ORIGINAL

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

UNITED STATES OF AMERICA	)	
	)	Case No.
v.	)	3-21CR0442-N
	)	VIOLATIONS:
JACK RANDALL MUNN	)	21 U.S.C. Sections 331(k),
	)	333(a)(1), and 351(c) —
	)	Class A misdemeanor
	)	

INFORMATION

At all times relevant to this Information:

Defendant

1. JACK RANDALL MUNN was a pharmacist licensed by the State of Texas and was the owner of JMA Partners, Inc. ("JMA"), a Texas corporation d/b/a Guardian Pharmacy Services ("Guardian"). JMA was incorporated in 1997 and assumed the name Guardian Pharmacy Services in 2011. JMA obtained a pharmacy license from the State of Texas for compounding sterile and non-sterile drug products and conducted business at 7920 Elmbrook Drive, Suite 108, Dallas, Texas, 75247. MUNN controlled the financial and operational activities of Guardian.

The Food and Drug Administration and
The Federal Food, Drug, and Cosmetic Act

2. The United States Food and Drug Administration ("FDA") was an agency within the United States Department of Health and Human Services. The FDA had the responsibility to protect the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. One of the

primary purposes of the FDCA was to ensure that drugs for use in humans were safe and effective. The FDA's responsibilities included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

3. Under the FDCA, a "drug" included articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles other than food intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any such articles. 21 U.S.C. § 321(g)(1)(B-D).

4. Under the FDCA, "interstate commerce" included "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

5. Under the FDCA, a drug whose name was not recognized in an official drug compendium was deemed to be adulterated if its strength differed from, or its purity or quality fell below, that which the drug purported or was represented to possess. 21 U.S.C. § 351(c).

6. Under the FDCA, it was a crime to adulterate or misbrand a drug while it was held for sale after shipment of a drug component in interstate commerce. 21 U.S.C. § 331(k).

Drug Compounding

7. Compounding generally referred to the practice in which a licensed pharmacist or physician combined, mixed, or altered ingredients of a drug to create a medication. Compounded drugs were often tailored to the needs of individual patients.

8. Under the FDCA, 21 U.S.C. § 353a, compounded drugs could be exempt from three specified provisions of the FDCA: CGMP requirements (21 U.S.C. § 351(a)(2)(B)); "adequate directions for use" in labeling (21 U.S.C. § 352(f)(1)); and approval of new drugs for humans (21 U.S.C. § 355). These exceptions were applicable to compounded drugs that complied with all of the conditions set forth in 21 U.S.C. § 353a.

9. Whereas drugs compounded in compliance with the conditions set forth in 21 U.S.C. § 353a were exempt from three specific requirements under the FDCA, such compounded drugs remained subject to all of the FDCA's other applicable adulteration and misbranding provisions. For instance, compounded drugs were not exempt from the provision that a drug is adulterated if its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess, 21 U.S.C. § 351(c).

Cataract Surgery

10. A cataract was an ophthalmological condition that caused the lens of the eye to become cloudy. As a cataract grew, it would cause increasingly blurry vision, making it difficult for a person to see and carry on normal activities. Cataract surgery was a common outpatient surgical procedure in which an ophthalmologist (an eye doctor)

removed the cloudy lens of a person's eye and replaced it with an artificial lens that allowed for clear vision.

11. During cataract surgery, a doctor could administer injections of drugs into the eye, called intravitreal injections. Because of the sensitivity of the tissues that make up the eye, it was critical that any drug — including a compounded drug — that was administered to the eye was made with great care and precision. If a drug administered to the eye was not correctly made, it could cause damage to the eye, leading to impaired vision or blindness.

12. Tri-Moxi® was a trademarked name for a compounded drug made by a company outside Texas (the "Out-of-State Company"). The drug was a sterile, injectable compound which combined the active ingredients triamcinolone acetonide ("triamcinolone") and moxifloxacin hydrochloride ("moxifloxacin"). Triamcinolone was a steroid that reduced inflammation; moxifloxacin was an antibiotic that prevented infection. Tri-Moxi® kept both the active ingredients in suspension, meaning the particles would be suspended throughout a liquid solvent that could be injected into the eye, and, keeping the active ingredients safely in suspension required significant pharmaceutical skill and the correct balance of inactive ingredients. Because of the sensitivity of the tissues in the eye, sterile, injectable compounded ophthalmic drugs were high-risk drugs.

Defendant Compounded and Adulterated a Drug That Was Administered to Cataract Patients in Two Dallas Surgical Centers

13. In the fall of 2016, Guardian was contacted by a Dallas outpatient surgical center ("Surgical Center 1") to compound a version of Tri-Moxi®. Surgical Center 1 had used Tri-Moxi® made by the Out-of-State Company without incident for many prior surgeries. Nevertheless, Surgical Center 1 stopped purchasing drugs from the Out-of-State Company and contacted Guardian to make a compounded version of Tri-Moxi®. Guardian represented to Surgical Center 1 that Guardian would compound a drug that would have the same quality as Tri-Moxi®.

14. At JACK RANDALL MUNN's direction, an employee of Guardian contacted a pharmacy compounding consulting company based in Houston, Texas (the "Pharmacy Consultants"). MUNN and Guardian asked for the Pharmacy Consultants' suggestions and advice in order to compound a triamcinolone-moxifloxacin drug for Surgical Center 1. The Pharmacy Consultants suggested the use of an inactive ingredient, known as a pluronic. Guardian used a pluronic known as Poloxamer 407. After speaking with the Pharmacy Consultants, Guardian, under MUNN'S direction, created a compounded drug, containing triamcinolone and moxifloxacin (hereafter, "Guardian's trimoxi"), with components purchased through interstate commerce. Guardian's trimoxi initially contained a concentration of poloxamer 407 that was 12% weight by volume. The concentration of Poloxamer 407 was excessive and caused Guardian's trimoxi to fall below the quality of the drug that Guardian represented it would make for Surgical Center 1.

15. In November 2016, Surgical Center 1 used Guardian's trimoxi in approximately 15 cataract surgeries.

16. Surgical Center 2 was another outpatient surgical center in Dallas that performed cataract surgeries and that had been using the Out-of-State Company's Tri-Moxi®. In January 2017, JACK RANDALL MUNN represented that Guardian was successfully compounding Guardian's trimoxi for other surgical centers and that Guardian would be able to compound the drug for Surgical Center 2. MUNN represented that Guardian's trimoxi would have the same quality as Tri-Moxi®.

17. During January and February 2017, at MUNN's direction, Guardian compounded Guardian's trimoxi for Surgical Center 2. Guardian's trimoxi contained an excessive concentration of poloxamer, ranging from 6 to 12 % weight by volume. Surgical Center 2 used Guardian's trimoxi in approximately 85 cataract surgeries during January and February 2017. The excessive concentration of Poloxamer 407 caused the quality of Guardian's trimoxi to fall below that of the drug that MUNN had represented Guardian would compound for Surgical Center 2.

— NOTHING FURTHER ON THIS PAGE —

The United States Attorney charges:

Count One
Adulteration of a Drug
(Violation of 21 U.S.C. §§ 331(k), 333(a)(1), and 351(c))

The United States Attorney re-alleges and incorporates by reference herein the allegations contained in Paragraphs 1-17 of this Information.

18. In or around January and February of 2017, in the Northern District of Texas, the defendant, JACK RANDALL MUNN did and caused an act with respect to a drug — namely, Guardian's trimoxi — while such drug was held for sale after shipment of a drug component in interstate commerce, that resulted in such drug being adulterated, namely: JACK RANDALL MUNN represented that Guardian would compound Guardian's trimoxi, a drug that was not recognized in an official compendium; and Guardian's trimoxi was compounded with an excessive concentration of Poloxamer 407, making the strength of Guardian's trimoxi differ from, and its purity and quality fall below, that which the drug purported and was represented to possess.

— NOTHING FURTHER ON THIS PAGE —

All in violation of Title 21, United States Code, Sections 331(k), 333(a)(1), and 351(c).

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