UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA	)	**CRIMINAL NO. _____**
	)	
v.	)	
	)	
	)	**VIOLATION:**
DAVID LEE ALLEN, and	)	**21 USC §§ 331(k), 333(a) (1)**
WILLIAM TIMOTHY ROGERS	)	**and 351(a)(1), (a)(2)(A)**
	)	**(adulterated drugs)**

INFORMATION

THE UNITED STATES CHARGES:

At all times relevant to this Information:

The Federal Food, Drug, and Cosmetic Act

1. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), by ensuring that drugs intended for use in humans were safe and effective for their intended uses, and by ensuring that the labeling of such drugs bore true and accurate information. Pursuant to that responsibility, the FDA published and administered regulations relating to the approval, manufacture, labeling and distribution of drugs.

2. Under the FDCA, the term "drug" included: (1) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or

other animals; and (2) articles (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(g)(1)(B) and (C).

3. Under the FDCA, it was illegal to do or to cause to be done any act with respect to a drug if the act was done while the drug was held for sale after shipment of one or more of its components in interstate commerce, and the act resulted in the drug being adulterated. 21 U.S.C. § 331(k).

4. A drug was adulterated if consisted in whole or in part of any filthy, putrid, or decomposed substance. 21 U.S.C. § 351(a)(1).

5. A drug was adulterated if it was prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 351(a)(2)(A).

Background

6. Advanced Specialty Pharmacy, d/b/a Meds IV ("Meds IV"), was a compounding pharmacy located in Birmingham, Alabama. Meds IV compounded various drugs for human use, including an intravenous drug known as total parenteral nutrition ("TPN"). TPN was liquid nutrition administered intravenously to patients who could not or should not receive their nutrition through eating.

7. The TPN compounded and distributed by Meds IV was a drug within the meaning of 21 U.S.C. § 321(g)(1).

Defendants

8. David Lee Allen was the pharmacist-in-charge of Meds IV. Allen supervised all compounding at Meds IV, and was specifically responsible for reviewing and approving TPN formulations. Allen was also responsible for filling the individual prescriptions Meds IV received for patient-specific TPN products.

9. William Timothy Rogers was a licensed pharmacist and the president of Meds IV. Rogers was ultimately responsible for overseeing all of the day-to-day operations of Meds IV.

Serratia marcescens Outbreak

10. Prior to the end of 2010, Meds IV had been compounding TPN using, among other ingredients, a commercially available amino acid solution.

11. Beginning in or around February of 2011, Meds IV compounded its own amino acid solution, which it then mixed with other ingredients to form TPN.

12. One or more of the components Meds IV used to compound its own amino acid solution was shipped to Meds IV from outside the state of Alabama.

13. The amino acid solution was prepared outside a laminar airflow workbench, and was kept unrefrigerated, in a room that was not sterile, in a large pot sitting on the floor, sometimes overnight, before it was sterilized and used.

14. On or around February 25, 2011, Meds IV shipped TPN which had been compounded from its own amino acid solution ("Lot 2011-0255") to area hospitals.

15. On March 1, 2011, Meds IV sent a sample of the TPN which contained amino acid solution from Lot 2011-0255 to an outside laboratory for sterility and endotoxin testing.

16. On March 4, 2011, the outside laboratory notified Meds IV that the sample tested positive for endotoxins. Patients at local hospitals continued receiving the TPN.

17. On March 8, 2011, the outside laboratory notified Meds IV that a second sample of the TPN which contained amino acid solution from Lot 2011-0255 had tested positive for endotoxins. Meds IV discarded the amino acid solution from Lot 2011-0255, and compounded a new amino acid solution ("Lot 2011-0288"), and compounded TPN using amino solution acid from Lot 2011-0288. Patients at local hospitals continued receiving TPN which contained amino acid solution from Lot 2011-0288.

18. *Serratia marcescens* ("*S. marcescens*") is gram-negative bacteria that can cause bloodstream infections if introduced into the bloodstream through contaminated medications. These infections can cause serious medical complications, including death, because *S. marcescens* is resistant to many antibiotics.

19. Between March 5 and 15, 2011, nine patients at various Birmingham-area hospitals who developed bloodstream infections caused by *S. marcescens* died. Several other hospital patients developed *S. marcescens* bloodstream infections but survived. All of these patients had been given TPN that was compounded and distributed by Meds IV. While a number of the patients who died had underlying medical conditions which may have contributed to their deaths, medical records of some patients suggest that the *S. marcescens* bloodstream infections were also a significant factor.

20. Meds IV was notified on March 14, 2011, by a hospital in the Birmingham area, that four patients receiving TPN had tested positive for *S. Marcescens*. The TPN was compounded and distributed by Meds IV. This notification was the first time Meds IV was informed of a link between its TPN and patients testing positive for *S. Marcescens*. On or about March 16, 2011, Meds IV

began notifying some customers that compounding of TPN was suspended until further notice.

21. During an inspection at Meds IV starting on March 22, 2011, United States Centers for Disease Control and Prevention ("CDC") investigators found *S. Marcescens* that was indistinguishable to the outbreak strain on a tap-water faucet, in an open container of amino acid powder, and on the surface of mixing equipment that had been used to make TPN.

22. FDA and investigators from CDC linked *S. marcescens* to TPN that had been compounded by Meds IV.

COUNTS ONE THROUGH TWO
21 U.S.C. §§ 331(k), 333(a)(1)
(Adulterating Drugs While Held for Sale)

The allegations set forth in paragraphs 1 through 22 of this Information are realleged as if fully set forth in these counts.

On or about the dates listed below, each constituting a separate count in this information, within the Northern District of Alabama, the defendants,

DAVID LEE ALLEN, and
WILLIAM TIMOTHY ROGERS

committed and caused to be committed an act, namely, compounding the drug total parenteral nutrition ("TPN"), that caused the drug and its components to become

adulterated while held for sale after shipment of one or more of their components in interstate commerce in the following ways:

(a) It consisted in whole or in part of a filthy, putrid, or decomposed substance, namely *Serratia Marcescens*;

(b) It was prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

COUNT	DATE COMPOUNDED	AMINO ACID LOT #
1	2/25/2011	2011-0255
2	3/8/2011	2011-0288

All in violation of Title 21, United States Code, Sections 331(k), 333(a)(1), and 351(a)(1), (a)(2)(A).

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