

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

v.

BOSTON SCIENTIFIC
CORPORATION, MICHAEL F.
MAHONEY, and DANIEL J.
BRENNAN,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff, individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Boston Scientific Corporation ("Boston Scientific" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of all persons and entities who purchased or otherwise acquired Boston Scientific securities between February 26, 2015, and April 16, 2019, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Boston Scientific was founded in 1979 and is headquartered in Marlborough, Massachusetts. The Company develops, manufactures, and markets medical devices for use in various interventional medical specialties worldwide.

3. Within the Company’s Urology and Women’s Health business segment it develops, manufactures and sells devices to treat various urological and gynecological disorders, including transvaginal surgical mesh products indicated for pelvic organ prolapse (“POP”). At the beginning of the Class Period, the Company reported worldwide net sales of Urology and Women's health products of \$535 million for the year ended December 31, 2014, equal to approximately seven percent of its consolidated net sales for that year.

4. In July 2011, the U.S. Food and Drug Administration (“FDA”) released a Public Health Notice update regarding complications related to the use of urogynecologic surgical mesh for pelvic organ prolapse and stress urinary incontinence. By February 24, 2015, over 25,000 product liability cases or claims related to transvaginal surgical mesh had been filed against Boston Scientific, as well as cases in the United Kingdom.

5. At all relevant times, the Company has skirted any admissions of liability or guilt, stating, *inter alia*, that it “intend[s] to vigorously contest the cases and claims asserted against [it.]”

6. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Boston Scientific’s surgical mesh products indicated for the transvaginal repair of POP were unsafe; (ii) accordingly, Boston Scientific’s continued marketing and sales of these devices in the United States was unlikely to be sustainable; (iii) separately, the Company had sold vaginal mesh implants containing counterfeit or adulterated resin products imported from China; (iv) the foregoing conduct subjected the Company to a heightened risk of regulatory scrutiny and/or government investigations; and (v) as a result, the Company’s public statements were materially false and misleading at all relevant times.

7. On February 24, 2016, Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2015 (the “2015 10-K”). Therein, Boston Scientific disclosed that a putative class action had been filed against it alleging, *inter alia*, that the Company had used counterfeit or adulterated resin products imported from China in their vaginal mesh implants, resulting in personal injury. Furthermore, the 2015 10-K disclosed that Boston Scientific was in contact with the U.S. Attorney’s Office for the Southern District of West Virginia regarding its alleged use of counterfeit imports from China. Nevertheless, the Company continued to “deny the plaintiff’s allegations and intend[s] to defend [itself] vigorously.”

8. On May 13, 2018, CBS's *60 Minutes* aired a story highlighting the Company's alleged use of counterfeit imports in its surgical mesh products. In response, Boston Scientific stated that it has "extensively tested the [plastic] resin to confirm its composition, safety and performance."

9. Finally, despite years of denials by Boston Scientific in response to questions concerning the safety of its vaginal mesh products, the apparent full extent of the Company's misstatements was revealed on April 16, 2019, when the FDA announced that it had "ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse . . . to stop selling and distributing their products in the U.S. immediately." The FDA stated that "the manufacturers, Boston Scientific and Coloplast, have not demonstrated a reasonable assurance of safety and effectiveness for these devices," as required to continue marketing the devices in the United States. According to Jeffrey Shuren ("Shuren"), M.D., director of the FDA's Center for Devices and Radiological Health: "In order for these mesh devices to stay on the market, we determined that we needed evidence that they worked better than surgery without the use of mesh to repair POP. That evidence was lacking in these premarket applications, and we couldn't assure women that these devices were safe and effective long term[.]"

10. On this news, Boston Scientific's stock price fell \$2.90 per share, or 7.67%, over the following two trading sessions, closing at \$34.91 per share on April 17, 2019.

11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Boston Scientific's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

12. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

14. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Boston Scientific's securities trade on the NYSE, located within this District.

15. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

16. Plaintiff, as set forth in the attached Certification, acquired Boston Scientific securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

17. Defendant Boston Scientific is a Delaware corporation with its principal executive offices located at 300 Boston Scientific Way, Marlborough, Massachusetts 01752-1234. Boston Scientific's common stock trades in an efficient market on the New York Stock Exchange ("NYSE") under the ticker symbol "BSX."

18. Defendant Michael F. Mahoney ("Mahoney") was the Chief Executive Officer ("CEO") of Boston Scientific at all relevant times.

19. Defendant Daniel J. Brennan (“Brennan”) was the Executive Vice President and Chief Financial Officer (“CFO”) of Boston Scientific at all relevant times.

20. Defendants Mahoney and Brennan are sometimes referred to herein collectively as the “Individual Defendants.”

21. The Individual Defendants possessed the power and authority to control the contents of the Company’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

22. Boston Scientific was founded in 1979 and is headquartered in Marlborough, Massachusetts. The Company develops, manufactures, and markets medical devices for use in various interventional medical specialties worldwide.

23. Within the Company’s Urology and Women’s Health business segment it develops, manufactures and sells devices to treat various urological and gynecological disorders, including transvaginal surgical mesh products indicated for POP. At the beginning of the Class Period, the Company reported worldwide net sales of Urology and Women's health products

of \$535 million for the year ended December 31, 2014, equal to approximately seven percent of its consolidated net sales for that year.

24. In July 2011, the FDA released a Public Health Notice update regarding complications related to the use of urogynecologic surgical mesh for pelvic organ prolapse and stress urinary incontinence. By February 24, 2015, over 25,000 product liability cases or claims related to transvaginal surgical mesh had been filed against Boston Scientific, as well as cases in the United Kingdom.

25. At all relevant times, the Company has skirted any admissions of liability or guilt, stating, *inter alia*, that it “intend[s] to vigorously contest the cases and claims asserted against [it.]”

Materially False and Misleading Statements Issued During the Class Period

26. The Class Period begins on February 26, 2015, the day after Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2014 (the “2014 10-K”). The 2014 10-K reported on the ongoing litigation against Boston Scientific related to its transvaginal surgical mesh products, and simultaneously downplayed the dangers associated with those products. Specifically, the 2014 10-K stated, in relevant part:

As of February 24, 2015, *there were over 25,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse pending against us.* The cases are pending in various federal and state courts in the United States and include eight putative class actions. There were also fewer than 20 cases in Canada, inclusive of three putative class actions, and fewer than 10 claims in the United Kingdom. *Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims* During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We

have responded to those requests. We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as costs of defense thereof associated with our transvaginal surgical mesh products. While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. ***We intend to vigorously contest the cases and claims asserted against us***; however, the final resolution is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. ***Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.***

(Emphases added).

27. Appended as exhibits to the 2014 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified that “the information contained in the [2014 10-K] fairly presents, in all material respects, the financial condition and results of operations of Boston Scientific Corporation.”

28. On February 24, 2016, Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2015. The 2015 10-K discussed Boston Scientific’s costs associated with its ongoing defense of products liability claims related to its transvaginal surgical mesh products, and simultaneously downplayed the risks associated with those products, stating, in relevant part:

We recorded net litigation-related charges in the amount of \$1.105 billion in 2015, \$1.036 billion in 2014, and \$221 million in 2013. ***The net charges recorded in 2015 include amounts related to transvaginal surgical mesh product liability cases and claims The 2014 net charges also include amounts related to transvaginal surgical mesh product liability cases and claims*** These charges are excluded by management for purposes of evaluating operating performance. ***We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation*** and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

* * *

Our accrual for legal matters that are probable and estimable was \$1.936 billion as of December 31, 2015 and \$1.577 billion as of December 31, 2014, and includes certain estimated costs of settlement, damages and defense. The increase in our legal accrual was primarily due to litigation-related charges recorded during the year. During 2015, 2014 and 2013, we recorded litigation-related net charges in the amount of \$1.105 billion, \$1.036 billion, and \$221 million, respectively. The net charges recorded in 2015 include amounts related to transvaginal surgical mesh product liability cases and claims The 2014 net charges also include amounts related to transvaginal surgical mesh product liability cases and claims ***We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation*** and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

(Emphases added).

29. While discussing the progress of litigation related to Boston Scientific's transvaginal surgical mesh products, the 2015 10-K continued to downplay the risks associated with those products, stating, in relevant part:

As of February 23, 2016, ***over 35,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us.*** The pending cases are in various federal and state courts in the United States and include eight putative class actions. There were also fewer than 20 cases in Canada, inclusive of four putative class actions, and fewer than 15 claims in the United Kingdom. ***Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims*** During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. During April 2015, we entered into an initial master settlement agreement with certain plaintiffs' counsel to settle 2,970 pending cases and claims, including the case in the District Court of Dallas County (TX) for which there is a judgment of approximately \$35 million that is currently subject to appeal, for approximately \$119 million. Subsequently, we entered into several additional master settlement agreements with certain plaintiffs' counsel. As of February 23, 2016, we have entered into master settlement agreements to resolve an aggregate of over 10,000 cases and claims. ***Each master settlement agreement was entered into solely by way of***

compromise and without any admission or concession by us of any liability or wrongdoing

On or about January 12, 2016, Teresa L. Stevens filed a claim against us and three other defendants *asserting for herself, and on behalf of a putative class of similarly-situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China The complaint . . . alleges Racketeer Influenced and Corrupt Organizations Act (RICO) violations, fraud, misrepresentation, deceptive trade practices and unjust enrichment* On January 26, 2016, the Court issued an order staying the case and directing the plaintiff to submit information to allow the FDA to issue a determination with respect to her allegations. In addition, we are in contact with the U.S. Attorney's Office for the Southern District of West Virginia, and are responding voluntarily to their requests in connection with that office's review of the allegations concerning the use of mesh resin in the complaint. *We deny the plaintiff's allegations and intend to defend ourselves vigorously.*

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof associated with our transvaginal surgical mesh products. While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs' counsel regarding potential resolution of pending cases and claims *and intend to vigorously contest the cases and claims asserted against us*; that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. *Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.*

(Emphasis added).

30. Appended as exhibits to the 2015 10-K were signed SOX certifications, wherein the Individual Defendants certified that "the information contained in the [2015 10-K] fairly presents, in all material respects, the financial condition and results of operations of Boston Scientific Corporation."

31. On February 23, 2017, Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fiscal year ended December 31, 2016 (the "2016 10-K"). The 2016 10-K discussed Boston Scientific's costs associated with its ongoing defense of products liability claims related to its transvaginal surgical mesh products, and simultaneously downplayed the risks associated with those products, stating, in relevant part:

We recorded net litigation-related charges in the amount of \$804 million in 2016, \$1.105 billion in 2015, and \$1.036 billion in 2014. ***The net charges recorded in 2016 include primarily amounts related to transvaginal surgical mesh product liability cases and claims. The net charges recorded in 2015 include amounts primarily related to transvaginal surgical mesh product liability cases and claims The 2014 net charges also include amounts related to transvaginal surgical mesh product liability cases***

Litigation related charges and credits are excluded by management for purposes of evaluating operating performance.

We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

(Emphasis added).

32. While discussing the progress of litigation related to Boston Scientific's transvaginal surgical mesh products, the 2016 10-K continued to downplay the risks associated with those products, stating, in relevant part:

As of February 21, 2017, ***approximately 43,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us.*** The pending cases are in various federal and state courts in the United States and include eight putative class actions. There were also fewer than 20 cases in Canada, inclusive of one certified and three putative class actions, and fewer than 20 claims in the United Kingdom. ***Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty,***

fraud, violations of state consumer protection laws and loss of consortium claims During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. As of February 21, 2017, we have entered into master settlement agreements in principle or are in the final stages of entering one with certain plaintiffs’ counsel to resolve an aggregate of approximately 31,000 cases and claims *All settlement agreements were entered into solely by way of compromise and without any admission or concession by us of any liability or wrongdoing.*

On or about January 12, 2016, Teresa L. Stevens filed a claim against us and three other defendants *asserting for herself, and on behalf of a putative class of similarly-situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China The complaint . . . alleges Racketeer Influenced and Corrupt Organizations Act (RICO) violations, fraud, misrepresentation, deceptive trade practices and unjust enrichment* On January 26, 2016, the Court issued an order staying the case and directing the plaintiff to submit information to allow the FDA to issue a determination with respect to her allegations. In addition, we are in contact with the U.S. Attorney’s Office for the Southern District of West Virginia, and are responding voluntarily to their requests in connection with that office’s review of the allegations concerning the use of mesh resin in the complaint. *We deny the plaintiff’s allegations and intend to defend ourselves vigorously.*

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof *associated with our transvaginal surgical mesh products.* While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs’ counsel regarding potential resolution of pending cases and claims *and intend to vigorously contest the cases and claims asserted against us;* that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. *Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.*

(Emphasis added).

33. Appended as exhibits to the 2016 10-K were signed SOX certifications, wherein the Individual Defendants certified that “the information contained in the [2016 10-K] fairly

presents, in all material respects, the financial condition and results of operations of Boston Scientific Corporation.”

34. On February 20, 2018, Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2017 (the “2017 10-K”). The 2017 10-K discussed Boston Scientific’s costs associated with its ongoing defense of products liability claims related to its transvaginal surgical mesh products, and simultaneously downplayed the risks associated with those products, stating, in relevant part:

We recorded litigation-related net charges in the amount of \$285 million in 2017, \$804 million in 2016 and \$1.105 billion in 2015. ***The net charges recorded in 2017 and 2016 include amounts primarily related to transvaginal surgical mesh product liability cases and claims. The net charges recorded in 2015 include amounts primarily related to transvaginal surgical mesh product liability cases and claims*** Litigation related charges and credits are excluded by management for purposes of evaluating operating performance.

We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

(Emphasis added).

35. While discussing the progress of litigation related to Boston Scientific’s transvaginal surgical mesh products, the 2017 10-K continued to downplay the risks associated with those products, stating, in relevant part:

As of January 31, 2018, ***approximately 49,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us.*** The pending cases are in various federal and state courts in the U.S. and include eight putative class actions. There were also fewer than 25 cases in Canada, inclusive of one certified and three putative class actions and fewer than 20 claims in the United Kingdom. ***Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and***

manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. As of January 31, 2018, we have entered into master settlement agreements in principle or are in the final stages of entering one with certain plaintiffs' counsel to resolve an aggregate of approximately 44,000 cases and claims *All settlement agreements were entered into solely by way of compromise and without any admission or concession by us of any liability or wrongdoing.*

On or about January 12, 2016, Teresa L. Stevens filed a claim against us and three other defendants *asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China The complaint . . . alleges Racketeer Influenced and Corrupt Organizations Act (RICO) violations, fraud, misrepresentation, deceptive trade practices and unjust enrichment* On January 26, 2016, the Court issued an order staying the case and directing the plaintiff to submit information to allow the FDA to issue a determination with respect to her allegations. In addition, we are in contact with the U.S. Attorney's Office for the Southern District of West Virginia and are responding voluntarily to their requests in connection with that office's review of the allegations concerning the use of mesh resin in the complaint. *We deny the plaintiff's allegations and intend to defend ourselves vigorously.*

On February 27, 2017, Carolyn Turner filed a complaint against us and five other defendants *asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China. The complaint . . . alleges violations of the RICO, negligence, strict liability, breach of an express or implied warranty, intentional and negligent misrepresentation, fraud and unjust enrichment We deny the plaintiff's allegations and intend to defend ourselves vigorously.*

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof *associated with our transvaginal surgical mesh products.* While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs' counsel regarding potential resolution of pending cases and claims *and intend to vigorously contest the cases and claims asserted against us,* that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. *Initial trials involving our transvaginal*

surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.

(Emphases added).

36. Appended as exhibits to the 2017 10-K were signed SOX certifications, wherein the Individual Defendants certified that “the information contained in the [2017 10-K] fairly presents, in all material respects, the financial condition and results of operations of Boston Scientific Corporation.”

37. On May 13, 2018, CBS’s *60 Minutes* aired a story highlighting the Company’s alleged use of counterfeit imports in its surgical mesh products. In response, Boston Scientific stated that it has “extensively tested the [plastic] resin to confirm its composition, safety and performance.”

38. On February 19, 2019, Boston Scientific filed its annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2018 (the “2018 10-K”). The 2018 10-K discussed Boston Scientific’s costs associated with its ongoing defense of products liability claims related to its transvaginal surgical mesh products, and simultaneously downplayed the risks associated with those products, stating, in relevant part:

In 2018, 2017 and 2016, our litigation-related net charges were primarily in connection with transvaginal surgical mesh product liability cases and claims.

We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation, and therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

* * *

Our accrual for legal matters that are probable and estimable was \$929 million as of December 31, 2018 and \$1.612 billion as of December 31, 2017 and includes certain estimated costs of settlement, damages and defense. The decrease in our legal accrual was *primarily due to settlement payments authorized in 2018 associated with product liability cases or claims related to transvaginal surgical mesh products* We recorded litigation-related net charges in the amount of \$103 million in 2018, \$285 million in 2017 and \$804 million in 2016. *We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation* and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

(Emphasis added).

39. While detailing the progress of litigation related to Boston Scientific's transvaginal surgical mesh products, the 2018 10-K continued to downplay the risks associated with those products, stating, in relevant part:

As of February 5, 2019, *approximately 53,000 product liability cases or claims related to transvaginal surgical mesh products designed to treat stress urinary incontinence and pelvic organ prolapse have been asserted against us.* The pending cases are in various federal and state courts in the U.S. and include eight putative class actions. There were also fewer than 25 cases in Canada, inclusive of one certified and three putative class actions and fewer than 25 claims in the United Kingdom. *Generally, the plaintiffs allege personal injury associated with use of our transvaginal surgical mesh products. The plaintiffs assert design and manufacturing claims, failure to warn, breach of warranty, fraud, violations of state consumer protection laws and loss of consortium claims* During the fourth quarter of 2013, we received written discovery requests from certain state attorneys general offices regarding our transvaginal surgical mesh products. We have responded to those requests. As of February 5, 2019, we have entered into master settlement agreements in principle or are in the final stages of entering one with certain plaintiffs' counsel to resolve an aggregate of approximately 50,000 cases and claims *All settlement agreements were entered into solely by way of compromise and without any admission or concession by us of any liability or wrongdoing.*

On or about January 12, 2016, Teresa L. Stevens filed a claim against us and three other defendants *asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China The complaint . . . alleges Racketeer Influenced and Corrupt Organizations Act (RICO) violations, fraud, misrepresentation,*

deceptive trade practices and unjust enrichment On January 26, 2016, the Court issued an order staying the case and directing the plaintiff to submit information to allow the FDA to issue a determination with respect to her allegations. In addition, we are in contact with the U.S. Attorney's Office for the Southern District of West Virginia and are responding voluntarily to their requests in connection with that office's review of the allegations concerning the use of mesh resin in the complaint. *We deny the plaintiff's allegations and intend to defend ourselves vigorously.*

On February 27, 2017, Carolyn Turner filed a complaint against us and five other defendants *asserting for herself and on behalf of a putative class of similarly situated women, that she was harmed by a vaginal mesh implant that she alleges contained a counterfeit or adulterated resin product that we imported from China. The complaint . . . alleges violations of the RICO, negligence, strict liability, breach of an express or implied warranty, intentional and negligent misrepresentation, fraud and unjust enrichment We deny the plaintiff's allegations and intend to defend ourselves vigorously.*

We have established a product liability accrual for known and estimated future cases and claims asserted against us as well as with respect to the actions that have resulted in verdicts against us and the costs of defense thereof *associated with our transvaginal surgical mesh products*. While we believe that our accrual associated with this matter is adequate, changes to this accrual may be required in the future as additional information becomes available. While we continue to engage in discussions with plaintiffs' counsel regarding potential resolution of pending cases and claims *and intend to vigorously contest the cases and claims asserted against us*, that do not settle, the final resolution of the cases and claims is uncertain and could have a material impact on our results of operations, financial condition and/or liquidity. *Initial trials involving our transvaginal surgical mesh products have resulted in both favorable and unfavorable judgments for us. We do not believe that the judgment in any one trial is representative of potential outcomes of all cases or claims related to our transvaginal surgical mesh products.*

(Emphases added).

40. The 2018 10-K also touted Boston Scientific's commitment to safety and how this contributed to the Company's competitive strength, as well as its value to customers and stockholders, stating, in relevant part:

We believe that sound environmental, health and safety performance contributes to our competitive strength while benefiting our customers, stockholders and employees. We are focused on continuous improvement in these areas We are listed on the FTSE4Good Corporate Social Responsibility Index, managed by

the Financial Times and the London Stock Exchange, which measures the performance of companies that meet globally recognized standards of corporate responsibility. This listing recognizes our dedication to those standards and it places us in a select group of companies with a demonstrated commitment to responsible business practices

41. Additionally, the 2018 10-K generally discussed how Boston Scientific's medical products were subject to government regulation, and how certain of its products were subject to PMA application approval by the FDA. For example, the 2018 10-K stated in relevant part:

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on risk level of the device.

In the U.S., authorization to distribute a new device can generally be met in one of three ways.

* * *

The second process requires the submission of a premarket approval (PMA) application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with [Investigational Device Exemption] requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the Quality System Regulation (QSR). For novel technologies, the FDA will generally seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device.

(Emphasis added).

42. The 2018 10-K also contained merely generic, boilerplate representations concerning the possibility that Boston Scientific's products might fail to meet required regulatory hurdles, which could lead to, *inter alia*, product recalls and market exclusion. For example, the 2018 10-K stated in relevant part:

We are subject to extensive and dynamic medical device regulation, which may impede or hinder the approval or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved products.

* * *

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals *We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products or could increase the cost and time to obtain such approvals in the future.*

* * *

The FDA can ban certain medical devices Any adverse regulatory action, depending on its magnitude, *may restrict a company from effectively marketing and selling its products*, may limit a company’s ability to obtain future premarket clearances or approvals and could result in a substantial modification to our business practices and operations.

* * *

If we, or our manufacturers, fail to adhere to [the necessary regulatory] requirements, this could delay production of our products and lead to . . . difficulties in obtaining regulatory clearances, recalls . . . or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

(First emphasis in original).

43. The 2018 10-K also represented that Boston Scientific could not predict the impact of its possible failure to meet regulatory hurdles, including issues caused by a “later discovery” of “previously unknown problems” with its products, stating, in relevant part:

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change. *We cannot predict what impact, if any, those changes might have on our business.* Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. *Later discovery of previously unknown problems with a product or manufacturer could result in . . . delays or suspensions of regulatory clearances or approvals, seizures or recalls of*

products The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products . . . or the withdrawal of product approval by the FDA . . . could have a material adverse effect on our business, financial condition or results of operations.

(Emphasis added).

44. Appended as exhibits to the 2018 10-K were signed SOX certifications, wherein the Individual Defendants certified that “the information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of Boston Scientific Corporation.”

45. The statements referenced in ¶¶ 26-44 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Boston Scientific’s surgical mesh products indicated for the transvaginal repair of POP were unsafe; (ii) accordingly, Boston Scientific’s continued marketing and sales of these devices in the United States was unlikely to be sustainable; (iii) separately, the Company had sold vaginal mesh implants containing counterfeit or adulterated resin products imported from China; (iv) the foregoing conduct subjected the Company to a heightened risk of regulatory scrutiny and/or government investigations; and (v) as a result, the Company’s public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

46. On April 16, 2019, the FDA announced that it had “ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse . . . to stop selling and distributing their products in the U.S. immediately.” The FDA stated that “the manufacturers, Boston Scientific and Coloplast, have not demonstrated a

reasonable assurance of safety and effectiveness for these devices,” as required to continue marketing the devices in the United States. According to Jeffrey Shuren (“Shuren”), M.D., director of the FDA’s Center for Devices and Radiological Health: “In order for these mesh devices to stay on the market, we determined that we needed evidence that they worked better than surgery without the use of mesh to repair POP. That evidence was lacking in these premarket applications, and we couldn’t assure women that these devices were safe and effective long term[.]”

47. On this news, Boston Scientific’s stock price fell \$2.90 per share, or 7.67%, over the following two trading sessions, closing at \$34.91 per share on April 17, 2019.

48. Boston Scientific later responded to the FDA’s decision to ban its surgical mesh products for POP, stating, in relevant part:

We are deeply disappointed by this decision and believe the inaccessibility of these products will severely limit treatment options for the 50% of women in the U.S. who will suffer from POP during their lives. We have been working with the FDA for many years to develop the clinical evidence necessary to keep these important treatment options available. Unfortunately, today’s announcement by the FDA removes that possibility for the foreseeable future.

In light of the FDA’s decision and ongoing discussions with regulators outside of the U.S., Boston Scientific will stop global sales of its transvaginal mesh products indicated for pelvic organ prolapse: Uphold™ LITE Vaginal Support System, Xenform™ Soft Tissue Repair Matrix, Pinnacle™ Lite Posterior and Polyform™. After we review our plans with the FDA and other appropriate regulatory authorities, we will provide instruction following our approved process for removal of existing customer inventory in the coming days.

PLAINTIFF’S CLASS ACTION ALLEGATIONS

49. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Boston Scientific securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are

Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

50. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Boston Scientific securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Boston Scientific or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

51. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

52. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

53. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Boston Scientific;

- whether the Individual Defendants caused Boston Scientific to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Boston Scientific securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

54. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

55. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Boston Scientific securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Boston Scientific securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

56. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

57. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

58. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

59. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

60. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to,

and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Boston Scientific securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Boston Scientific securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

61. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Boston Scientific securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Boston Scientific's finances and business prospects.

62. By virtue of their positions at Boston Scientific, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

63. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Boston Scientific, the Individual Defendants had knowledge of the details of Boston Scientific's internal affairs.

64. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Boston Scientific. As officers and/or directors of a publicly-held Company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Boston Scientific's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Boston Scientific securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Boston Scientific's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Boston Scientific securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

65. During the Class Period, Boston Scientific securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Boston Scientific securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have

purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Boston Scientific securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Boston Scientific securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

66. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

67. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

68. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

69. During the Class Period, the Individual Defendants participated in the operation and management of Boston Scientific, and conducted and participated, directly and indirectly, in the conduct of Boston Scientific's business affairs. Because of their senior positions, they knew the adverse non-public information about Boston Scientific's misstatement of income and expenses and false financial statements.

70. As officers and/or directors of a publicly owned Company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Boston Scientific's financial condition and results of operations, and to correct promptly any public statements issued by Boston Scientific which had become materially false or misleading.

71. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Boston Scientific disseminated in the marketplace during the Class Period concerning Boston Scientific's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Boston Scientific to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Boston Scientific within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Boston Scientific securities.

72. Each of the Individual Defendants, therefore, acted as a controlling person of Boston Scientific. By reason of their senior management positions and/or being directors of Boston Scientific, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Boston Scientific to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Boston Scientific and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

73. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Boston Scientific.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.