d)(7).

Agreements Relating to Sentencing

12. Because the defendant is residing in Germany, the government will recommend that the Court place the defendant on one year unsupervised probation and impose a \$10,000 fine which will be payable at the time of sentencing.

13. It is understood by the parties that the Court is neither a party to nor bound by this Plea Agreement and, after consideration of the Sentencing Guidelines, may impose the maximum penalties as set forth above. Defendant further acknowledges that if the Court does not accept the sentencing recommendation of the parties, defendant will have no right to withdraw his guilty plea. Similarly, the defendant understands that any recommendation by the Court related to location of imprisonment is not binding on the Bureau of Prisons.

14. Defendant agrees to pay the special assessment of \$25.00 at or before the time of sentencing with a check or money order payable to the Clerk of the United States District Court.

Presentence Investigation Report/Post-Sentence Supervision

15. Defendant understands that the United States Attorney's Office, in its submission to the Probation Office as part of the Pre-Sentence Report and at sentencing, shall fully apprise the District Court and the United States Probation Office of the nature, scope, and extent of defendant's

conduct regarding the charges against him, as well as any related matters. The government will make known all matters in aggravation and mitigation relevant to the issue of sentencing.

16. Defendant agrees to execute truthfully and completely a Financial Statement (with supporting documentation) prior to sentencing, to be provided to and shared among the Court, the United States Probation Office, and the United States Attorney's Office regarding all details of his financial circumstances, including his recent income tax returns as specified by the Probation Officer. Defendant understands that providing false or incomplete information, or refusing to provide this information, may be used as a basis for denial of a reduction for acceptance of responsibility pursuant to U.S.S.G. § 3E1.1 and enhancement of his sentence for obstruction of justice under U.S.S.G. § 3C1.1, and may be prosecuted as a violation of Title 18, United States Code, Section 1001, or as a contempt of the Court.

17. This Plea Agreement concerns criminal liability only. Except as expressly set forth in this Plea Agreement, nothing herein shall constitute a limitation, waiver, or release by the United States or any of its agencies of any administrative or judicial civil claim, demand, or cause of action it may have against defendant or any other person or entity. The obligations of this Plea Agreement are limited to the United States Attorney's Office for the Middle District of Tennessee and cannot bind any other federal, state, or local prosecuting, administrative, or regulatory authorities, except as expressly set forth in this Plea Agreement.

Waiver of Appellate Rights

18. Defendant further understands he is waiving all appellate rights that might have been available if he exercised his right to go to trial. It is further agreed that (i) defendant will not file a direct appeal, nor litigate under Title 28, United States Code, Section 2255 and/or Section 2241, any

sentence within or below the Anticipated Guidelines Range and (ii) the government will not appeal any sentence within or above the Anticipated Guidelines Range. This provision is binding on the parties even if the Court employs a U.S.S.G. analysis different from that stipulated to herein. Furthermore, it is agreed that any appeal as to the defendant's sentence that is not foreclosed by this provision will be limited to that portion of the sentencing calculation that is inconsistent with (or not addressed by) the above stipulated U.S.S.G. analysis. Such waiver does not apply, however, to a claim of involuntariness, prosecutorial misconduct, or ineffective assistance of counsel.

Other Terms

19. The defendant waives the statute of limitations as to the offense charged in the Superseding Information.

20. The United States agrees not to seek additional criminal charges in the Middle District of Tennessee against defendant for the events between January 1998 and the date of this plea, which occurred in the Middle District of Tennessee and which are now known to the government. The FDA agrees not to investigate the defendant for any criminal offenses he may have committed between January 1998 and the date of this plea which are now known to FDA. However, nothing in this Plea Agreement limits the United States in the prosecution of defendant in other districts or for crimes not known to the government.

21. Should defendant engage in additional criminal activity after he has pled guilty but prior to sentencing, defendant shall be considered to have breached this Plea Agreement, and the government at its option may void this Plea Agreement.

Conclusion

22. Defendant understands that the information and this Plea Agreement will be filed with the Court, will become matters of public record, and may be disclosed to any person.

23. Defendant understands that his compliance with each part of this Plea Agreement extends throughout the period of his sentence, and failure to abide by any term of the Plea Agreement is a violation of the Plea Agreement. Defendant further understands that in the event he violates this Plea Agreement, the government, at its option, may move to vacate the Plea Agreement, rendering it null and void, and thereafter prosecute defendant not subject to any of the limits set forth in this Plea Agreement, or may move to resentence defendant or require defendant's specific performance of this Plea Agreement.

24. Defendant and his attorney acknowledge that no threats, promises, or representations have been made, nor agreements reached, other than those set forth in this Plea Agreement, to cause defendant to plead guilty.

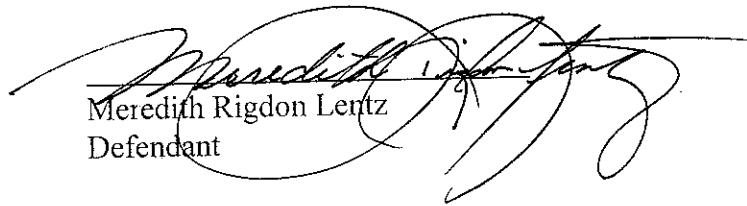
25. Defendant acknowledges that he has read this Plea Agreement and carefully reviewed each provision with his attorney. Defendant further acknowledges that he understands and voluntarily accepts each and every term and condition of this Agreement.

26. No promises, agreements, or conditions have been entered into other than those set forth in this Plea Agreement, and none will be entered into unless memorialized in writing and signed by all of the parties listed below.

27. Defendant's Signature: I hereby agree that I have consulted with my attorney and fully understand all rights with respect to the pending Superseding Information. Further, I fully understand all rights with respect to the provisions of the Sentencing Guidelines that may apply in

my case. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement, and I voluntarily agree to it.

Date: Jan. 06, 2006


Meredith Rigdon Lentz
Defendant

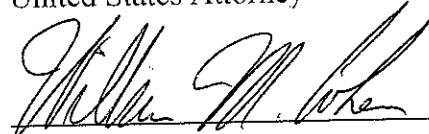
28. Defense Counsel Signature: I am counsel for the defendant in this case. I have fully explained to the defendant his rights with respect to the pending Superseding Information. Further, I have reviewed the provisions of the Sentencing Guidelines and Policy Statements, and I have fully explained to the defendant the provisions of those guidelines that may apply in this case. I have reviewed carefully every part of this Plea Agreement with the defendant. To my knowledge, the defendant's decision to enter into this Plea Agreement is an informed and voluntary one

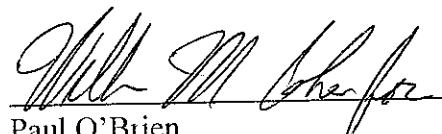
Date: 1-6-06


Hal D. Hardin

Respectfully submitted,

James K. Vines
United States Attorney

By: 
William M. Cohen
Assistant U.S. Attorney


Paul O'Brien
Criminal Chief