IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA : CRIMINAL NO. 23-89

V.

PETER N. STOLL, III

:

GUILTY PLEA AGREEMENT

Under Rule 11 of the Federal Rules of Criminal Procedure, the government, the defendant, and the defendant's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania or the Consumer Protection Branch of the United States Department of Justice.

- 1. The defendant agrees to plead guilty to Count One of an information charging him with causing the introduction into interstate commerce of a medical device that was adulterated and misbranded with the intent to defraud and mislead, a felony, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(2), all arising from the introduction into interstate commerce of various articles of device, namely the Aesculap ELAN-4 Air Drill and the Aesculap JS SterilContainer 2 which were adulterated under 21 U.S.C. § 351(f)(1)(B) and misbranded under 21 U.S.C. § 352(o). The defendant further acknowledges his waiver of rights, as set forth in the attachment to this agreement.
 - 2. At the time of sentencing, the government will:

- a. Make a recommendation of a sentence of imprisonment within the applicable Sentencing Guidelines range without further specification.
- b. Comment on the evidence and circumstances of the case; bring to the Court's attention all facts relevant to sentencing including evidence relating to dismissed counts, if any, and to the character and any criminal conduct of the defendant; address the Court regarding the nature and seriousness of the offense; respond factually to questions raised by the Court; correct factual inaccuracies in the presentence report or sentencing record; and rebut any statement of facts made by or on behalf of the defendant at sentencing.
- c. Nothing in this agreement shall limit the government in its comments in, and responses to, any post-sentencing matters.
- 3. The defendant understands, agrees, and has had explained to him by counsel that the Court may impose the following statutory maximum sentences: Count One (causing the introduction into interstate commerce of an adulterated and misbranded medical device with the intent to defraud and mislead), three years of imprisonment, a one-year period of supervised release, a fine of up to \$250,000, and a \$100 special assessment.

Total Maximum Sentence is: three years of imprisonment, a one-year period of supervised release, a fine of \$250,000, and a \$100 special assessment.

4. The defendant further understands that supervised release may be revoked if its terms and conditions are violated. When supervised release is revoked, the original term of imprisonment may be increased by up to one year on Count One. Thus, a violation of supervised release increases the possible period of incarceration and makes it possible that the defendant will have to serve the original sentence, plus a substantial additional period, without credit for time already spent on supervised release.

- 5. In order to facilitate the collection of the criminal monetary penalties to be imposed in connection with this prosecution, the defendant agrees fully to disclose all income, assets, liabilities, and financial interests, held directly or indirectly, whether held in his own name or in the name of a relative, spouse, associate, another person, or entity, and whether held in this country or outside this country. Accordingly:
- a. The defendant will submit a completed Financial Statement of Debtor to the United States, in a form it provides and as it directs, within 14 days of execution of this plea agreement. The defendant promises that his financial statement and disclosures will be complete, accurate, and truthful.
- b. The defendant expressly authorizes the United States to obtain a credit report on him in order to evaluate the defendant's ability to satisfy any monetary penalty imposed by the Court.
- c. Upon request by the United States, the defendant also agrees to submit to a financial deposition or interview prior to sentencing and provide all documents within the defendant's possession or control as requested by the United States regarding the defendant's financial resources and that of the defendant's household.
- d. The defendant agrees not to transfer, assign, dispose, remove, conceal, pledge as collateral, waste, or destroy property with the effect of hindering, delaying, or defrauding the United States or victims. The defendant otherwise shall not devalue any property worth more than \$1,000 before sentencing, without the prior approval of the United States.
- e. The defendant also agrees to execute any documents necessary to release any funds held in any repository, bank, investment, other financial institution, or any other

location in order to make partial or total payment toward any monetary penalty that the Court may impose.

- f. If the defendant fails to comply with this paragraph of the plea agreement or if any of the defendant's representations pursuant to the requirements set forth in this paragraph are false or inaccurate, the government may elect to: void this agreement; and/or argue that the defendant is not entitled to a downward adjustment for acceptance of responsibility under Guideline Section 3E1.1.
- 6. This agreement is limited to the Consumer Protection Branch of the United States
 Department of Justice and the United States Attorney's Office for the Eastern District of
 Pennsylvania and cannot bind other federal, state, or local authorities. However, the United
 States will bring this agreement to the attention of other prosecuting offices, if requested. This
 agreement was reached without regard to any civil or administrative matters that may be pending
 or commenced in the future against the defendant. This agreement does not prohibit the United
 States, any agency thereof (including the Food and Drug Administration, the Internal Revenue
 Service, and the Securities and Exchange Commission), or any third party from initiating or
 prosecuting any civil or administrative proceeding against the defendant.
- 7. The defendant may not withdraw his plea because the Court declines to follow any recommendation, motion, or stipulation by the parties to this agreement. No one has promised or guaranteed to the defendant what sentence the Court will impose.
- 8. Pursuant to U.S.S.G. § 6B1.4, the parties enter into the following stipulations under the 2021 Sentencing Guidelines Manual. It is understood and agreed that: (1) the parties are free to argue (except as stated below) the applicability of any other provision of the Sentencing Guidelines, including offense conduct, offense characteristics, criminal history,

adjustments, and departures; (2) these stipulations are not binding upon either the Probation

Office or the Court; and (3) the Court may make factual and legal determinations that differ from these stipulations and that may result in an increase or decrease in the Sentencing Guidelines range and the sentence that may be imposed:

- a. The parties agree and stipulate that U.S.S.G. § 2N2.1 applies to the offense charged and further agree and stipulate that because the offense involved fraud, pursuant to § 2N2.1(c)(1), the guidelines at U.S.S.G. § 2B1.1 are to be applied.
- b. The parties agree and stipulate that under U.S.S.G. § 2B1.1(a)(2), the base offense level is 6.
- c. The defendant understands that the government will argue that the total loss amount is more than \$95,000, but less than \$150,000, resulting in an increase in the offense level of 8 pursuant to U.S.S.G. § 2B1.1(b)(1)(E). The parties agree that the defendant may argue at sentencing that the loss amount is lower.
- d. The parties agree and stipulate that, as of the date of this agreement, the defendant has demonstrated acceptance of responsibility for his offense, making him eligible for a 2-level downward adjustment under U.S.S.G. § 3E1.1(a), resulting in a total offense level of 12 which corresponds to an advisory guidelines range of 10 to 16 months incarceration if the defendant is in Criminal History Category I.
- e. The parties agree and stipulate that no other adjustments, cross-references, or application notes apply. The government agrees not to seek a departure or variance as to imprisonment.
- 9. The defendant understands that the government will inform the U.S. Department of Health and Human Services ("HHS") of the disposition of the criminal charges filed against

the defendant in this case, and that HHS may exclude the defendant from participation in federal health care programs pursuant to its authority set forth in 42 U.S.C. § 1320a-7.

- 10. If the defendant commits any federal, state, or local crime between the date of this agreement and his sentencing, or otherwise violates any other provision of this agreement, the government may declare a breach of the agreement, and may at its option: (a) prosecute the defendant for any federal crime including, but not limited to, perjury, obstruction of justice, and the substantive offenses arising from this investigation, based on and using any information provided by the defendant during the investigation and prosecution of the criminal case; (b) upon government motion, reinstate and try the defendant on any counts which were to be, or which had been, dismissed on the basis of this agreement; (c) be relieved of any obligations under this agreement regarding recommendations as to the defendant's sentence; and (d) be relieved of any stipulations under the Sentencing Guidelines. Moreover, the defendant's previously entered guilty plea will stand and cannot be withdrawn by him. The decision shall be in the sole discretion of the government both whether to declare a breach, and regarding the remedy or remedies to seek. The defendant understands and agrees that the fact that the government has not asserted a breach of this agreement or enforced a remedy under this agreement will not bar the government from raising that breach or enforcing a remedy at a later time.
- agreement, the defendant voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, fine, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. As part of this knowing and voluntary waiver of the right to appeal or collaterally attack the conviction and sentence, the defendant

expressly waives the right to raise on appeal or on collateral review any argument that (1) the statutes to which the defendant is pleading guilty are unconstitutional and (2) the admitted conduct does not fall within the scope of the statutes.

- a. Notwithstanding the waiver provision above, if the government appeals from the sentence, then the defendant may file a direct appeal of his sentence.
- b. If the government does not appeal, notwithstanding the waiver provision set forth in this paragraph, the defendant may file a direct appeal or petition for collateral relief but may raise only a claim, if otherwise permitted by law in such a proceeding:
- i. that the defendant's sentence on any count of conviction exceeds the statutory maximum for that count as set forth in paragraph 3 above;
- ii. challenging a decision by the sentencing judge to impose an "upward departure" pursuant to the Sentencing Guidelines;
- iii. challenging a decision by the sentencing judge to impose an "upward variance" above the final Sentencing Guideline range determined by the Court; and
- iv. that an attorney who represented the defendant during the course of this criminal case provided constitutionally ineffective assistance of counsel.
- 12. If the defendant does appeal or seek collateral relief, no issue may be presented by the defendant in such a proceeding other than those described in this agreement. The defendant acknowledges that pursuing an appeal or any collateral attack waived in the preceding paragraph may constitute a breach of this plea agreement. The government recognizes that the mere filing of a notice of appeal is not a breach of the plea agreement. The government may declare a breach only after the defendant or his counsel thereafter states, either orally or in writing, a determination to proceed with an appeal or collateral attack raising an issue the government

deems barred by the waiver. The parties acknowledge that the pursuit of an appeal constitutes a breach only if a court determines that the appeal does not present an issue that a judge may reasonably conclude is permitted by an exception to the waiver stated in the preceding paragraph or constitutes a "miscarriage of justice" as that term is defined in applicable law.

- 13. The defendant waives any claim under the Hyde Amendment, 18 U.S.C. §3006A (Statutory Note), for attorney's fees and other litigation expense arising out of the investigation or prosecution of this matter.
- 14. The defendant waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.
- 15. The defendant is satisfied with the legal representation provided by the defendant's lawyer; the defendant and his lawyer have fully discussed this plea agreement; and the defendant is agreeing to plead guilty because the defendant admits that he is guilty.

16. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements, or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements, or understandings will be entered into unless in writing and signed by all parties.

JACQUELINE C. ROMERO United States Attorney

AMANDA N. LISKAMM
Director, Consumer Protection Branch

PETER N. STOLL, III

Defendant

Date:

ROCCO CIPPARONE
Counsel for the Defendant

Date: July 14, 2023

RICHARD BARRETT

Chief, Criminal Division

Assistant United States Attorney

/M. Beth Leahy

M. BETH LEAHY

Assistant United States Attorney

ROSS S. GOLDSTEIN

Assistant Director

Consumer Protection Branch

MAX J. GOLDMAN

Trial Attorney

Consumer Protection Branch

Attachment

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

v. : CRIMINAL NO. 23-89

PETER N. STOLL, III

ACKNOWLEDGMENT OF RIGHTS

I hereby acknowledge that I have certain rights that I will be giving up by pleading guilty.

- 1. I understand that I do not have to plead guilty.
- 2. I may plead not guilty and insist upon a trial.
- 3. At that trial, I understand
- a. that I would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with my attorney, I would have the right to participate in the selection of that jury;
- b. that the jury could only convict me if all 12 jurors agreed that they were convinced of my guilt beyond a reasonable doubt;
- c. that the government would have the burden of proving my guilt beyond a reasonable doubt and that I would not have to prove anything;
- d. that I would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that I was guilty;
- e. that I would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if I could not afford to hire a lawyer, the court would appoint one for me free of charge;
- f. that through my lawyer I would have the right to confront and cross-examine the witnesses against me;
- g. that I could testify in my own defense if I wanted to and I could subpoena witnesses to testify in my defense if I wanted to; and

- h. that I would not have to testify or otherwise present any defense if I did not want to and that if I did not present any evidence, the jury could not hold that against me.
- 4. I understand that if I plead guilty, there will be no trial and I would be giving up all of the rights listed above.
- 5. I understand that if I decide to enter a plea of guilty, the judge will ask me questions under oath and that if I lie in answering those questions, I could be prosecuted for the crime of perjury, that is, for lying under oath.
- 6. I understand that if I plead guilty, I have given up my right to appeal, except as set forth in the appellate waiver provisions of my plea agreement.
- 7. Understanding that I have all these rights and that by pleading guilty I am giving them up, I still wish to plead guilty.
- 8. I acknowledge that no one has promised me what sentence the Court will impose. I am aware and have discussed with my attorney that, at sentencing, the Court will calculate the Sentencing Guidelines range (including whether any departures apply), and then, in determining my sentence, will consider the Guideline range and all relevant policy statements in the Sentencing Guidelines, along with other sentencing factors set forth in 18 U.S.C. § 3553(a), including
 - (1) the nature and circumstances of the offense and my personal history and characteristics;
 - (2) the need for the sentence imposed—(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;
 - (3) the kinds of sentences available;
 - (4) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and

(5) the need to provide restitution to any victims of the offense.

PETER N. STOLL, III

Defendant

ROCCO CIPPARONE

Counsel for the Defendant

Dated: <u>July 14, 2023</u>