Media advisory

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Mostyn Law calls on FDA to ban Boston Scientific surgical mesh

- **Petition says company imported counterfeit product from China**
- **Company's defective implant is a health risk, should be recalled**
- **Action stems from racketeering lawsuit against Boston Scientific**

HOUSTON — Citing an urgent need to protect the health of women, Houston-based Mostyn Law petitioned the Food and Drug Administration today to recall Boston Scientific Corp.'s surgical mesh products, allegedly made of defective, counterfeit material from China.

The request, filed on behalf of a West Virginia woman who suffered health problems from a Boston Scientific pelvic mesh implant, accuses the company of smuggling from China more than 34,000 pounds of unverified synthetic resin to make the mesh.

The petition cites internal, previously undisclosed Boston Scientific emails that say the company bought the stock in 2011 and 2012 from a suspected counterfeiter in China without fully testing it or getting FDA approval for its use as a vaginal implant.

Boston Scientific ran out of FDA-approved supplies and "started using counterfeit resin from China with no history as to when it was made, how it was made, who made it, no title, and was smuggled out" in a series of transactions "mimicking an international drug deal," the petition says.

The petition also includes a recent letter from Boston Scientific to customers, acknowledging that the plastic resin being used to make the surgical mesh is not the FDA-approved brand but is still being made into vaginal inserts.

The allegations also are the basis of a federal racketeering lawsuit that Mostyn Law, headed by Steve and Amber Mostyn, filed against Boston Scientific in January. Because the FDA has primary jurisdiction over the safety of medical devices and authority to issue recalls, the judge in that case has suspended legal action to give the regulatory agency time to act.

The citizen petition from Teresa Stevens, lead plaintiff in the federal class-action suit, says the FDA should recall all Boston Scientific products made from the substandard Chinese resin and issue warnings about the product, which is used to shore up pelvic organs and treat incontinence.

Earlier this year, the FDA deemed vaginal surgical mesh procedures as "high-risk," possibly resulting in "severe pelvic pain and organ perforation." Implant manufacturers are facing thousands of lawsuits from women who say they have suffered discomfort, bleeding, infections, painful intercourse, urinary problems and other complications from the implants.

“The FDA needs to do its job and ban this outright. We’ve clearly documented the health risks,” said attorney Amber Mostyn. “Acknowledging there is a problem is not enough. It’s a like a firefighter watching a building burn while warning us not to play with matches.”

The FDA petition provides the most detailed account to date on how 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.

Boston Scientific ignored those explicit warnings and began a global hunt to find another source for the polypropylene resin pellets, under the brand name Marlex – important because that was the product the FDA had approved for making those implants.

The company found online a Chinese supplier, offering what it said was Marlex in storage from the same U.S. manufacturer, but provided no records documenting that. The U.S. manufacturer later said the lot number shown on one of the Chinese supply bags was bogus.

The petition, based on internal Boston Scientific documents, gives new details on the extraordinary steps the company took to move the resin out of China. It split about 37,400 pounds into four shipments, sending them on different dates, by different methods (one by air and three by ocean transit) to avoid detection and limit losses if confiscated by customs agents.

The shipper was instructed to tell Chinese authorities the product was made there, meaning it didn’t need certain paperwork for export. The company then switched its story, getting it into the U.S. by claiming the material was authentic American-made Marlex, the petition says.

A Boston Scientific employee in China says in an email: “For this material, we have lost all of the original paperwork so we can’t prove that was legally imported in the country. And if we don’t get rid of the original bags or the writing on the bags when we claim they are from China (we have to say they are from China since we don’t have the original paperwork attached), if it is caught by custom, we will be in trouble. Therefore the shipper told me it is better to consider to re-pack all of them or find a way to get rid of all of the words/writing on the bags.”

According to the petition, Boston Scientific tests showed significant differences between the Chinese resin and certified Marlex. Still, Boston Scientific ordered production, a conflict with FDA requirements that medical device manufacturers re-apply for clearance when substantial material is changed in a permanent implant.

“Desperate [Boston Scientific] staff blindly waved its shoddy product on through,” the petition says.

Tests also showed that the Chinese resin had high levels of selenium. Selenium is not present in Marlex resin, Mostyn Law said. The firm said that element will react with hydrogen peroxide produced by the body from inflammation caused by the implant, degrading the plastic itself and the surrounding tissue.

The Mostyn Law class-action lawsuit is believed to the first that invokes the Racketeering and Corrupt Organizations Act (RICO) against a company that makes vaginal surgical mesh. The RICO statute is typically used by federal law enforcement agencies to target organized criminal gangs.

About 55,000 women receive Boston Scientific's pelvic mesh each year. The Massachusetts-based company makes $120 million in revenue annually from the mesh products, according to Mostyn Law.

For more information and copies of the FDA petition, federal suit and related filings see:
https://vaginalmeshclassaction.com/

The case is styled Stevens v. Boston Scientific Corp., et. al., 2:16-0265, U.S. District Court, Southern District of West Virginia (Charleston).

For media questions, contact:
Joseph C. Madden, Mostyn Law
jcmadden@mostynlaw.com
713-714-0000 (office)
713-443-9421 (cell)

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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