

U.S. DISTRICT COURT
N.D. OF N.Y.
FILED

AUG 1 2009

LAWRENCE K. BAERMAN, CLERK
ALBANY

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA

INFORMATION

v.

**Vio: 21 U.S.C. §§ 331(k), 352(i)(3), and
333(a)(1) (Misbranding Drugs),
18 U.S.C. § 2**

DOUGLAS M. HARGRAVE, MD

Criminal No. 09-CR- (426)

Defendant.

1 Misdemeanor Count

INFORMATION

THE UNITED STATES ATTORNEY CHARGES:

1. THE PLASTIC SURGERY GROUP, LLP, (hereinafter "TPSG") is a limited liability partnership whose members consisted of professional corporations organized under the laws of New York State. Defendant DOUGLAS M. HARGRAVE, MD, was the principal of one such professional corporation. The medical offices of TPSG are located in Albany, in the State and Northern District of New York.

2. TPSG provides a number of plastic surgery treatments to patients, including Botulinum Toxin Type A injections for the treatment of facial wrinkles. BOTOX®/BOTOX® Cosmetic, a product manufactured by Allergan, Inc., is the only Botulinum Toxin Type A product approved by the United States Food and Drug Administration ("FDA") for use on humans for the treatment of facial wrinkles.

3. Beginning in or about January 2004, TPSG stopped purchasing BOTOX®/BOTOX® Cosmetic and began exclusively purchasing, for use in its practice, a form of Botulinum Toxin Type A distributed by Toxin Research International, Inc. ("TRI") of Arizona (hereinafter, "TRI-toxin") that was not approved by the FDA.

4. From approximately February 2004 to December 2004, defendant DOUGLAS M. HARGRAVE, MD, injected approximately twenty-five (25) patients seeking treatment for facial wrinkles with TRI-toxin. During this time period, the patients believed that they were being injected with FDA-approved BOTOX®/BOTOX® Cosmetic.

COUNT ONE

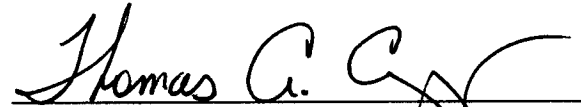
5. On or about March 12, 2004, in the Northern District of New York, defendant DOUGLAS M. HARGRAVE, MD, misbranded and caused the misbranding of a drug, namely, Botulinum Toxin Type A manufactured by Toxin Research International, Inc. in Arizona ("TRI-toxin"), while it was held for sale and after shipment in interstate commerce, in that defendant DOUGLAS M. HARGRAVE, MD, in connection with the injection of a patient, offered the TRI-

toxin for sale to a patient under the name of another drug, namely BOTOX®/ BOTOX®
Cosmetic.

All in violation of Title 21 U.S.C. §§ 331(k), 352(i)(3), 333(a)(1), and 18 U.S.C. §2.

ANDREW T. BAXTER
UNITED STATES ATTORNEY
NORTHERN DISTRICT OF NEW YORK

BY:



Thomas A. Capezza
Assistant United States Attorney
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Special Assistant United States Attorney