



**FOR IMMEDIATE RELEASE**

P06-65

May 3, 2006

**Media Inquiries:**

Catherine McDermott, 301-827-6242

**Consumer Inquiries:**

888-INFO-FDA

## ***Two Executives Convicted in Unapproved Sterilization Device Scheme***

Two executives of a Mundelein, Ill., company were convicted April 13, 2006, of fraudulently selling uncleared surgical sterilizing devices that led to eye damage in eighteen patients, causing them to lose sight in one eye.

Mr. Ross Caputo was president and CEO of AbTox, and Mr. Robert Riley was the vice-president of regulatory affairs of AbTox, when the company received permission to market a small gas plasma sterilizer only for use in sterilizing flat stainless-steel surgical instruments without lumens (tubes) or hinges. The defendants instead marketed a larger, unauthorized version of the sterilizer and promoted its use for a wide array of non stainless-steel instruments.

The hospitals that purchased the larger unauthorized units were shown by AbTox the clearance letter for the smaller, authorized unit. These larger units were used in an unauthorized manner, because AbTox marketed them that way, to sterilize complex instruments, including cataract instruments that have small tubes which are used to put solution into the patient's eye. One unauthorized use was to sterilize ophthalmic instruments that had brass joints which reacted to the sterilizing agent creating a toxic residue. AbTox knew of the reaction but did not advise users or seek proper corrective action. The blindness was caused by a harmful copper acetate residue that remained in the tube of the instrument after sterilization by this machine.

One hundred sixty eight (168) of the unauthorized units were sold to hospitals nationwide, including Department of Veterans Affairs hospitals and other government agencies, totaling over \$18 million in sales. Hospitals in Chicago, Ill., Columbia, Mo., and St. Louis, Mo, reported to AbTox that their sterilizer was suspected of causing injuries to several patients. The company failed to notify the FDA about these reports as required.

"These convictions are evidence of FDA's resolve to ensure the safety and efficacy of human medical devices. Our criminal investigators aggressively pursue those that endanger the public health by manufacturing and selling unsafe products", said Margaret O'K. Glavin, FDA's Associate Commissioner for Regulatory Affairs.

The conviction of these two men is the result of an investigation conducted by the U.S. Food and Drug Administration's Office of Criminal Investigations (OCI). The defendants were convicted of three counts of wire fraud, four counts of mail fraud, seven counts of selling an adulterated (unapproved) or misbranded (mis-labeled) human medical device, and conspiracy to defraud the FDA. Mr. Riley was also convicted of one count of making a false statement for lying to the FDA.

The defendants face significant penalties including incarceration, fines, and restitution. Sentencing will be at a later date. Two other defendants, Mark E. Schmitt, formerly director of marketing of AbTox, and Marilyn M. Lynch, formerly director of clinical services of Abtox, previously pled guilty in this case.

The defendants were found guilty after a nine-week trial in the Northern District of Illinois as the result of a successful prosecution under the direction of Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois, in conjunction with the US Department of Veteran's Affairs – Office of Inspector General, Investigations (VA-OIG), Naval Criminal Investigative Service (NCIS), and the Air Force Office of Special Investigations (OSI), along with the FDA.