

Media advisory

For immediate release: January 27, 2016

Mostyn Law calls on FDA and Boston Scientific to Stop the Use of Counterfeit Surgical Mesh

- **Federal judge says FDA should be first to investigate Boston Scientific**
- **Recently released court document sheds light on company's efforts to import counterfeit material from China**
- **RICO case against Boston Scientific continues in federal court**

HOUSTON — A federal judge in West Virginia urged a plaintiff in a lawsuit against Boston Scientific Corp. to ask the Food and Drug Administration (FDA) to investigate the company's use of a plastic resin from China to make vaginal surgical mesh.

The Jan. 26 decision by U.S. District Judge Joseph Goodwin in Charleston, West Virginia, directed plaintiff Teresa Stevens to ask the FDA for a determination on the safety of products made by Boston Scientific Corp. The plaintiff filed a lawsuit claiming Boston Scientific used counterfeit resin smuggled from China. Judge Goodwin said the regulatory agency should be given the first opportunity to decide whether Boston Scientific's mesh should be banned for use in vaginal implants under the doctrine of "primary jurisdiction." This doctrine allows a judge to halt a case while a regulatory agency determines technical matters.

Judge Goodwin did not dismiss any of the claims made by Mostyn Law on Mrs. Stevens' behalf but did halt action on them while the FDA investigates. The Court also recognized that the FDA cannot resolve all of the claims by Mrs. Stevens, retaining its jurisdiction over the case and ordering a status report on the FDA's investigation on May 1, 2016.

Houston-based Mostyn Law, headed by attorneys Amber and Steve Mostyn, sued Boston Scientific and three other companies under the Racketeering and Corrupt Organizations Act (RICO) on behalf of Mrs. Stevens and other women who have suffered severe discomfort, bleeding, infections, painful intercourse, urinary problems and other complications from the plastic mesh implants, which are used to treat urinary incontinence and shore up pelvic organs.

"Our efforts to get justice for women who have been harmed by Boston Scientific's dangerous surgical mesh are far from over. The court has given the FDA an opportunity to act, but retained jurisdiction over the lawsuit while the FDA investigates. Boston Scientific is making a product that harms tens of thousands of women with counterfeit plastic that contains high levels of toxic selenium. The company should take this product off the market immediately. And if Boston Scientific won't do the right thing, the FDA should make them do it without delay," Amber Mostyn said.

She added: “In the meantime, Boston Scientific should release its documents to the FDA and the public. We won’t stop until we get to the bottom of this and will continue to seek justice for women who have already suffered from Boston Scientific’s reckless disregard for their health.”

Goodwin’s ruling was the latest development in a groundbreaking lawsuit that accuses Boston Scientific of engaging in an international conspiracy to import counterfeit plastic resin from China for its surgical mesh.

The lawsuit against Boston Scientific is based largely on internal company emails and other communications that remain confidential. Mostyn Law obtained the internal Boston Scientific messages in connection with other civil suits against the mesh-maker. In its latest filing, the firm said Boston Scientific has fought to keep its internal communications private because it wants to “conceal serious misconduct.”

Mostyn Law has asked Goodwin to publicly release all of the internal communications to protect “public health and safety.” The judge has not ruled that request. However, Goodwin agreed last week to release a court document filed by Mostyn Law that refers to “facts taken from internal documents and emails” obtained from Boston Scientific.

The internal company messages from 2011 to 2012 reveal that despite worries about the reliability of the Chinese resin supplier, Boston Scientific devised ways to smuggle from China 34,000 pounds of the material without verifying or fully testing it. According to the newly released court filing, a Boston Scientific employee worried, “God knows what grade, or even recycled material” was in the Chinese resin.

Boston Scientific has continuously blocked release of the internal emails and documents while maintaining that the suit has no merit. “If Boston Scientific thinks we’re wrong, it could immediately release the documents and let the FDA and the public decide for themselves. Right now, we can’t share our evidence with the FDA,” said Amber Mostyn.

The unsealed Mostyn filing includes a detailed timeline describing how Boston Scientific turned to a known counterfeiter in China after a U.S. manufacturer warned that the plastic resin should not be used in the human body and stopped selling it for surgical mesh.

The federal court lawsuit is an unusual use of the RICO statute, which is typically used by the Justice Department to target criminal organizations but can also apply to civil lawsuits.

For more information and copies of the federal suit and related filings, including a timeline of Boston Scientific’s internal communications, 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.

###