RICO case targets company over tainted vaginal implants

- **Women's health put at risk by surgical mesh deemed unfit for humans**
- **Boston Scientific Corp. ignored warnings from U.S. provider**
- **Material smuggled from China supplier described as counterfeit**

HOUSTON [Jan. 14, 2016] — Mostyn Law, a Houston-based firm, has accused a leading U.S. medical company of running an international conspiracy that sold defective vaginal surgical mesh, made of counterfeit supplies it smuggled from China.

The firm, headed by attorneys Amber and Steve Mostyn, sued Boston Scientific Corp. and three other companies under the Racketeering and Corrupt Organizations Act (RICO) on behalf of women who have suffered severe discomfort, bleeding, infections, painful intercourse, urinary problems and other complications from the plastic mesh implants.

The class-action lawsuit says that after losing its U.S. supplier of the synthetic resin to produce the mesh, Boston Scientific bought unverified, substandard material from a known counterfeiter in China. The company took extraordinary measures to avoid being caught by U.S. and Chinese authorities, at times acting like a drug dealer to hide multiple overseas shipments, the suit says.

The U.S. Justice Department typically uses the RICO statute and penalties to target criminal organizations, but private citizens can seek to apply it in certain civil cases. The suit, which the Mostyn firm filed late Tuesday for a West Virginia woman with mesh-related health problems, asks the U.S. District Court in Charleston to prohibit Boston Scientific immediately from selling any medical devices containing the harmful material.

The RICO lawsuit is ground breaking, the first to accuse Massachusetts-based Boston Scientific of engaging in an international conspiracy to import tainted plastic resin for the mesh. The suit names a Chinese company that allegedly sold the inferior stock and participated in the smuggling operation and two other companies.

"We have asked for the court to shut down sales from this company and to protect women from the pain and suffering that can result from this dangerous product," said attorney Amber Mostyn. She said Boston Scientific put profits ahead of health concerns, calling the company's disrespect for women "disgusting and appalling."

Transvaginal surgical mesh is a polypropylene-based product, used along with surgical stitches, to shore up sagging pelvic organs, such as the bladder, uterus and bowels, and to treat incontinence. Women have complained about the embedded mesh eroding through the stitched tissue and requiring painful removal surgeries.

The procedure – now considered a high-risk procedure by the Food and Drug Administration – has resulted in more than 70,000 lawsuits, including 15,000 against Boston Scientific. It makes $120 million in revenue from the mesh products.

The new federal suit provides a clearest picture yet of the scramble by Boston Scientific after Chevron Phillips Chemical Co. in 2005 stopped selling its polypropylene resin for surgical mesh. The chemical company said it should not be used in medical devices "involving permanent implantation in the human body or permanent contact with internal body fluids or tissues."

Boston Scientific ignored those explicit warnings and began a global hunt to find another source for the resin pellets, known as Marlex, important because that was the only product the FDA had approved for making that company's implants.

But with no U.S. supplier, Boston Scientific concocted a scheme in 2011 and 2012 to smuggle from China 34,000 pounds of the material, without verifying or fully testing all the contents, the suit says.

It came from EMAI Plastic Raw Materials Inc., a "known counterfeiter of plastic products" in Guangzhou, China, the suit says. That company offered what it said was Marlex from Phillips that it had in storage but provided no records documenting that. Phillips later said the lot number shown on one of the EMAI supply bags was bogus.

Despite knowing that, the suit says, Boston Scientific bought the resin and orchestrated secretive plans to smuggle it out of China.

Like a "drug deal,'' the suit says, Boston Scientific discussed bribing Chinese officials to help get the material out. Later, it decided to divide the bulk of the product into more than 500 bags, sending them by three ocean shipments on three different dates, after being warned that the bigger the load the greater the risk of inspection by Customs agents.

The company told 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 Phillips Marlex.

"Boston Scientific knowingly sold a product that put women's health and their lives at risk. It conspired with questionable suppliers in China to get material that it couldn't get in the U.S. and went to great lengths to hide it," Amber Mostyn said.

Tests showed significant differences between the Chinese resin and certified Phillips Marlex. Still, Boston Scientific went ahead and ordered production, a conflict with FDA requirements that device manufacturers re-apply for clearance when any material is changed in a permanent implant device.

Boston Science failed to re-apply, the suit says, and instead it "deceptively promoted, marketed, packaged, labeled, sold and distributed this mesh as being manufactured with authentic Marlex and approved by the FDA."

The lead plaintiff is Teresa Stevens, a 46-year-old grandmother from Lincoln County, West Virginia, who had a mesh implant procedure in October 2014. Since then, she has suffered pain, bladder infections and other complications.

The suit seeks unspecified damages for the thousands of women who received a Boston Scientific transvaginal mesh product after September 2012, as many as 55,000 each year.

The suit comes the same month that the FDA announced tighter regulations for surgical mesh products. They were reclassified as high-risk rather than moderate-risk medical devices when used in procedures that go through the vagina to repair organ prolapse, which can occur with age and after childbirth.

For more information and copies of the federal RICO 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).

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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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