RDW2012R00628

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Criminal No. 16-
	:	
v.	:	21 U.S.C. §§ 331(a), 333(a)(1), and 352(c)
	:	
PHARMACEUTICAL INNOVATIONS, INC.	:	
	:	
	:	INFORMATION

The United States Attorney for the District of New Jersey charges:

COUNT ONE
(Shipment of Adulterated Devices)

Background

At all times relevant to this Information:

1. Defendant PHARMACEUTICAL INNOVATIONS, INC. ("PHARMACEUTICAL INNOVATIONS"), located in Newark, New Jersey, was a manufacturer of medical devices, as defined by 21 U.S.C. § 321(h).

2. Among other devices, PHARMACEUTICAL INNOVATIONS manufactured an ultrasound transmission gel known as Other-Sonic Generic Ultrasound Transmission Gel ("Other-Sonic Gel"). Other-Sonic Gel was used to facilitate ultrasound or imaging procedures. Other-Sonic Gel could be applied directly on the patient or could be applied to a probe used in ultrasound or imaging procedures, which then contacted the patient. PHARMACEUTICAL INNOVATIONS distributed Other-Sonic Gel to customers, such as hospitals, in the United States and in foreign countries.

3. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting 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 purpose of the FDCA was to ensure that medical devices intended for use in the treatment of human beings are safe and effective for their intended uses.

4. The FDCA, among other things, governed the manufacture and interstate distribution of medical devices for human use.

5. Other-Sonic Gel was a medical device under the FDCA.

6. Under the FDCA, a medical device is "adulterated" if its purity and quality fall below that which it purports or is represented to possess.

7. Under the FDCA, it is a prohibited act to introduce or deliver for introduction into interstate commerce any medical device that is adulterated.

8. *Pseudomonas aeruginosa* and *Klebsiella oxytoca* are bacterial pathogens that could colonize or lead to the accumulation of bacteria without any signs of infection and cause a range of medical conditions, including serious or potentially life-threatening infections.

9. In or about July 2011, PHARMACEUTICAL INNOVATIONS manufactured a lot of Other-Sonic Gel with the lot number 090111.

10. From in or about October 2011 to in or about February 2012, PHARMACEUTICAL INNOVATIONS sold and shipped in interstate commerce Other-Sonic Gel from lot 090111.

11. On or about February 15, 2012, the FDA received a report from a hospital in Michigan that 16 surgical patients were infected with *Pseudomonas aeruginosa*. The hospital determined that the most likely source of the bacteria was Other-Sonic Gel, including lot 090111.

12. On or about February 23, 2012, the FDA collected a sample of lot 090111 from PHARMACEUTICAL INNOVATIONS. FDA's analysis of the sample revealed the presence of significant amounts of *Pseudomonas aeruginosa.*

13. On or about February 27, 2012, PHARMACEUTICAL INNOVATIONS sent a sample from lot 090111 to its own testing facility, which reported that the sample contained *Pseudomonas aeruginosa.*

14. From in or about October 2011 to in or about February 2012, in Essex County, in the District of New Jersey, and elsewhere, defendant

PHARMACEUTICAL INNOVATIONS, INC.

introduced and delivered for introduction into interstate commerce adulterated devices, that is, ultrasound transmission gel, which were adulterated, in that such devices' purity and quality fell below that which they purport or are represented to possess, because they were contaminated with bacterial pathogens, specifically *Pseudomonas aeruginosa.*

In violation of Title 21, United States Code, Section 331(a), Section 333(a)(1), and Section 351(c).

COUNT TWO
(Shipment of Adulterated Devices)

15. The allegations of paragraphs 1 through 13 are incorporated herein by reference.

16. In or about April 2012, PHARMACEUTICAL INNOVATIONS made a lot of Other-Sonic Gel with lot number 040212.

17. Lot 040212 was contaminated with *Pseudomonas aeruginosa* and *Klebsiella oxytoca.*

18. On or about April 17, 2012, PHARMACEUTICAL INNOVATIONS shipped Other-Sonic Gel from lot 040212 in interstate commerce.

19. On or about April 17, 2012, in Essex County, in the District of New Jersey, and elsewhere, defendant

PHARMACEUTICAL INNOVATIONS, INC.

introduced and delivered for introduction into interstate commerce adulterated devices, that is, ultrasound transmission gel, which were adulterated, in that such devices' purity and quality fell below that which they purport or are represented to possess, because they were contaminated with bacterial pathogens, specifically *Pseudomonas aeruginosa* and *Klebsiella oxytoca.*

In violation of Title 21, United States Code, Section 331(a), Section 333(a)(1), and Section 351(c).

FORFEITURE ALLEGATION

1. The allegations contained in all paragraphs of this Information are hereby re-alleged and incorporated by reference for purpose of noticing forfeiture pursuant to Title 21, United States Code, Section 853(p) and Title 28, United States Code, Section 2461.

2. The United States hereby gives notice to the defendant that, upon conviction of the offense charged in this Information, the government will seek forfeiture of lots 090111 and 040212 of Other-Sonic Generic Ultrasound Transmission Gel, which were medical devices introduced into interstate commerce, contrary to the provisions of Title 21, United States Code, Section 331.

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), to seek forfeiture of any other property of said defendant up to the value of the above forfeitable property, that is, $50,000.

Paul J. Fishman

PAUL J. FISHMAN
United States Attorney

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UNITED STATES OF AMERICA

v.

PHARMACEUTICAL INNOVATIONS, INC.

INFORMATION

21 U.S.C. §§ 331(a), 333(a)(1), and 352(c)

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