AG Kaul: Announces $188.6 Million Multistate Settlement with Medical Device Manufacturer Boston Scientific Corporation; Wisconsin to Receive More Than $3.7 Million

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MADISON – Attorney General Josh Kaul today announced a multistate settlement with Boston Scientific Corporation (Boston) to resolve allegations of deceptive marketing of its surgical mesh products for women. The settlement requires Boston to pay $188.6 million to 47 states and the District of Columbia to resolve allegations that it deceptively marketed transvaginal surgical mesh devices to patients. Wisconsin's share of the settlement is $3,779,303.

"Patients and doctors need to be able to put their trust in medical device manufacturers. Those companies must disclose the potential complications from the products they sell," said Attorney General Kaul.

Surgical mesh is a synthetic woven fabric that is implanted in the pelvic floor through the vagina to treat common health conditions in women such as stress urinary incontinence and pelvic organ prolapse. These are common conditions faced by women due to a weakening in their pelvic floor muscles caused by childbirth, age, or other factors. Although use of surgical mesh involves the risk of serious complications and is not proven to be any more effective than traditional tissue repair, millions of women were implanted with the devices and thousands of women are alleged to have suffered serious complications resulting from these devices.

The complaint alleges that Boston misrepresented the safety of these products by failing to disclose the full range of potential serious and irreversible complications caused by mesh, including chronic pain, voiding dysfunction, and new onset of incontinence.

The settlement provides comprehensive injunctive relief. Under the terms of the settlement, Boston is required to:

Marketing Reforms:

• For marketing materials intended for consumers, describe complications in understandable terms;
• For certain marketing materials, disclose significant complications, including the inherent risks of mesh;
• Refrain from representing that any inherent risks of mesh are risks common to any pelvic floor or other surgery not involving mesh;
• Refrain from representing that inherent mesh complications can be eliminated with surgical experience or technique;
• Refrain from representing that surgical mesh does not cause a foreign body reaction;
• Refrain from representing that surgical mesh remains soft, supple, or pliable after mesh is implanted inside the body;
• Refrain from representing that surgical mesh does not potentiate infection or does not increase the likelihood of infection;
• Refrain from representing that surgical mesh repair is superior to native tissue repair unless such representations are supported by valid scientific evidence;

Training Reforms:

• Inform healthcare providers of significant complications when providing training regarding procedures for insertion and implantation;
• Maintain policies requiring that its independent contractors, agents, and employees who sell, market, or promote mesh are adequately trained to report patient complaints and adverse events to the company;

Clinical Trial Reforms:

• When submitting a clinical study or clinical data regarding mesh for publication, disclose the company's role as a sponsor and any author's potential conflict of interest;
• Refrain from citing any clinical study, clinical data, preclinical data, research, or article regarding mesh for which the company has not complied with the disclosure requirements in the injunction;
• Include a sponsorship disclosure provision requiring consultants to contractually agree to disclose in any public presentation or submission for publication any sponsorships by Boston related to the contracted-for activity;
• Register all Boston-sponsored clinical studies regarding mesh with ClinicalTrials.gov.

The investigation that resulted in today's settlement was led by California and Washington along with Florida, Indiana, Maryland, Ohio, South Carolina, and Texas. Joining this multistate settlement are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia

This resolution does not relate to a civil action filed by the State of Wisconsin. The requirements of 2017 Wis. Act 369 do not apply.

Relevant filings are here.

Press release: https://www.doj.state.wi.us/news-releases/ag-kaul-announces-1886-million-multistate-settlement-medical--device-manufacturer