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ATTORNEY GENERAL RAOUL ANNOUNCES \$188 MILLION MULTISTATE SETTLEMENT WITH SURGICAL MESH MANUFACTURER

Chicago — Attorney General Kwame Raoul, as part of a coalition of 48 states, announced a settlement with Boston Scientific Corp. (Boston) to resolve allegations Boston deceptively marketed transvaginal surgical mesh devices to patients.

Raoul and the coalition <u>alleged that Boston misrepresented the safety</u> of its 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 requires Boston to pay \$188.6 million, with nearly \$5.6 million being directed to Illinois.

""Boston Scientific misrepresented the significant and sometimes irreversible side effects of its products, and thousands of women experienced serious complications as a result," Raoul said. "This settlement holds Boston accountable and ensures that future patients have access to information that will allow them to better understand surgical mesh products before they are implanted."

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 weakening in their pelvic floor muscles caused by childbirth, age or other factors. The 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 have made claims that they suffered serious complications as a result, including erosion of mesh through organs, pain during sexual intercourse and voiding dysfunction.

Under the terms of the settlement, Boston is required to:

- Disclose significant complications, including the inherent risks of mesh.
- Use understandable terms to describe complications in marketing materials intended for consumers.
- Refrain from misrepresenting certain medical risks, long-term qualities and other aspects of mesh.
- Inform health care providers of significant complications when providing training regarding insertion and implantation procedures.
- Enact policies requiring individuals who sell, market or promote mesh on behalf of Boston to be adequately trained to report patient complaints and adverse events to the company.
- Disclose the company's role as a sponsor and any author's potential conflict of interest when submitting a clinical study or clinical data regarding mesh for publication.
- Refrain from citing any clinical study, clinical data, preclinical data, research or article regarding mesh for which the company has not complied with the injunction's disclosure requirements.
- 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.

Joining Raoul in the settlement are the attorneys general of Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota,

Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wisconsin.