March 23, 2021

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 alleged that Boston misrepresented the safety 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.

IN THE CIRCUUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT-CHANCERY DIVISION

PEOPLE OF THE STATE OF ILLINOIS,	)	Case No. 2021CH01353
Plaintiff,	)	
vs.	)	
BOSTON SCIENTIFIC CORPORATION	)	
Defendant.	)	

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

NOW COMES the Plaintiff, the PEOPLE OF THE STATE OF ILLINOIS, by and through KWAME RAOUL, ATTORNEY GENERAL OF ILLINOIS, and brings this action against Defendant Boston Scientific Corporation for violating the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* ("Consumer Fraud Act") and the Illinois Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 *et seq.* ("UDTPA"), and states as follows:

Public Interest

1. THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, ATTORNEY GENERAL OF THE STATE OF ILLINOIS, believes this action to be in the public interest of the citizens of the State of Illinois and brings this lawsuit pursuant to the Consumer Fraud Act, 815 ILCS 505/7(a).

The Parties

2. Plaintiff, the PEOPLE OF THE STATE OF ILLINOIS, is charged, *inter alia*, with enforcement of the Consumer Fraud Act and the UDTPA.

3. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation and headquartered at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

4. At all times relevant hereto, Defendant Boston Scientific transacted business in the State of Illinois, and nationwide by marketing, promoting, advertising, offering for sale, selling, and distributing transvaginal surgical mesh devices.

5. Defendant was at all times relative hereto, engaged in trade or commerce in the State of Illinois as defined in Subsection 1(f) of the Consumer Fraud Act, 815 ILCS 505/1(f).

Jurisdiction and Venue

6. This action is brought for and on behalf of THE PEOPLE OF THE STATE OF ILLINOIS, by KWAME RAOUL, ATTORNEY GENERAL OF THE STATE OF ILLINOIS, pursuant to the provisions of the Consumer Fraud Act and UDTPA.

7. This Court has jurisdiction over the Defendant pursuant to Section 2-209 (a)(1) of the Illinois Code of Civil Procedure, 735 ILCS 5/2-209 (a) (1) because Defendant Boston Scientific has transacted business within the State of Illinois at all times relevant to the Complaint.

8. Venue is proper in Cook County, Illinois pursuant to Section 2-101 and 2-102(a) because Defendant Boston Scientific has carried on a regular business in Cook County, Illinois or some of the transactions upon which this action is based occurred in Cook County, Illinois.

Background

9. "Surgical Mesh," as used in this Complaint, is a medical device that contains synthetic polypropylene mesh intended to be implanted in the pelvic floor to treat stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP) manufactured and sold by Boston Scientific in the United States.

10. SUI and POP are common conditions that pose lifestyle limitations and are not life-

threatening.

11. SUI is a leakage of urine during episodes of physical activity that increase abdominal pressure, such as coughing, sneezing, laughing, or exercising. SUI can happen when pelvic tissues and muscles supporting the bladder and urethra become weak and allow the neck of the bladder to descend during bursts of physical activity, and the descent can prevent the urethra from working properly to control the flow of urine. SUI can also result when the sphincter muscle that controls the urethra weakens and is not able to stop the flow of urine under normal circumstances and with an increase in abdominal pressure.

12. POP happens when the tissue and muscles of the pelvic floor fail to support the pelvic organs resulting in the drop of the pelvic organs from their normal position. Not all women with POP have symptoms, while some experience pelvic discomfort or pain, pressure, and other symptoms.

13. In addition to addressing symptoms, such as wearing absorbent pads, there are a variety of non-surgical and surgical treatment options to address SUI and POP. Non-surgical options for SUI include pelvic floor exercises, pessaries, transurethral bulking agents, and behavior modifications. Surgery for SUI can be done through the vagina or abdomen to provide support for the urethra or bladder neck with either stitches alone, tissue removed from other parts of the body, tissue from another person, or with material such as surgical mesh, which is permanently implanted. Non-surgical options for POP include pelvic floor exercises and pessaries. Surgery for POP can be done through the vagina or abdomen using stitches alone or with the addition of surgical mesh.

14. Boston Scientific marketed and sold Surgical Mesh devices to be implanted transvaginally for the treatment of POP for approximately 10 years or more. Boston Scientific

ceased the sale of Surgical Mesh devices to be implanted transvaginally for the treatment of POP after the Food and Drug Administration (FDA) ordered manufacturers of such products to cease the sale and distribution of the products in April 2019.

15. Boston Scientific began marketing and selling Surgical Mesh devices to be implanted transvaginally for the treatment of SUI by 2003, and continues to market and sell Surgical Mesh devices to be implanted transvaginally for the treatment of SUI.

16. The FDA applies different levels of scrutiny to medical devices before approving or clearing them for sale.

17. The most rigorous level of scrutiny is the premarket approval (PMA) process, which requires a manufacturer to submit detailed information to the FDA regarding the safety and effectiveness of its device.

18. The 510(k) review is a much less rigorous process than the PMA review process. Under this process, a manufacturer is exempt from the PMA process and instead provides premarket notification to the FDA that a medical device is "substantially equivalent" to a legally marketed device. While PMA approval results in a finding of safety and effectiveness based on the manufacturer's submission and any other information before the FDA, 510(k) clearance occurs after a finding of substantial equivalence to a legally marketed device. The 510(k) process is focused on equivalence, not safety.

19. Boston Scientific's SUI and POP Surgical Mesh devices entered the market under the 510(k) review process. Boston Scientific marketed and sold Surgical Mesh devices without adequate testing.

Boston Scientific's Course of Conduct

20. In marketing Surgical Mesh devices, Boston Scientific misrepresented and failed to disclose the full range of risks and complications associated with the devices, including misrepresenting the risks of Surgical Mesh as compared with the risks of other surgeries or surgically implantable materials.

21. Boston Scientific misrepresented the safety of its Surgical Mesh by misrepresenting the risks of its Surgical Mesh, thereby making false and/or misleading representations about its risks.

22. Boston Scientific also made material omissions when it failed to disclose the risks of its Surgical Mesh.

23. Boston Scientific misrepresented and/or failed to adequately disclose serious risks and complications of one or more of its transvaginally-placed Surgical Mesh products, including the following:

a. heightened risk of infection;

b. rigid scar plate formation;

c. mesh shrinkage;

d. voiding dysfunction;

e. de novo incontinence;

f. urinary tract infection;

g. risk of delayed occurrence of complications; and

h. defecatory dysfunction.

24. Throughout its marketing of Surgical Mesh, Boston Scientific continually failed to disclose risks and complications it knew to be inherent in the devices and/or misrepresented

those inherent risks and complications as caused by physician error, surgical technique, or perioperative risks.

25. In 2008, the FDA issued a Public Health Notification to inform doctors and patients about serious complications associated with surgical mesh placed through the vagina to treat POP or SUI. In 2011, the FDA issued a Safety Communication to inform doctors and patients that serious complications associated with surgical mesh for the transvaginal repair of POP are not rare, and that a systematic review of published literature showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair and that mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.

26. In 2012, the FDA ordered post-market surveillance studies by manufacturers of surgical mesh to address specific safety and effectiveness concerns related to surgical mesh used for the transvaginal repair of POP. In 2016, the FDA issued final orders to reclassify transvaginal POP devices as Class III (high risk) devices and to require manufacturers to submit a PMA application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP in order to continue marketing the devices.

27. In April 2019, the FDA ordered manufacturers of surgical mesh devices intended for transvaginal repair of POP to cease the sale and distribution of those products in the United States. The FDA determined that Boston Scientific had not demonstrated a reasonable assurance of safety and effectiveness for these devices under the PMA standard. On or around April 16, 2019, Boston Scientific announced it would stop global sales of its transvaginal mesh products indicated for POP.

Violation of the Illinois Consumer Fraud Act

28. Plaintiff realleges and incorporates by reference each and every allegation contained in the preceding paragraphs 1 through 27 as if they were set out at length herein.

29. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific has engaged in a course of trade or commerce which constitutes false, deceptive or misleading acts or practices, and is therefore unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, with the intent that consumers rely upon such deceptive conduct, including but not limited to making false statements about and/or misrepresenting risks of Surgical Mesh products.

30. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, with the intent that consumers rely upon such deceptive conduct, including but not limited to by representing that Surgical Mesh products have characteristics, uses, benefits, and/or qualities that they did not have. Boston Scientific further violated Section 2 of the Consumer Fraud Act when it misrepresented the characteristics, uses, benefits and/or qualities of its Surgical Mesh products, which violates Section 2(a)(5) of the UDTPA.

31. In the course of marketing, promoting, selling, and distributing Surgical Mesh products, Boston Scientific has engaged in a course of trade or commerce which constitutes false, deceptive or misleading acts or practices, and is therefore unlawful under Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, with the intent that consumers rely upon such deceptive conduct, including but not limited to by making material omissions concerning the risks and complications associated with Surgical Mesh products.

Request for Relief

32. WHEREFORE, Plaintiff respectfully requests that this Honorable Court enter an Order:

a. Finding pursuant to Section 1(f) of the Consumer Fraud Act, that Defendant engaged in trade or commerce;

b. Adjudging and decreeing that Defendant has engaged in the acts or practices complained of herein, and that such constitute unfair and/or deceptive acts or practices in violation of the Illinois Consumer Fraud Act and/or the Illinois Uniform Deceptive Trade Practices Act;

c. Issuing a permanent injunction prohibiting Defendant, its agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive trade practices in the marketing, promoting, selling and distributing of Defendant's Surgical Mesh devices;

d. Ordering Defendant to pay civil penalties in the amount of $50,000 per deceptive act or practice, and an additional amount of $50,000 for each act or practice found to have been committed with the intent to defraud;

e. Ordering Defendant to pay an additional civil penalty of $10,000 per violation of the Consumer Fraud Act found by the Court to have been committed against a person 65 years of age and older as provided in Section 7(c) of the Consumer Fraud Act, 815 ILCS 505/7(c);

f. Ordering Defendant to pay all costs and reasonable attorney's fees for the prosecution and investigation of this action;

g. Ordering such other and further equitable relief as the Court may deem just and proper.

THE PEOPLE OF THE STATE OF ILLINOIS, by
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