



U. S. Department of Justice

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**FOUR FORMER ABTOX, INC, EXECUTIVES INDICTED FOR
ALLEGEDLY SELLING UNAPPROVED HOSPITAL STERILIZER**

CHICAGO -- Four former executives of AbTox, Inc., a now-defunct corporation which was based in north suburban Mundelein, have been indicted on federal conspiracy and fraud charges involving the manufacture and promotion of the AbTox Plazlyte Sterilization System, a device that purportedly could be used by hospitals to sterilize medical instruments. The indictment alleges that the defendants conspired to defraud the United States by impeding and impairing the lawful regulatory functions of the U.S. Food and Drug Administration, and further committed fraud by selling approximately 160 sterilizers to hospitals around the country, including to hospitals of the Department of Veterans Affairs, despite the fact that sterilizer had not been cleared or approved by the FDA as required by federal law. The charges were brought in a 19-count indictment returned late yesterday by a federal grand jury, announced Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois; Michael E. Cleary, Special Agent-in-Charge of the FDA's Chicago Field Office, Office of Criminal Investigations; and John Brooks, Special Agent-in-Charge of the VA's Central Field Office, Office of Inspector General.

The defendants are: **Ross A. Caputo**, 53, of 4735 Wellington Dr., Long Grove, Ill., formerly president and chief executive officer of AbTox; **Robert M. Riley**, 56, of 436 Forest Way Dr.,

Buffalo Grove, Ill., formerly vice president of regulatory affairs; **Mark E. Schmitt**, 44, of Chesterfield, Mo., formerly director of marketing; and **Marilyn M. Lynch**, of Milwaukee, formerly director of clinical services.

All four defendant were charged with one count of conspiracy and seven counts of introducing an adulterated and misbranded sterilizer into the market. Caputo and Riley were also charged with four counts of mail fraud and four counts of wire fraud in connection with sales of the unapproved sterilizers to unwitting hospitals. Finally, Riley, Lynch, and Schmitt were charged with one count of making false statements to an FDA investigator. All four will be ordered to appear for arraignment at a later date in U.S. District Court in Chicago.

According to the indictment, in December 1994, the FDA cleared AbTox's request to market a small low-temperature hospital sterilizer for use in cleaning flat stainless steel surgical instruments. From then until the company filed for bankruptcy in July, 1998, AbTox manufactured and marketed a different, much larger sterilizer, with different design and engineering characteristics than the device that was cleared by the FDA.. The sterilizer AbTox actually marketed was never either cleared or approved by the FDA, while AbTox never marketed or attempted to market the small sterilizer which was cleared by the FDA. Moreover, AbTox promoted the sterilizer for use on types of instruments for which neither sterilizer was ever cleared. AbTox sold approximately 160 of the unapproved sterilizers to hospitals nationwide for prices ranging between \$75,000 and \$115,000 each. Twelve of these unapproved sterilizers were sold for approximately \$1.2 million to VA hospitals, a few more to government agencies such as the Department of Defense and the Indian Health Services, and the remainder to private hospitals. The indictment charges that the hospitals

that purchased the sterilizer were deceived into believing that the AbTox sterilizer had, in fact, been cleared by the FDA.

“The Food and Drug Administration plays an enormously important role in safeguarding public health and ensuring that medical devices marketed to hospitals are both safe and effective for their intended use. Companies that seek to evade federal law and deny hospitals and patients the protections that those laws provide, do so at the risk of prosecution and serious penalties,” Mr. Fitzgerald said.

Mr. Fitzgerald praised the investigative work of FDA Special Agent John Stich and VA Assistant Special Agent-in-Charge Gregg Hirstein, who were assisted by investigators from the United States Navy and United States Air Force.

If convicted, the offenses charged in the indictment carry the following maximum sentences on each count; conspiracy -- five years imprisonment and a \$250,000 fine; mail fraud and wire fraud -- five years and a \$250,000 fine; false statements -- five years and a \$250,000 fine; and introducing an adulterated sterilizer into commerce -- one year and a \$100,000 fine.

The public is reminded that an indictment contains only charges and is not evidence of guilt. The defendants are presumed innocent and are entitled to a fair trial at which the United States has the burden of proving guilt beyond a reasonable doubt.

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