

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 21-CR-_____

STEVEN R. BRANDENBURG,

Defendant.

PLEA AGREEMENT

1. The United States of America, by its undersigned attorneys, and the defendant, Steven R. Brandenburg, individually and by attorney Jason D. Baltz, pursuant to Rule 11 of the Federal Rules of Criminal Procedure, enter into the following plea agreement:

CHARGES

2. The defendant has been charged in an information with two violations of Title 18, United States Code, Section 1365(a)(1).

3. The defendant has read and fully understands the charges contained in the information. He fully understands the nature and elements of the crimes with which he has been charged, and the charges and the terms and conditions of the plea agreement have been fully explained to him by his attorney.

4. The defendant voluntarily agrees to waive prosecution by indictment in open court.

5. The defendant voluntarily agrees to plead guilty to the following counts set forth in full as follows:

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

On or about December 24, 2020, in the State and Eastern District of Wisconsin,

STEVEN R. BRANDENBURG,

with reckless disregard for the risk that another person would be placed in danger of death and bodily injury, and under circumstances manifesting extreme indifference to such risk, attempted to tamper with certain vials of Moderna, Inc.'s COVID-19 vaccine, then located at 975 Port Washington Road in Grafton, Wisconsin, and such vaccine was a consumer product that affected interstate commerce.

In violation of Title 18, United States Code, Section 1365(a)(1).

COUNT TWO

THE UNITED STATES ATTORNEY FURTHER CHARGES THAT:

On or about December 25, 2020, in the State and Eastern District of Wisconsin,

STEVEN R. BRANDENBURG,

with reckless disregard for the risk that another person would be placed in danger of death and bodily injury, and under circumstances manifesting extreme indifference to such risk, attempted to tamper with certain vials of Moderna, Inc.'s COVID-19 vaccine, then located at 975 Port Washington Road in Grafton, Wisconsin, and such vaccine was a consumer product that affected interstate commerce.

In violation of Title 18, United States Code, Section 1365(a)(1).

6. The defendant acknowledges, understands, and agrees that he is, in fact, guilty of the offenses described in paragraph 5. The parties acknowledge and understand that if this case were to proceed to trial, the government would be able to prove the facts in Attachment A beyond a reasonable doubt. The defendant admits that these facts are true and correct and

establish his guilt beyond a reasonable doubt. This information is provided for the purpose of setting forth a factual basis for the plea of guilty. It is not a full recitation of the defendant's knowledge of, or participation in, these offenses.

PENALTIES

7. The parties understand and agree that the offenses to which the defendant will enter a plea of guilty each carry the following maximum term of imprisonment and fine: 10 years' imprisonment and \$250,000. Each count also carries a mandatory special assessment of \$100, and a maximum of three years of supervised release. The parties further recognize that a restitution order may be entered by the court, pursuant to Title 18, United States Code, 3663A(c)(1)(A)(iv).

8. The defendant acknowledges, understands, and agrees that he has discussed the relevant statutes as well as the applicable sentencing guidelines with his attorney.

ELEMENTS

9. The parties understand and agree that in order to sustain the charge of attempted tampering with a consumer product, as set forth in Count One and Count Two, the government must prove each of the following propositions beyond a reasonable doubt:

First, defendant attempted to tamper with a consumer product;

Second, the consumer product at issue affected interstate commerce;

Third, defendant acted with reckless disregard for the risk that another person would be placed in danger of death or bodily injury; and

Fourth, defendant acted under circumstances manifesting extreme indifference to such risk.

SENTENCING PROVISIONS

10. The parties agree to waive the time limits in Fed. R. Crim. P. 32 relating to the presentence report, including that the presentence report be disclosed not less than 35 days before the sentencing hearing, in favor of a schedule for disclosure, and the filing of any objections, to be established by the court at the change of plea hearing.

11. The parties acknowledge, understand, and agree that any sentence imposed by the court will be pursuant to the Sentencing Reform Act, and that the court will give due regard to the Sentencing Guidelines when sentencing the defendant.

12. The parties acknowledge and agree that they have discussed all of the Sentencing Guidelines provisions which they believe to be applicable to the offenses set forth in paragraph 5. The defendant acknowledges and agrees that his attorney in turn has discussed the applicable Sentencing Guidelines provisions with him to the defendant's satisfaction.

13. The parties acknowledge and understand that prior to sentencing the United States Probation Office will conduct its own investigation of the defendant's criminal history. The parties further acknowledge and understand that, at the time the defendant enters a guilty plea, the parties may not have full and complete information regarding the defendant's criminal history. The parties acknowledge, understand, and agree that the defendant may not move to withdraw the guilty plea solely as a result of the sentencing court's determination of the defendant's criminal history.

Sentencing Guidelines Calculations

14. The defendant acknowledges and understands that the Sentencing Guidelines recommendations contained in this agreement do not create any right to be sentenced within any particular sentence range, and that the court may impose a reasonable sentence above or below the guideline range. The parties further understand and agree that if the defendant has provided

false, incomplete, or inaccurate information that affects the calculations, the government is not bound to make the recommendations contained in this agreement.

Relevant Conduct

15. The parties acknowledge, understand, and agree that pursuant to Sentencing Guidelines Manual § 1B1.3, the sentencing judge may consider relevant conduct in calculating the Sentencing Guidelines range, even if the relevant conduct is not the subject of the offenses to which the defendant is pleading guilty.

Base Offense Level

16. The parties agree to recommend to the sentencing court that the applicable base offense level for the offenses charged in Count One and Count Two is 25 under Sentencing Guidelines Manual § 2N1.1(a).

Acceptance of Responsibility

17. The government agrees to recommend a two-level decrease for acceptance of responsibility as authorized by Sentencing Guidelines Manual § 3E1.1(a), but only if the defendant exhibits conduct consistent with the acceptance of responsibility. The defendant acknowledges, understands, and agrees that conduct consistent with the acceptance of responsibility includes but is not limited to the defendant's voluntary identification and disclosure to the government of any and all actual or potential victims of the offenses or any related conduct prior to sentencing. In addition, if the court determines at the time of sentencing that the defendant is entitled to the two-level reduction under § 3E1.1(a), the government agrees to make a motion recommending an additional one-level decrease as authorized by Sentencing Guidelines Manual § 3E1.1(b) because the defendant timely notified authorities of his intention to enter a plea of guilty.

Sentencing Recommendations

18. Both parties reserve the right to provide the district court and the probation office with any and all information which might be pertinent to the sentencing process, including but not limited to any and all conduct related to the offenses as well as any and all matters which might constitute aggravating or mitigating sentencing factors.

19. Both parties reserve the right to make any recommendation regarding any and all factors pertinent to the determination of the Sentencing Guideline range; the fine to be imposed; the amount of restitution and the terms and condition of its payment; the length of supervised release and the terms and conditions of the release; the defendant's custodial status pending the sentencing; and any other matters not specifically addressed by this agreement.

20. The government agrees to recommend a sentence within the applicable Sentencing Guideline range, as determined by the court.

Court's Determinations at Sentencing

21. The parties acknowledge, understand, and agree that neither the sentencing court nor the United States Probation Office is a party to or bound by this agreement. The United States Probation Office will make its own recommendations to the sentencing court. The sentencing court will make its own determinations regarding any and all issues relating to the imposition of sentence and may impose any sentence authorized by law up to the maximum penalties set forth in paragraph 7 above. The parties further understand that the sentencing court will be guided by the sentencing guidelines but will not be bound by the sentencing guidelines and may impose a reasonable sentence above or below the calculated guideline range.

22. The parties acknowledge, understand, and agree that the defendant may not move to withdraw the guilty plea solely as a result of the sentence imposed by the court.

FINANCIAL MATTERS

23. The defendant acknowledges and understands that any and all financial obligations imposed by the sentencing court are due and payable in full upon entry of the judgment of conviction. The defendant further understands that any payment schedule imposed by the sentencing court shall be the minimum the defendant is expected to pay and that the government's collection of any and all court imposed financial obligations is not limited to the payment schedule. The defendant agrees not to request any delay or stay in payment of any and all financial obligations. If the defendant is incarcerated, the defendant agrees to participate in the Bureau of Prisons' Inmate Financial Responsibility Program, regardless of whether the court specifically directs participation or imposes a schedule of payments.

24. The defendant agrees to provide to the Financial Litigation Unit (FLU) of the United States Attorney's Office, at least 30 days before sentencing, and also upon request of the FLU during any period of probation or supervised release imposed by the court, a complete and sworn financial statement on a form provided by the FLU and any documentation required by the form. The defendant further agrees, upon request of the FLU, whether made before or after sentencing, to promptly cooperate in the identification of assets in which the defendant has an interest, cooperate in the liquidation of any such assets, and participate in an asset deposition.

Special Assessment

25. The defendant agrees to pay the special assessment in the amount of \$200 prior to or at the time of sentencing.

Restitution

26. The defendant agrees to pay restitution as ordered by the court. The defendant understands that because restitution is mandatory for the offenses to which he is pleading guilty, pursuant to Title 18, United States Code, 3663A(c)(1)(A)(iv), an amount of restitution shall be

imposed by the court regardless of the defendant's financial resources. The defendant agrees to cooperate in efforts to collect the restitution obligation. The defendant understands that imposition or payment of restitution will not restrict or preclude the filing of any civil suit or administrative action.

DEFENDANT'S WAIVER OF RIGHTS

27. In entering this agreement, the defendant acknowledges and understands that he surrenders any claims he may have raised in any pretrial motion, as well as certain rights which include the following:

- a. If the defendant persisted in a plea of not guilty to the charges against him, he would be entitled to a speedy and public trial by a court or 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.
- b. If the trial is a jury trial, the jury would be composed of twelve citizens selected at random. The defendant and his attorney would have a say in who the jurors would be by removing prospective jurors for cause where actual bias or other disqualification is shown, or without cause by exercising peremptory challenges. The jury would have to agree unanimously before it could return a verdict of guilty. The court would instruct the jury that the defendant is presumed innocent until such time, if ever, as the government establishes guilt by competent evidence to the satisfaction of the jury beyond a reasonable doubt.
- c. If the trial is held by the judge without a jury, the judge would find the facts and determine, after hearing all of the evidence, whether or not he was persuaded of defendant's guilt beyond a reasonable doubt.
- d. At such trial, whether by a judge or a jury, the government would be required to present witnesses and other evidence against the defendant. The defendant would be able to confront witnesses upon whose testimony the government is relying to obtain a conviction and he would have the right to cross-examine those witnesses. In turn the defendant could, but is not obligated to, present witnesses and other evidence on his own behalf. The defendant would be entitled to compulsory process to call witnesses.
- e. At such 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.

28. The defendant acknowledges and understands that by pleading guilty he is waiving all the rights set forth above. The defendant further acknowledges the fact that his attorney has explained these rights to him and the consequences of his waiver of these rights. The defendant further acknowledges that as a part of the guilty plea hearing, the court may question the defendant under oath, on the record, and in the presence of counsel, about the offenses to which the defendant intends to plead guilty. The defendant further understands that the defendant's answers may later be used against the defendant in a prosecution for perjury or false statement.

29. The defendant acknowledges and understands that he will be adjudicated guilty of the offenses to which he will plead guilty and thereby may be deprived of certain rights, including but not limited to the right to vote, to hold public office, to serve on a jury, to possess firearms, and to be employed by a federally insured financial institution.

30. The defendant knowingly and voluntarily waives all claims he may have based upon the statute of limitations, the Speedy Trial Act, and the speedy trial provisions of the Sixth Amendment. The defendant agrees that any delay between the filing of this agreement and the entry of the defendant's guilty plea pursuant to this agreement constitutes excludable time under the Speedy Trial Act.

31. Based on the government's concessions in this agreement, the defendant knowingly and voluntarily waives his right to appeal his sentence in this case and further waives his right to challenge his conviction or sentence in any post-conviction proceeding, including but not limited to a motion pursuant to Title 18, United States Code, Section 2255. As used in this paragraph, the term "sentence" means any term of imprisonment, term of supervised release,

term of probation, supervised release condition, fine, forfeiture order, and restitution order. The defendant's waiver of appeal and post-conviction challenges includes the waiver of any claim that (1) the statute or Sentencing Guidelines provisions under which the defendant is convicted or sentenced are unconstitutional, and (2) the conduct to which the defendant has admitted does not fall within the scope of the statute or Sentencing Guidelines. This waiver does not extend to an appeal or post-conviction motion based on (1) any punishment in excess of the statutory maximum, (2) the sentencing court's reliance on any constitutionally impermissible factor, such as race, religion, or sex, (3) ineffective assistance of counsel in connection with the negotiation of the plea agreement or sentencing, or (4) a claim that the plea agreement was entered involuntarily.

Further Civil or Administrative Action

32. The defendant acknowledges, understands, and agrees that the defendant has discussed with his attorney and understands that nothing contained in this agreement, including any attachment, is meant to limit the rights and authority of the United States of America or any other state or local government to take further civil, administrative, or regulatory action against the defendant, including but not limited to any listing and debarment proceedings to restrict rights and opportunities of the defendant to contract with or receive assistance, loans, and benefits from United States government agencies.

GENERAL MATTERS

33. The parties acknowledge, understand, and agree that this agreement does not require the government to take, or not to take, any particular position in any post-conviction motion or appeal.

34. The parties acknowledge, understand, and agree that this plea agreement will be filed and become part of the public record in this case.

35. The parties acknowledge, understand, and agree that the United States Attorney's Office and the Department of Justice are free to notify any other local, state, or federal agency of the defendant's conviction.

36. The defendant understands that pursuant to the Victim and Witness Protection Act, the Justice for All Act, the Crime Victims' Rights Act, and regulations promulgated thereto by the Attorney General of the United States, the victim of a crime may make a statement describing the impact of the offense on the victim and further may make a recommendation regarding the sentence to be imposed. The defendant acknowledges and understands that comments and recommendations by a victim may be different from those of the parties to this agreement.

EFFECT OF DEFENDANT'S BREACH OF PLEA AGREEMENT

37. The defendant acknowledges and understands if he violates any term of this agreement at any time, engages in any further criminal activity prior to sentencing, or fails to appear for sentencing, this agreement shall become null and void at the discretion of the government. The defendant further acknowledges and understands that the government's agreement to dismiss any charge is conditional upon final resolution of this matter. If this plea agreement is revoked or if the defendant's conviction ultimately is overturned, then the government retains the right to reinstate any and all dismissed charges and to file any and all charges which were not filed because of this agreement. The defendant hereby knowingly and voluntarily waives any defense based on the applicable statute of limitations for any charges filed against the defendant as a result of his breach of this agreement. The defendant understands, however, that the government may elect to proceed with the guilty plea and sentencing. If the defendant and his attorney have signed a proffer letter in connection with this case, then the

defendant further acknowledges and understands that he continues to be subject to the terms of the proffer letter.

VOLUNTARINESS OF DEFENDANT'S PLEA

38. The defendant acknowledges, understands, and agrees that he will plead guilty freely and voluntarily because he is in fact guilty of the offenses charged in the information. The defendant further acknowledges and agrees that no threats, promises, representations, or other inducements have been made, nor agreements reached, other than those set forth in this agreement, to induce the defendant to plead guilty.

ATTACHMENT A

Had this case proceeded to trial, the United States of America would have proven the following facts beyond a reasonable doubt. The information is provided for the purpose of setting forth a factual basis for the defendant's guilty plea. It is not a full recitation of the defendant's knowledge of, or participation in, these offenses.

Background

In early 2020, public health authorities in both the United States of America and abroad began to identify, treat and study coronavirus disease 2019 ("COVID-19"), an infectious disease caused by a novel coronavirus, now known as "severe acute respiratory syndrome coronavirus 2" or "SARS-CoV-2." In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the United States of America declared a public health emergency. Research concerning COVID-19 is ongoing, but it is predominantly a respiratory illness that can affect other organs. The severity of COVID-19 symptoms ranges from mild to very severe. Symptoms of COVID-19 may appear 2 to 14 days after exposure to the virus and may include fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and diarrhea. Some people can experience severe symptoms, including confusion, trouble breathing, pneumonia, and death. As of January 17, 2021, the Centers for Disease Control and Prevention ("CDC") indicate that over 23 million cases of COVID-19 have been reported in the United States, with over 390,000 associated deaths.

Several governments and pharmaceutical companies—including but not limited to Moderna, Inc. ("Moderna")—have understandably attempted to develop drugs to prevent and treat COVID-19. Moderna specifically developed a biological product that is injected into a recipient's muscle for active immunization to prevent COVID-19 in individuals 18 years of age and older (the "Moderna COVID-19 Vaccine"). The Moderna COVID-19 Vaccine was initially authorized for administration to the public by the Food and Drug Administration ("FDA"), pursuant to an Emergency Use Authorization, on December 18, 2020.

The Moderna COVID-19 Vaccine has strict specifications regarding its storage and subsequent administration, as detailed in the "Fact Sheet For Healthcare Providers Administering Vaccine" (available at <https://www.fda.gov/media/144637/download>). This same Fact Sheet, which is available to both providers of the vaccine and their employees, provides, in relevant part, as follows:

As Displayed on the Vial Labels and Cartons: The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.

Additional Storage Information Not Displayed on the Vial Labels and Cartons: Do not store on dry ice or below -40°C (-40°F). Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze once thawed.

Brandenburg's Conduct

In late December 2020, the Office of Criminal Investigation at the FDA ("FDA-OCI"), the Federal Bureau of Investigation ("FBI"), and the Grafton Police Department ("GPD") began investigating reports that the defendant, Steven R. Brandenburg ("Brandenburg"), a pharmacist at the Aurora Medical Center located at 975 Port Washington Road in Grafton, Wisconsin ("the Grafton Facility"), had purposefully removed some amount of Moderna COVID-19 Vaccine from the required refrigeration.

Agents from the FDA-OCI, FBI, and GPD interviewed employees of the Grafton Facility; reviewed electronic records concerning access to and operation of the pharmacy at the Grafton Facility; analyzed Brandenburg's communications; collected surveillance footage; and interviewed Brandenburg himself. That investigation revealed the following:

- Brandenburg has been licensed as a pharmacist in Wisconsin since August 22, 1997;
- Brandenburg, in late December 2020, was employed at the Grafton Facility as a "third shift" pharmacist, working from approximately 11:00 PM to 7:00 AM;
- One of Brandenburg's employment obligations was to ensure that drugs and vaccines at the Grafton Facility's pharmacy were stored and maintained properly;
- Brandenburg believes in various "conspiracy theories" and notions of "alternative history," and he has communicated these same beliefs to his co-workers at the Grafton Facility for at least the past two years;
- Brandenburg is skeptical of vaccines in general and the Moderna COVID-19 Vaccine specifically, and he has similarly communicated those same beliefs to his co-workers at the Grafton Facility;
- Brandenburg, as a trained, licensed, and experienced pharmacist, knew and understood that: (1) public health authorities, including but not limited to the CDC, believe COVID-19 currently poses a serious global health threat; and (2) the Moderna COVID-19 Vaccine is intended to help mitigate that same threat;
- Brandenburg, as a trained, licensed, and experienced pharmacist, knew and understood that when vaccines—including but not limited to the Moderna COVID-19 Vaccine—are not stored in a manner consistent with the specifications articulated by public health authorities, their administration to patients poses a risk of bodily harm and death, insofar as the vaccines at issue may: (1) be rendered less potent or even inert; (2) break down into component parts which are themselves dangerous; or (3) become contaminated with foreign pollutants or pathogens;

- Brandenburg knew and understood—based on his review of multiple sources of information, including but not limited to the previously mentioned “Fact Sheet For Healthcare Providers Administering Vaccine”—that the Moderna COVID-19 Vaccine was not to be left out of refrigeration for more than twelve hours prior to its administration to patients;
- Recklessly disregarding his knowledge of the applicable storage specifications and the associated risks, Brandenburg, on two successive shifts that began on the evenings of December 24 and December 25, 2020, removed the same box of Moderna COVID-19 Vaccine from the refrigerator in the pharmacy at the Grafton Facility, for periods of multiple hours, intending to render that same vaccine inert or ineffective;
- The box of Moderna COVID-19 Vaccine that Brandenburg removed from refrigeration affected interstate commerce, insofar as that same vaccine had previously been transported in interstate commerce; and,
- On the morning of December 26, 2020, 57 individuals at the Grafton Facility received doses of Moderna COVID-19 Vaccine that Brandenburg had previously removed from refrigeration. Efforts to determine whether Brandenburg’s misconduct had rendered those doses inert or otherwise harmful are ongoing.

ACKNOWLEDGMENTS

I am the defendant. I am entering into this plea agreement freely and voluntarily. I am not now on or under the influence of any drug, medication, alcohol, or other intoxicant or depressant, whether or not prescribed by a physician, which would impair my ability to understand the terms and conditions of this agreement. My attorney has reviewed every part of this agreement with me and has advised me of the implications of the sentencing guidelines. I have discussed all aspects of this case with my attorney and I am satisfied that my attorney has provided effective assistance of counsel.


Date: 1-20-2021



STEVEN R. BRANDENBURG
Defendant

I am the defendant's attorney. I carefully have reviewed every part of this agreement with the defendant. To my knowledge, my client's decision to enter into this agreement is an informed and voluntary one.

Date: 1/20/2021



JASON D. BALTZ
Attorney for Defendant

For the United States of America:

Date: 1/21/2021



MATTHEW D. KRUEGER
United States Attorney

Date: 1/21/2021



KEVIN C. KNIGHT
Assistant United States Attorney

Date: 1/22/21



GUSTAV W. EYLER
Director
Consumer Protection Branch
United States Department of Justice

Date: 1/22/2021



ROSS S. GOLDSTEIN
Senior Litigation Counsel
Consumer Protection Branch
United States Department of Justice