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Florida Attorney General's Office News Release

Millions Secured for Florida Through Multistate Investigation

TALLAHASSEE, Fla.—Attorney General Ashley Moody today secured a multistate agreement with Boston Scientific Corporation to resolve allegations of deceptive marketing of its surgical mesh products for women. Attorney General Moody's office took a lead role in conducting the nationwide multistate investigation and negotiating a multimillion-dollar resolution. The agreement requires BSC to pay more than $188 million to 47 states and the District of Columbia to resolve allegations that it deceptively marketed transvaginal surgical mesh devices to patients. Florida's share of the agreement is $11.5 million.

Attorney General Ashley Moody said, "Patients undergoing any surgical procedure are under a great deal of uncertainty and stress, often putting their full trust in medical personnel and devices to relieve major symptoms. The deceptive marketing practices by this company created even greater pain and stress for patients in Florida and nationwide. I am proud of my office for taking lead in this case and hope that the strong injunctive relief our coalition has secured will prevent this from happening again in the future."

This is the third major multistate case against a mesh manufacturer that was resolved with the Florida Attorney General's Office leadership. The first two cases involved Johnson & Johnson, and its wholly-owned subsidiary Ethicon, Inc., and C.R. Bard, Inc., resulting in strong injunctive terms and payment of more than $176 million nationwide.

Surgical mesh is a synthetic woven fabric that is implanted in the pelvic floor 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. A significant percentage of women implanted with surgical mesh have suffered serious complications, including erosion of mesh into organs and pain.

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

The agreement provides comprehensive injunctive relief. Under the terms of the agreement, BSC is required to conduct the following actions:

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 alone;
- 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; and
- Refrain from representing that surgical mesh repair is superior to traditional 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; and
- 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 disclosure provision requiring consultants to contractually agree to disclose in any public presentation or submission for publication any support by BSC related to the

contracted-for activity; and
- Register all BSC-sponsored clinical studies regarding mesh with ClinicalTrials.gov.

Consumer Protection Division assistant attorneys general Patrice Malloy and Diane Oates represented Florida, who led this investigation along with the states of California, Indiana, Maryland, Ohio, South Carolina, Texas and Washington. Joining the multistate agreement are Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, 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 and Wisconsin.

To view the complaint, click here.

To view the stipulated judgment submitted for court approval, click here.