

Media advisory

For immediate release

Mostyn Law says FDA should increase scrutiny of Chinese-imported material used in surgical mesh

- **Houston law firm says FDA is overlooking evidence that material Boston Scientific used to make mesh implants is counterfeit**
- **Firm says raw product possibly being “equivalent” to FDA-approved brand does not clear Boston Scientific of violating federal counterfeit laws.**
- **Letter also criticizes FDA for allowing Boston Scientific to test its own product**

HOUSTON [April 13, 2016] – Mostyn Law called on the FDA today to step up its investigation into the source of allegedly counterfeit material from China, used by a leading medical company for its surgical mesh implants.

In a letter to the FDA commissioner, Dr. Robert Califf, and Health and Human Services Secretary Sylvia Mathews Burwell, the Houston-based law firm repeated its contention that the implants are defective and criticized the FDA's decision to rely on Boston Scientific Corp. (BSC) to test the China supplies.

"The FDA's investigation should not be into the quality of the raw material, but rather the source of the raw material," Amber Mostyn said in the letter. "The FDA's proposal to allow BSC to test its own product for equivalency is flawed at its core and stands in stark contrast to statements by the FDA, statutes enacted by Congress, and the public policies behind them."

The letter urges the FDA to seek immediate Department of Justice guidance, saying Boston Scientific allegedly remains in violation of counterfeiting laws even if the company's China-imported stock is equivalent to an FDA-approved brand.

Equivalence is not a defense to trafficking counterfeit raw material under federal counterfeiting statutes, the letter says.

"If this is the position of the FDA, it is flawed and demonstrates a fundamental lack of understanding of Congress' anti-counterfeiting laws," the letter says.

Federal regulators, in a safety alert April 1, said they are examining whether Boston Scientific used counterfeit raw material in vaginal mesh implants to treat incontinence and pelvic organ problems in women. Many have said they've suffered discomfort, bleeding, infections and other complications from the implants.

Mostyn Law raised the allegations in a federal racketeering suit filed in January against the BSC and more recently in a citizen petition it filed with the FDA on behalf of a West Virginia woman, who said the defective products should be recalled immediately.

The letter blasts the FDA's decision allowing Boston Scientific to conduct new tests on the safety and effectiveness of the product over the next few months, and to submit the results to the agency for review.

The Houston-based law firm says enough evidence has been provided to the FDA to show that the material BSC imported from China is counterfeit. Waiting months to determine if the end mesh is somehow equivalent conflicts with federal law involving company trafficking in counterfeit material, the letter says.

The letter summarizes internal Boston Scientific emails and other information uncovered by the law firm, including allegations that the company smuggled from China more than 37,000 pounds of unverified synthetic resin in 2011 and 2012 to make the mesh and failed to get FDA approval of the material.

Boston Scientific turned to the Chinese supplier after its U.S. manufacturer several years ago concluded that the plastic resin should not be used in the human body and refused to sell it for surgical mesh.

The letter includes photographs of a bag marked with the brand name "Marlex," a plastic resin that had FDA approval, but the internal emails show that Boston Scientific had been warned that the bag's lot number was bogus. Despite that evidence that the resin was counterfeit, the company went ahead and bought the material from its Chinese supplier.

"These spurious markings coupled with BSC's knowledge that the bag contained an invalid lot number are direct evidence of trafficking in counterfeit goods by BSC," the letter says. "These counterfeit marks are still being used by BSC on or in connection with the surgical mesh sold by BSC in a manner that is likely to deceive the general public."

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About Mostyn Law

The Houston-based firm is one of the country's leading civil litigation firms, headed by Steve Mostyn and Amber Anderson Mostyn. Their work has focused on representing clients who have been victims of negligence, bad faith or other wrongdoing by medical device manufacturers, pharmaceutical companies, insurance companies and others.

Steve, a graduate of the South Texas College of Law, is a founding member of the Texas Association of Consumer Lawyers and former president of the Texas Trial Lawyers Association. Amber, a graduate of the University of Texas Law School in Austin, has been an adjunct professor at Texas Wesleyan Law School and at South Texas College of Law.

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