



# Department of Justice

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## **ALBANY PLASTIC SURGERY GROUP PLEADS GUILTY IN CONNECTION WITH USE OF UNLICENSED "BOTOX" SUBSTITUTE ON UNSUSPECTING PATIENTS**

### *Five Physicians, Administrator and Supervisory Nurse Admit Misdemeanor Violations*

ALBANY, NEW YORK—THE PLASTIC SURGERY GROUP, LLP ("TPSG"), of Albany, New York, pled guilty today to one felony count of misbranding drugs in connection with the use, on unsuspecting patients, of a cheaper "BOTOX" substitute that was not approved by the Food and Drug Administration. TPSG admitted that, with intent to mislead, it injected patients with Botulinum Toxin Type A manufactured by Toxin Research International, Inc. of Arizona ("TRI-toxin") misbranded under the name of another drug, namely BOTOX®/BOTOX® Cosmetic. Five physicians, the practice administrator, and the Supervisory Nurse of TPSG also pled guilty today, to strict-liability misdemeanor misbranding violations arising from the same conduct in 2004.

TPSG entered its guilty plea to felony charges before Senior U.S. District Judge Thomas J. McAvoy, who will sentence THE PLASTIC SURGERY GROUP, LLP on December 14, 2009 at 1:30 p.m. in Albany, New York. TPSG faces a fine of up to \$500,000 and an order to pay restitution to about 150 patients, who paid a total of approximately \$100,000 for TRI-toxin injections while believing they were being treated with genuine BOTOX®. Pleading guilty to misdemeanor charges before U.S. Magistrate Judge David R. Homer were:

- Dr. William F. DeLuca, Jr., 58 of Latham, NY;
- Dr. Steven Lynch, 65 of Slingerlands, NY;
- Dr. Douglas M. Hargrave, 56 of Delmar, NY;
- Dr. John D. Noonan, 62 of Slingerlands, NY;
- Dr. Jeffrey L. Rockmore, 42, of Delmar, NY;
- Practice Administrator Peter M. Slattery, 48 of West Sand Lake, NY; and
- Supervisory Nurse Susan Knott (nee: Cole), 49, of Latham, NY.

The individual defendants face up to one year in prison and fines of up to \$100,000 when they are sentenced before Judge Homer on December 15, 2009 at 1:30 p.m. in Albany.

Gary Tunkavige, Acting Special Agent-in-Charge of the Food and Drug Administration Office of Criminal Investigations and Office of Chief Counsel, stated: "The FDA will continue to work tirelessly, on its own and in cooperation with the Department of Justice, to prevent and deter the illegal sale and use of unlicensed and unapproved drugs." United States Attorney Andrew T. Baxter stated: "The Plastic Surgery Group of Albany misled about 150 patients who believed they were being treated with FDA-approved BOTOX® when, in fact, they were being injected with a cheaper, unlicensed substitute. The dispositions announced today reflect a

considered assessment of the nature and seriousness of that criminal conduct in the context of the positive contributions that the doctors and employees of this plastic surgery group have otherwise made to the Albany community over many years.”

In entering its guilty plea, an attorney for TPSG admitted that, starting in approximately February 2004, defendant TPSG stopped using the FDA-approved BOTOX® and BOTOX® Cosmetic on its patients seeking treatments with Botulinum Toxin Type A for facial wrinkles. Instead, from in or about February 2004 through December 2004, TPSG injected approximately one hundred and fifty (150) patients with TRI-toxin, which had not been approved by the FDA for use on humans. TPSG never disclosed to any patient that they were being injected with a product other than BOTOX® or BOTOX® Cosmetic. In fact, TPSG repeatedly misled patients into believing they were being treated with an FDA-approved BOTOX® substance, for example, through the use of the BOTOX® name on various brochures, promotional materials, consent forms, and invoices provided to patients. (In pleading guilty to the felony charge, TPSG admitted that its intent to mislead patients was established by the collective conduct, knowledge, and intent of its doctors and staff. The elements of the misdemeanor misbranding offenses, to which the individual defendants pled guilty, do not include intent to mislead or defraud.) Notwithstanding the lower cost of the TRI-toxin to TPSG, patients were charged the same dollar amount they were previously charged for BOTOX® treatments. About 150 patients paid a total of over \$100,000 for these treatments during the period in 2004 when TPSG was administering TRI-toxin.

The charges against the above-defendants are the result of an investigation conducted by the Food and Drug Administration, Office of Criminal Investigations. Assistant U. S. Attorney Thomas A. Capezza and Special Assistant U.S. Attorney Jason Hedges of the Food and Drug Administration handled the prosecution for the United States.

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