ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA	NO.
v.	3-22CR0378-N
RAYNALDO RIVERA ORTIZ JR.	

INDICTMENT

The Grand Jury Charges:

At all times material to the indictment:

BACKGROUND

The Defendant

1. **RAYNALDO RIVERA ORTIZ JR. ("Ortiz")** was an anesthesiologist who frequently provided medical services to surgical patients at a surgical center located in Dallas ("Facility-1"), as well as other surgical facilities in the area. Ortiz was, since 1991, a licensed anesthesiologist in the State of Texas.

The Regulatory Agency

2. The United States Food and Drug Administration (FDA) was the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs were safe and effective for their intended uses and bore labeling that contained true and accurate information. FDA's responsibilities included regulating the manufacture and distribution of drugs,

including prescription drugs, shipped and received in interstate commerce, as well as the labeling of such drugs. FDA carried out its responsibilities by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399f, and other pertinent laws and regulations, including the Federal Anti-Tampering Act, 18 U.S.C. § 1365.

3. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles…intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B) and (C). The Federal Anti-Tampering Act defined a "consumer product" to include "any drug" as defined in the FDCA. 18 U.S.C. § 1365(h)(1)(A).

4. The FDCA described an adulterated drug as including a drug where "any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor." 21 U.S.C. § 351(d).

Ortiz and Facility-1

5. A substantial portion of Ortiz's work was performed at Facility-1, and a substantial portion of his income was derived from his work at Facility-1.

6. Ortiz had a disciplinary history with the Texas Medical Board related to incidents of both personal and professional misconduct.

7. Starting in or around late 2020, the Texas Medical Board investigated Ortiz related to an incident where a patient had experienced an adverse event while under Ortiz's care at a surgery center in Garland, Texas ("Facility-2"). Ortiz resigned from the medical staff of Facility-2 over the incident.

8. In or around May 2022, another incident occurred at Facility-1 involving a patient under Ortiz's that experienced an adverse event. Facility-1 began an internal investigation into the May 2022 incident.

Adverse Event Incidents at Facility-1

9. Multiple incidents of cardiac emergencies, which at the time were unexplained, occurred between May and August 2022 at Facility-1 during otherwise routine surgeries. Ortiz performed services at Facility-1 on or about days leading up to the cardiac incidents, but was not the anesthesiologist for any of the cardiac emergencies.

10. On or about June 21, 2022, M.K., a 55-year-old female anesthesiologist who performed services at Facility-1, took a bag of lactated ringer's intravenous solution (an "IV bag") from Facility-1 home with her to hydrate herself following an illness. Very shortly after she administered the IV bag to herself, she suffered a cardiac episode and died. An autopsy revealed the unexplained presence of a pharmaceutical called bupivacaine in her bloodstream.

11. On or about August 4, 2022, T.Y., a 56-year-old female, was in Operating Room 1 at Facility-1 for a scheduled surgery. Ortiz was not the anesthesiologist for the procedure. At or around 12:11 p.m., a nurse obtained an IV bag from Facility-1's "warmer," a device that warms IV bags for use in surgery. After that IV bag was "placed"—meaning attached to the patient via a tube with a needle inserted into the patient's vein—T.Y. developed hypertension and cardiac arrhythmias. She was given emergency treatment and transferred to an emergency facility.

12. On or about August 9, 2022, J.E., a 78-year-old male, was in Operating Room 4 for a scheduled surgery. Ortiz was not the anesthesiologist for the procedure. At or around 10:54 a.m., a staff member exited Operating Room 4 and retrieved an IV bag from the warmer. After the bag was placed, J.E.'s blood pressure spiked at or around 11:02 a.m. Emergency measures were employed, and J.E. was transferred to an emergency facility.

13. On or about August 19, 2022, K.P., a 54-year-old female, was in Operating Room 2 at Facility-1 for a scheduled surgery. Ortiz was not the anesthesiologist for the procedure. At or around 10:42 a.m., a staff member exited Operating Room 2 and retrieved an IV bag from the warmer. After the bag was placed, K.P.'s blood pressure spiked at or around 11 a.m. Emergency measures were employed, and K.P. was transferred to an emergency facility.

14. On or about August 24, 2022, J.A., an 18-year-old male, was in Operating Room 1 at Facility-1 for a scheduled surgery. Ortiz was not the anesthesiologist for the procedure. During the surgery, unexpected complications arose after a second IV bag was used and J.A.'s blood pressure spiked. CPR was employed to save J.A.'s life. J.A. was transferred to an emergency medical facility.

15. The adverse events that T.Y., J.E., K.P., and J.A. experienced were similar to each other and unusual, and had no apparent explanation to the medical professionals involved.

16. On or about August 25, 2022, Facility-1 staff discovered two IV bags in the warmer with small puncture holes in their outside wrappers. Chemical testing of the liquid in those IV bags revealed the presence of bupivacaine, which is not an ingredient included in the labeling for lactated ringer's intravenous solution.

17. Ortiz had access to the IV bags in Facility-1's warmer. Ortiz had access to a variety of pharmaceuticals, including the ones found in the IV bags described in the preceding paragraph.

18. Although Ortiz was not responsible for stocking the warmer with IV bags, Ortiz placed IV bags in the warmer prior to each of the above surgeries.

COUNTS ONE THROUGH FIVE
Tampering with Consumer Products
(Violation of 18 U.S.C. § 1365(a), (a)(3), (a)(4))

19. The Grand Jury re-alleges and incorporates by reference all of the allegations set out in Paragraphs 1 to 18 of this Indictment as though fully set forth herein.

20. On or about the dates described below, in the Dallas Division of the Northern District of Texas and elsewhere, the defendant, **RAYNALDO RIVERA ORTIZ JR.**, with reckless disregard for the risk that another person was placed in danger of death or bodily injury and under circumstances that manifested extreme indifference to such risk, tampered with a consumer product that affected interstate or foreign commerce—namely, lactated ringer's IV bags used in surgical procedures that had traveled in interstate commerce. In four instances, as listed below, the use of the tampered IV bags resulted in serious bodily injury:

Count	Date of Tampering (on or about):	Result:
1	August 4, 2022	Serious Bodily Injury
2	August 9, 2022	Serious Bodily Injury
3	August 16, 2022	Serious Bodily Injury
4	August 19, 2022	Serious Bodily Injury
5	August 23, 2022	

All in violation of 18 U.S.C. § 1365(a), (a)(3), (a)(4).

COUNTS SIX THROUGH TEN

Adulteration of Drug
(Violation of 21 U.S.C. §§ 331(k) and 333(b)(7))

21. The Grand Jury re-alleges and incorporates by reference all of the allegations set out in Paragraphs 1 through 18 of this Indictment as though fully set forth herein.

22. On or about the dates described below, in the Dallas Division of the Northern District of Texas and elsewhere, the defendant, **RAYNALDO RIVERA ORTIZ JR.**, knowingly and intentionally adulterated a drug—namely, lactated ringer's IV bags used in surgical procedures. These acts caused the drugs to be adulterated within the meaning of Title 21, United States Code, Section 351(d)(1) and (d)(2), and the adulteration had a reasonable probability of causing serious adverse health consequences and death to humans. The adulteration of this drug occurred after the drug had been shipped in interstate commerce, from outside of Texas to Texas, and while such drug was held for sale:

Count	Date of Adulteration (on or about):
6	August 4, 2022
7	August 9, 2022
8	August 16, 2022

9	August 19, 2022
10	August 23, 2022

All in violation of 21 U.S.C. § 331(k) and 21 U.S.C. § 333(b)(7).

A TRUE BILL

FOREPERSON

TXBN 00796455

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DALLAS DIVISION

THE UNITED STATES OF AMERICA

v.

RAYNALDO RIVERA ORTIZ JR.

INDICTMENT

18 U.S.C. § 1365(a), (a)(3), (a)(4)
Tampering with Consumer Products
(Counts 1-5)

21 U.S.C. §§ 331(k) and 333(b)(7)
Adulteration of Drug
(Counts 6-10)

10 Counts

A true bill rendered

Donalynn Henry

DALLAS FOREPERSON

Filed in open court this 5 day of October, 2022.

Defendant in Federal Custody since 9/14/2022

UNITED STATES MAGISTRATE JUDGE
Magistrate Court Number:
3:22-MJ-884-BK