

Eastern District of Kentucky

FILED

JAN 11 2021

AT LEXINGTON
ROBERT R. CARR
CLERK U.S. DISTRICT COURT

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON**

CRIMINAL ACTION NO. * 21-CR-02-KKC-1

UNITED STATES OF AMERICA

PLAINTIFF

V.

PLEA AGREEMENT

JANAINA NASCIMENTO

DEFENDANT

* * * * *

1. Pursuant to Federal Rule of Criminal Procedure 11(c), the Defendant will enter a guilty plea to the sole Count of the Information, charging a violation of 21 U.S.C. §§ 331(a) and 333(a)(1), introduction into interstate commerce of a misbranded device.

2. The essential elements of the Count are:

(a) The Defendant introduced or delivered for introduction, or caused such introduction or delivery, into interstate commerce a device, as defined in 21 U.S.C. § 321(h); and

(b) The device was misbranded, as defined in 21 U.S.C. § 352.

3. As to the charge, the United States could prove the following facts that establish the essential elements of the offense beyond a reasonable doubt, and the Defendant admits these facts:

(a) At all relevant times, the Defendant operated Lion Heart Surgical Supply, LLC ("Lion Heart"), a distributor of surgical supplies and devices located in Hollywood, Florida. In or around January 2019, the Defendant caused Lion Heart to purchase 70 boxes of a surgical device that the seller, Pure Care Traders F.Z.E. of the United Arab Emirates, represented to be Ethicon SURGICEL® Original

Hemostat (“SURGICEL”). SURGICEL is a sterile absorbable hemostat used in surgical procedures to control bleeding.

(b) In or around February 2019, the Defendant sold the SURGICEL purchased from Pure Care Traders to R.W., another distributor of surgical supplies in Florida. Upon receipt of the SURGICEL, R.W. advised the Defendant that the product was not authorized to be sold in the United States, and directed the Defendant’s attention to a warning on the box that stated “NOT FOR RE-EXPORT TO THE U.S.A.” The Defendant disagreed with R.W. responding “You are welcome to contact [the FDA] about [these] products they were imported legally as everything we deal with. Products are FDA approved. Products are legally imported to the USA.” R.W. returned the product to Lion Heart.

(c) In or around April 2019, the Defendant re-sold the SURGICEL purchased from Pure Care Traders to XS Supply, LLC, another distributor of surgical supplies in Florida. Before shipping the product to XS Supply, the Defendant removed the individual packages of SURGICEL from their boxes which contained the warning “NOT FOR RE-EXPORT TO THE U.S.A.”

(d) In or around April 2019, XS Supply sold the SURGICEL it had purchased from Lion Heart to the University of Kentucky Medical Center in Lexington, Kentucky, in the Eastern District of Kentucky. After complaints from one or more surgeons about the product, an investigation determined that the SURGICEL sold by the Defendant to XS Supply, and which was then sold to the University of Kentucky, was counterfeit product manufactured and prepared in an establishment not registered with the Food and Drug Administration (FDA) pursuant to 21 U.S.C. § 360.

4. The statutory punishment for the sole Count is imprisonment for not more than 1 year, and a fine of not more than \$1,000, and a term of supervised release of not more than 1 year. A mandatory special assessment of \$25 applies, and the Defendant will pay this assessment to the U.S. District Court Clerk at the time of the entry of the plea.

5. Pursuant to Rule 11(c)(1)(B), the United States and the Defendant recommend the following sentencing guidelines calculations, and they may object to or argue in favor of other calculations. This recommendation does not bind the Court.

(a) United States Sentencing Guidelines (U.S.S.G.), November 1, 2018, manual, will determine the Defendant's guidelines range.

(b) Pursuant to U.S.S.G. § 1B1.3, the Defendant's relevant conduct includes the acts described above in Paragraph 3 and in the discovery provided to the Defendant and the United States Probation Office.

(c) Pursuant to U.S.S.G. § 2N2.1, the base offense level is 6.

(d) Pursuant to U.S.S.G. § 3E1.1 and unless the Defendant commits another crime, obstructs justice, or violates a court order, decrease the offense level by 2 levels for the Defendant's acceptance of responsibility. If the offense level determined prior to this 2-level decrease is level 16 or greater, the United States will move at sentencing to decrease the offense level by 1 additional level based on the Defendant's timely notice of intent to plead guilty.

(e) Pursuant to U.S.S.G. § 5E1.1, restitution is not mandatory, but shall be imposed as a condition of supervised release in an amount to be determined at sentencing.

6. No agreement exists about the Defendant's criminal history category pursuant to U.S.S.G. Chapter 4.

7. The Defendant will not file a motion for a decrease in the offense level based on a mitigating role pursuant to U.S.S.G. § 3B1.2 or a departure motion pursuant to U.S.S.G. Chapter 5, Parts H or K. The United States reserves the right to seek a sentence above the advisory sentencing guidelines range as determined by the Court at sentencing.

8. The Defendant waives the right to appeal the guilty plea, conviction, and sentence. Except for claims of ineffective assistance of counsel, the Defendant also waives the right to attack collaterally the guilty plea, conviction, and sentence.

9. The United States will recommend releasing the Defendant on the current conditions for future court appearances if the Defendant does not violate the terms of the order setting conditions of release.

10. The Defendant agrees to cooperate fully with the United States Attorney's Office by making a full and complete financial disclosure. Within 30 days of pleading guilty, the Defendant agrees to complete and sign a financial disclosure statement or affidavit disclosing 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, and disclosing any transfer of assets that has taken place within three years preceding the entry of this plea agreement. The Defendant will submit to an examination, which may be taken under oath and may include a polygraph examination. The Defendant will not encumber, transfer, or dispose of any monies, property, or assets under the Defendant's custody or control without written approval from the United States Attorney's Office. If the Defendant is ever incarcerated in connection with this case, the Defendant will participate in the Bureau of Prisons Inmate Financial Responsibility Program, regardless of whether the Court specifically directs participation or imposes a schedule of payments. If the Defendant fails to comply with any of the provisions of this paragraph, the United States, in its discretion, may refrain from moving the Court pursuant to U.S.S.G. § 3E1.1(b) to reduce the offense level by one additional level, and may argue that the Defendant should not receive a two-level reduction for acceptance of responsibility under U.S.S.G. § 3E1.1(a).

11. The Defendant understands and agrees that, pursuant to 18 U.S.C. § 3613, whatever monetary penalties are imposed by the Court will be due and payable immediately and subject to immediate enforcement by the United States, unless otherwise ordered by the Court or the Probation Office. If the Court imposes a schedule of payments, the Defendant agrees that it is merely a minimum schedule of payments and not the only method, nor a limitation on the methods, available to the United States to enforce the judgment. The Defendant waives any requirement for demand of payment on any fine, restitution, or assessment imposed by the Court and agrees that any unpaid obligations will be submitted to the United States Treasury for offset. The Defendant authorizes the United States to obtain the Defendant's credit reports at any time. The Defendant authorizes the U.S. District Court to release funds posted as security for the Defendant's appearance bond in this case, if any, to be applied to satisfy the Defendant's financial obligations contained in the judgment of the Court.

12. If the Defendant violates any part of this Agreement, the United States may void this Agreement and seek an indictment for any violations of federal laws, and the Defendant waives any right to challenge the initiation of additional federal charges.

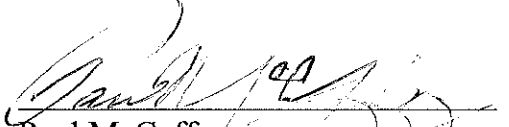
13. This document and the supplement contain the complete and only Plea Agreement between the United States Attorney for the Eastern District of Kentucky and the Defendant. The United States has not made any other promises to the Defendant.

14. This Agreement does not bind the United States Attorney's Offices in other districts, or any other federal, state, or local prosecuting authorities.

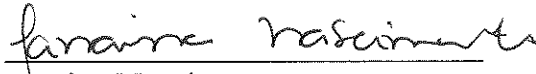
15. The Defendant and the Defendant's attorney acknowledge that the Defendant understands this Agreement, that the Defendant's attorney has fully explained this Agreement to the Defendant, and that the Defendant's entry into this Agreement is voluntary.

ROBERT M. DUNCAN, JR.
UNITED STATES ATTORNEY

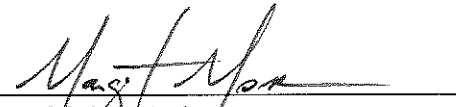
Date: 1/8/2021

By: 
Paul McCaffrey
Assistant United States Attorney

Date: 01/06/2021


Janaina Nascimento
Defendant

Date: Jan 6, 2021


David C. Markus
Margot Moss
Attorneys for Defendant