AO 91 (Rev. 11/11) Criminal Complaint

UNITED STATES DISTRICT COURT

for the

Northern District of Texas

FILED
September 13, 2022
KAREN MITCHELL
CLERK, U.S. DISTRICT COURT

United States of America
v.
RAYNALDO RIVERA ORTIZ JR.

Case No. 3:22-MJ-884-BK

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of mid 2022 in the county of Dallas in the Northern District of Texas, the defendant(s) violated:

Code Section	*Offense Description*
18 U.S.C. § 1365(a);	Tampering with a Consumer Product and Tampering with a Consumer Product Causing Death and/or Serious Bodily Injury;
21 U.S.C. § 331(k);	Doing of an Act that Results in a Drug being Adulterated while Held for Sale after Shipment of the Drug in Interstate Commerce;
21 U.S.C. § 333(b)(7); and	Intentional Adulteration of a Drug having a Reasonable Probability of Causing Serious Adverse Health Consequences; and
21 U.S.C. § 351(d).	Adulteration of a Drug by Mixing or Substituting Another Substance.

This criminal complaint is based on these facts:

Please see attached affidavit in support of criminal complaint.

☑ Continued on the attached sheet.

Complainant's signature

Chad Medaris, FDA, SA
Printed name and title

Agent sworn and signature confirmed via reliable electronic means, pursuant to Fed. R. Crim. P. 4.1.

Date: September 13, 2022

Judge's signature

City and state: Dallas, Texas

RENÉE HARRIS TOLIVER, U.S. Magistrate Judge
Printed name and title

AFFIDAVIT

I, CHAD MEDARIS, a Special Agent with the United States Food and Drug Administration Office of Criminal Investigations, being duly sworn, depose and state:

1. I am a "federal law enforcement officer" within the meaning of Federal Rule of Criminal Procedure 41(a)(2)(C), that is, a government agent engaged in enforcing the criminal laws; and I am duly authorized by the Attorney General to make criminal complaints. I have been a Special Agent with FDA-OCI for approximately nine years. Prior to working for FDA-OCI, I was employed for approximately eight years as a Special Agent with the United States Office of Personnel Management-Office of the Inspector General. I have had formal training in healthcare fraud, medical device fraud, and criminal activity related to foods and drugs under federal law.

2. I am familiar with the facts and circumstances of the investigation set forth below through my personal participation; from discussions with witnesses, other federal agents, and law enforcement officers; and from my review of records and reports relating to the investigation. Because this affidavit is submitted for the limited purpose of filing a criminal complaint, I have not included details of every aspect of the investigation; rather only those facts necessary to establish probable cause.

3. This affidavit is made in support of a criminal complaint against **RAYNALDO RIVERA ORTIZ JR. ("ORTIZ")** for violations of 18 U.S.C. § 1365(a) (tampering with a consumer product and tampering with a consumer product causing death and/or serious bodily injury); 21 U.S.C. §§ 331(k) (doing an act that results in a drug being adulterated while held for sale after shipment of the drug in interstate

commerce), 333(b)(7) (intentional adulteration of a drug having a reasonable probability of causing serious adverse health consequences); and 351(d) (adulteration of a drug by mixing or substituting another substance) in the Northern District of Texas.

FACTS

4. **ORTIZ** is an anesthesiologist who frequently provides medical services to surgical patients at a surgical center located in Dallas ("Facility-1"), as well as other surgical facilities in the area. As of mid-2022, 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. **ORTIZ** has been a licensed physician in Texas since 1991.

5. **ORTIZ** has a disciplinary history both with the Texas Medical Board and with medical facilities at which he has been employed. In November 2020, **ORTIZ** was the anesthesiologist for a procedure at a surgical facility in Garland, Texas ("Facility-2"), during which the patient suffered serious complications during anesthesia. In April 2021, in lieu of having his privileges revoked by Facility-2, **ORTIZ** relinquished his medical staff membership and all clinical privileges at Facility-2.

6. On August 19, 2022, **ORTIZ** entered into an agreed order with the Texas Medical Board related to the November 2020 incident at Facility-2. The Texas Medical Board found that **ORTIZ** "did not respond to the patient's issues in an appropriate manner," "failed to document the critical events," and "did not recognize the patient's inadequate oxygenation and ventilation." **ORTIZ** agreed to a number of conditions, including submitting to extensive ongoing monitoring by a Board-selected physician at **ORTIZ**'s expense, re-taking a Medical Jurisprudence Examination given by the Texas

Medical Board, completing 16 hours of continuing medical education credits, and paying a penalty of $3,000.

7. In addition to the above, there is another, nonpublic disciplinary inquiry currently pending against **ORTIZ** at Facility-1. Specifically, Facility-1 is investigating an incident on or around May 19, 2022 during which a patient, G.A., stopped breathing under **ORTIZ**'s care during a routine procedure. According to a review commissioned by Facility-1, **ORTIZ** deviated from the standard of care by failing to maintain the patient's airway and failing to document critical aspects of the incident—conduct of a type that also noted during the November 2020 incident at Facility-2.

8. According to Facility-1 personnel, **ORTIZ** was aware of the investigation into the May 2022 incident and expressed his unhappiness with it. He expressed to a fellow doctor that Facility-1 was trying to "crucify" him. A doctor who is a principal at Facility-1, who was personally familiar with **ORTIZ**, stated that **ORTIZ** losing his work at Facility-1 would be financially "devastating" to **ORTIZ**.

9. M.K. was a 55-year-old female who worked as an anesthesiologist at Facility-1. On June 21, 2022, M.K. was at home treating herself for dehydration using an IV bag that investigators believe she had obtained from Facility-1. Minutes after the IV bag was attached to M.K. intravenously, she experienced a major medical event and died before emergency medical personnel arrived on the scene. An autopsy report that was completed on or around August 24, 2022 concluded that M.K. died of an accident involving bupivacaine toxicity, and bupivacaine was found in her bloodstream. Bupivacaine is not a drug of abuse, but is rather a common "nerve block" agent used in

regional anesthesia procedures. Bupivacaine solution is stocked at Facility-1. Medical professionals with whom I consulted as part of the investigation told me that it is highly unlikely that a medical professional knowingly injected herself with bupivacaine intravenously. Furthermore, the investigation has shown that the circumstances of M.K.'s death do not indicate that she desired to commit suicide.

10. On August 24, 2022, J.A., an 18-year-old male, went to Facility-1 for a scheduled ENT surgery. During the surgery, unexpected complications arose when J.A.'s heart started beating out of control and his blood pressure spiked to around 200/150. CPR was employed to save J.A.'s life. J.A. was transferred to an emergency medical facility. J.A. was intubated for a time and spent about four days in the hospital.

11. Agents obtained, as relevant here, four IV bags from Facility-1: two bags that were used during J.A.'s surgery and two bags that Facility-1 believed had been compromised, which Facility-1 personnel obtained from Facility-1's "warmer" device. Physical inspection of the two suspected compromised IV bags obtained from Facility-1's warmer showed small puncture holes in the clear plastic packaging bags that encase the IV bags. The bags with puncture holes appeared to have been physically tampered with, as there is no explanation for why a supposedly sealed IV bag would have a puncture hole in the packaging surrounding it.

12. Chemical testing of IV fluid from the IV bag that was attached to J.A.'s arm when the adverse event began occurring was performed by scientists at the University of North Texas in Denton. That testing confirmed the presence in the IV bag of epinephrine, which is a potent pharmaceutical stimulant that—according to health

professionals I consulted—could easily cause the cardiac symptoms J.A. experienced if it had been administered unintentionally and intravenously. The fluid in the IV bag also tested positive for bupivacaine and lidocaine. The IV bag was a "lactated ringer's" saline solution not labeled to contain epinephrine, bupivacaine, or lidocaine. The two other suspected compromised bags obtained from Facility-1's warmer also tested positive for bupivacaine and lidocaine.

13. In reviewing the medical supplies at Facility-1, I noted that there are numerous vials of epinephrine solution, as well as bupivacaine, bupivacaine / epinephrine solution, and lidocaine, at Facility-1.

14. I contacted Company-1, which is headquartered in Illinois and provides the IV bags for use at Facility-1, including the IV bags used during the surgery on J.A. and the other bags obtained from Facility-1. Company-1 confirmed that the bags in use at Facility-1 had traveled in interstate commerce. Company-1 also confirmed that IV bags provided to Facility-1 would not, to the best of Company-1's knowledge, have puncture holes in the plastic bag surrounding the IV bag nor be compromised in the manner described herein.

15. After the incident involving J.A. and the autopsy report on M.K.'s death, Facility-1 personnel identified that the incidents involving J.A. and M.K. were likely not isolated and were likely part of a pattern of intentional adulteration of IV bags used for procedures at Facility-1. Facility-1 personnel determined that there were approximately ten other suspected incidents since late May 2022 where patients experienced unexpected cardiovascular complications during otherwise unremarkable surgeries.

16. Facility-1 personnel related that the incidents generally seemed to follow the same pattern—a patient's blood pressure would spike to dangerous levels at some point during the surgery, usually after the placement of additional IV bags. Facility-1 personnel told me that medical staff were typically able to save the lives of these patients only by using the "crash cart"—a set of emergency tools used when complications arise during surgeries—and by transferring the patients to emergency medical facilities.

17. Facility-1 personnel, as well as other medical professionals with whom I consulted, told me that approximately ten cardiac events during otherwise unremarkable surgeries at Facility-1 is a high and unnatural number of anesthesia complications in such a short time period. For example, Facility personnel stated that in the year 2021, Facility-1 had five "transfers" for emergency treatment for the entire year; this year, there were five transfers for the month of August 2022 alone.

18. Facility-1 personnel also determined that the cardiac incidents seemed to occur mostly during longer surgeries, when the patients required a second or subsequent IV bag from what Facility-1 personnel call the "warmer," or a device that increases the temperature of the IV bag to prepare it for use during the surgery. The warmer is a device that looks like a stainless-steel refrigerator and holds multiple IV bags. Facility-1 personnel explained to me that the second or subsequent IV bags used during a longer surgery would as a matter of practice come from the warmer, whereas the first, room-temperature IV bag used for a procedure at Facility-1 would as a matter of practice come from a different location.

19. Facility-1 personnel determined that, while **ORTIZ** was the

anesthesiologist during numerous surgeries at Facility-1 since May 2022, none of the suspected cardiovascular complications from IV bags had occurred during any surgery in which **ORTIZ** was the anesthesiologist.

20. Facility-1 personnel told me that **ORTIZ** was informed of the disciplinary inquiry against him related to the May 19 incident on or around Tuesday, May 24, 2022, and that the first cardiac incidents in the pattern under investigation occurred on or around Thursday and Friday, May 26 and 27, 2022, later the same week. **ORTIZ** appeared at another meeting related to the May 19 incident on or around Wednesday, June 22, 2022, and there was a suspected cardiovascular incident the following week on or around Monday, June 27, 2022.

21. Other cardiovascular incidents involving suspected compromised IV bags occurred on or around July 7, 15, and 18; and August 1, 4, 9, and 19. **ORTIZ** performed services at Facility-1 on or around—or on or around days leading up to—those days. **ORTIZ** was on vacation from on or around July 23 until on or around July 28, 2022. No cardiovascular events occurred during the time he was on vacation, but the incidents started occurring again after he returned to Facility-1 from vacation on or around July 29, 2022; the first suspected incident thereafter occurred on or around August 1, 2022.

22. Facility-1 personnel told me that **ORTIZ** had access to the IV bags at Facility-1 during the time periods in question as well as epinephrine, lidocaine, and bupivacaine, none of which are controlled substances.

23. Members of law enforcement as well as personnel from Facility-1—who are familiar with **ORTIZ** and are able to identify **ORTIZ**—have reviewed portions of the

surveillance footage that was obtained from Facility-1 during the time periods under investigation. Surveillance footage exists dating from on or around August 2, 2022—earlier footage is unavailable due to the automated deletion features of the digital video recorder attached to the surveillance system. The video in question was collected and reviewed by agents directly from Facility-1's surveillance system. The review of the video that that has been completed so far implicates **ORTIZ** in the August incidents under investigation.

24. A surveillance camera is mounted at, among other locations, an elevated position on one end of the hallway where the main operating rooms are located at Facility-1 (the "OR Hall"). The warmer is also located in the OR Hall, as well as other medical and surgical supplies. The room-temperature IV bags are located in a different area of Facility-1.

25. Surveillance video shows that, on August 4, 2022 at or around 11:35 a.m., **ORTIZ** exited Operating Room 5 and walked toward the warmer with an IV bag in his hand. No one else is visible in the video from the OR Hall at this time. In the footage, **ORTIZ** walked slightly past the warmer, then turned and quickly placed the IV bag into the warmer. After he placed the IV bag in the warmer, he looked both directions in the OR Hall and then quickly walked away. A short time later, **ORTIZ** opened the warmer and looked inside, then quickly closed the warmer.

26. T.Y., a 56-year-old female, was in Operating Room 1 for a scheduled cosmetic surgery at or around the same time that **ORTIZ** placed the IV bag in the warmer on August 4. At or around 12:11 p.m., video shows a nurse obtaining an IV bag

from the warmer for T.Y.'s surgery in Operating Room 1. Surveillance video shows that no other staff member accessed the warmer between the time **ORTIZ** accessed the warmer and the time that the staff member obtained the bag at 12:11 p.m. After that IV bag was placed, T.Y. developed severe hypertension and cardiac arrhythmias at or around 12:50 p.m. She was given emergency treatment and transferred to an emergency facility.

27. On August 9, 2022, at or around 10:19 a.m., surveillance video shows **ORTIZ** exiting Operating Room 5 with an IV bag in his hand. The OR Hall was empty at the time. **ORTIZ** walked to the warmer and quickly placed the IV bag in the warmer.

28. J.E., a 78-year-old male, was in Operating Room 4 for a scheduled wrist surgery at or around the time that **ORTIZ** placed the IV bag in the warmer on August 9. At or around 10:54 a.m., a staff member exited Operating Room 4 and retrieved an IV bag from the warmer. Surveillance video shows that no other staff member accessed the warmer between the time **ORTIZ** placed the IV bag in the warmer and the time that the staff member obtained the bag at 10:54 a.m. Medical records reflect that 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.

29. On August 19, 2022, at or around 10:34 a.m., surveillance video shows **ORTIZ** exiting Operating Room 5 with an IV bag hidden under what appears to be a paper folder. **ORTIZ** walked to the warmer and appeared to swap the IV bag under the paper folder for a different IV bag in the warmer.

30. K.P., a 54-year-old female, was in Operating Room 2 for a scheduled abdominal cosmetic procedure at or around the same time that **ORTIZ** placed the IV bag

in the warmer on August 19. At or around 10:42 a.m., a staff member exited Operating Room 2 and retrieved an IV bag from the warmer. Medical records reflect that the IV bag was administered to K.P. at or around 10:45 a.m., and that 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.

31. On August 23, 2022, at or around 8:30 a.m., surveillance video shows **ORTIZ** exiting Operating Room 5 with an IV bag. **ORTIZ** walked to the warmer and placed the IV bag in the warmer.

32. On August 23, 2022, at or around 11:49 a.m., a staff member at Facility-1 rolled a cart containing a large cardboard box to the warmer and restocked the warmer with what appears to be a number of new IV bags. J.A.'s incident, described above, occurred on August 24. According to Facility-1's records, **ORTIZ** was not at Facility-1 on August 24.

33. **ORTIZ**'s behavior as described in the preceding paragraphs—according to information received during the investigation—is alarming and unusual. Facility-1 personnel stated, and other portions of the surveillance footage show, that the warmer is stocked by staff members on an as-needed basis from cardboard boxes of IV bags. Facility personnel stated that doctors at Facility-1 did not typically place single IV bags in the warmer. Furthermore, Facility-1 personnel stated that IV bags that have been taken into an operating room for use or potential use in a medical procedure would not be brought back out into the hallway and placed into the warmer.

34. A nurse at Facility-1 told investigators that she was working during a

surgery that she recalls occurring in August 2022. She stated that **ORTIZ** was the anesthesiologist for the surgery. The nurse stated that she retrieved an IV bag from the warmer to use during the surgery, but that **ORTIZ** strongly refused to use the bag and physically waived the bag off. The nurse stated that she recalled the event as unusual. The nurse also stated that, around the same time, **ORTIZ** retrieved his own IV bags for use during his procedures. The nurse said that it was unusual for **ORTIZ** to engage in this practice, as doctors at Facility-1 did not typically obtain their own IV bags.

35. Based on the facts recited above, there is a direct and likely correlation between **ORTIZ** placing IV bags in the warmer and the incidents under investigation in which patients other than **ORTIZ**'s patients experienced severe adverse medical events. There also appears to be a likely correlation between **ORTIZ** coming under scrutiny for medical errors and the adverse events affecting other anesthesiologists' patients at Facility-1.

36. Other potential explanations have been investigated but do not fit the facts that the investigation has revealed. For example, in the surveillance video, investigators have not yet located other instances of people regularly placing single IV bags in the warmer, and certainly not anyone placing IV bags in the warmer that are so closely associated with the timing of the adverse events under investigation.

37. Furthermore, as described above, the warmer is typically stocked by Facility-1 staff from large cardboard boxes filled with IV bags from Company-1. If those IV bags had been compromised, there would have been many more adverse medical events and/or the phenomenon would likely be more widespread—but Company-1 has

not received similar reports of compromised IV bags or similar reports of adverse events from other facilities in this timeframe. Similarly, if IV bags at Facility-1 coming from a location other than the warmer were responsible for these events, patients would have experienced their adverse events at the beginning of their surgeries and not the middle or end. If someone else at Facility-1 other than **ORTIZ** were responsible for these events, there would likely be some video evidence of that person handling IV bags; instead, the video evidence shows **ORTIZ** inexplicably placing single IV bags in the warmer precisely near the times of the adverse events under investigation.

CONCLUSION

38. Based on the above information, Affiant believes there is probable cause to believe that **RAYNALDO RIVERA ORTIZ JR.** committed violations of 18 U.S.C. § 1365(a) (tampering with a consumer product and tampering with a consumer product causing death and/or serious bodily injury); 21 U.S.C. §§ 331(k) (doing an act that results in a drug being adulterated while held for sale after shipment of the drug in interstate commerce), 333(b)(7) (intentional adulteration of a drug having a reasonable probability of causing serious adverse health consequences); and 351(d) (adulteration of a drug by mixing or substituting another substance) in the Northern District of Texas.

Chad Medaris, Special Agent
FDA Office of Criminal Investigations

Agent sworn and signature confirmed via reliable electronic means, pursuant to Fed. R. Crim. P. 4.1. on this 13th day of September 2022.

RENÉE HARRIS TOLIVER
UNITED STATES MAGISTRATE JUDGE