UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FRANCES PEEL HENNINGTON,
Plaintiff

v. CIVIL ACTION NO. _____

BOSTON SCIENTIFIC CORPORATION, EMAI PLASTIC RAW MATERIAL CO, LTD., PROXY BIOMEDICAL LIMITED, LUXILON INDUSTRIES NV, SHENZHEN YFL INTERNATIONAL LOGISTICS LIMITED
Defendants.

PLAINTIFF'S ORIGINAL CLASS ACTION COMPLAINT

MOSTYN LAW FIRM
J. Steve Mostyn
Mark C. Sparks
3810 West Alabama Street
Houston, Texas 77027
(713) 861-6616 (Office)
(713) 861-8084 (Facsimile)

LAW OFFICES OF SHAWN J. WALLACH
Shawn J. Wallach
SW5611
52 Duane St, 7th Floor
New York, NY 10007
(646) 848-5400 (Office)
Wallach.shawn@gmail.com

TABLE OF CONTENTS

PLAINTIFF'S ORIGINAL CLASS ACTION COMPLAINT

Plaintiff, Frances Peel Hennington ("Plaintiff"), by and through her attorneys, brings this individual and class action complaint, pursuant to Rule 23 of the Federal Rules of Civil Procedure, against Defendant Boston Scientific Corporation ("BSC" or "Boston Scientific"), EMAI Plastic Raw Materials Co., Ltd. ("EMAI"), Proxy Biomedical Limited ("Proxy"), Luxilon Industries NV ("Luxilon"), Cambridge Polymer Group, Inc. ("Cambridge"), and Shenzhen YFL International Logistics Limited ("YFL") (collectively "Defendants") for violations of RICO - 18 U.S.C. § 1962. Plaintiff also brings causes of action against Defendant BSC for negligence, strict liability – design defect, strict liability – manufacturing defect, strict liability – failure to warn, breach of express warranty, breach of implied warranty, fraud, intentional misrepresentation, negligent misrepresentation, and unjust enrichment. Plaintiff alleges the following upon information and belief, except as to those paragraphs pertaining to Plaintiff's own actions, which are alleged upon personal knowledge. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF ACTION

1. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on her own behalf and on behalf of a class (the "Class") of similarly situated entities and individuals (the "Class Members") who were implanted with BSC transvaginal mesh products after January, 2012.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 18 U.S.C. §§1961, 1962, 1964, 28 U.S.C. §§ 1331, 1332(a), 1367, and 28 U.S.C. § 1332(d) (CAFA), because (a) there are 100 or more Class Members, (b) at least one Class Member is a citizen

of a state diverse from the citizenship of all Defendants, and (c) the matter in controversy exceeds $5,000,000, exclusive of interest and costs. The Court has personal jurisdiction over defendants pursuant to 18 U. S. C. §1965 (a) (b) and (d) as Defendants transacted their affairs in this district and the ends of justice require that Defendants be brought before this Court.

3. Defendants have significant contact with this federal judicial district such that they are subject to the personal jurisdiction of the court in this district. This Court's assertion of jurisdiction over these Defendants is consistent with the notions of fair play and substantial justice. One or more Defendants purposefully availed themselves of the benefits of this State such that they could reasonably anticipate being haled into Court here, or otherwise directed their conduct toward this State such that the effects of their damages were occasioned upon this Plaintiff within this State.

4. This Court is a proper venue for this action pursuant to 18 U.S.C. §1965 (a) and 28 U.S.C. §1391 (a) and (b)(2). Venue is proper in this judicial district because it is where a substantial part of the events and omissions giving rise to Plaintiff's causes of action took place.

PARTIES

5. Plaintiff Frances Peel Hennington in an individual who is a citizen of the State of New York and resides in this judicial district. Hennington suffers from Stress Urinary Incontinence ("SIU"). Hennington's urethral sling operation took place on October 17, 2014. Hennington was implanted with BSC's Advantage Fit Sling System in the State of New York.

6. Defendant Boston Scientific Corporation is a foreign corporation organized under the laws of the State of Delaware with its principal place of business in Marlborough, Massachusetts. BSC participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

7. Defendant EMAI Plastic Raw Materials, Co. Ltd. a/k/a Yi Mai Plastic Raw Materials, Co. Ltd. a/k/a Yi Mao Plastic Raw Materials, Co. Ltd. (referred to interchangeably as "EMAI") is / was a foreign corporation organized under the laws of China with its principal place of business in Guangzhou, China. EMAI directed its business activities to the United States, including New York, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

8. Defendant Proxy Biomedical Limited is a foreign corporation organized under the laws of Ireland with its principal place of business in Galway, Ireland. Proxy directed its business activities to the United States, including New York, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

9. Defendant Luxilon Industries NV is a foreign corporation organized under the laws of Belgium and with its principal place of business in Antwerp, Belgium. Luxilon directed its business activities to the United States, including New York, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

10. Defendant Cambridge Polymer Group, Inc. is a domestic corporation organized under the laws of Massachusetts and with its principal place of business in Charlestown, Massachusetts. Cambridge directed its business activities to the United States, including

New York, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

11. Defendant Shenzhen YFL International Logistics Limited is a foreign corporation organized under the laws of China with its principal place of business in Shenzhen, China. YFL directed its business activities to the United States, including New York, and participated in the scheme to defraud as more fully described herein and is liable to Plaintiff and Class Members for the damage suffered by them.

SUBSTANTIVE ALLEGATIONS

Background Facts

I. Introduction

12. BSC manufactures and markets transvaginal mesh—a medical device designed to be permanently implanted into women's bodies. It is a lucrative business. On average, BSC generates $120,000,000 in revenue every year from the sale of its transvaginal mesh products (the "Products"). Each year approximately 55,000 women receive a BSC mesh implant. BSC's transvaginal mesh is subject to regulation by the U.S. Food and Drug Administration ("FDA"), as well as other regulations and laws. BSC's transvaginal mesh was made from Marlex HGX-030-01,[1] a specific and unique polypropylene, which was cleared by the FDA under its 510(k) approval process.

13. At all relevant times, Marlex HGX-030-01 was manufactured and trademarked[2] by a joint venture between Chevron and Phillips Sumika (Phillips) in Pasadena, Texas. Marlex is sold in its raw form in pellets. By law, BSC is required to manufacture its transvaginal mesh

[1] Exhibit 1, Marlex Property Data Sheet.
[2] Exhibit 2, Trademark Information for Phillips Sumika Marlex.

from Marlex HGX-030-01.[3] If BSC used anything other than Marlex HGX-030-01 to form its mesh, the Products would not be cleared by the FDA. In short, Phillips Marlex comprises BSC's transvaginal mesh products. If BSC cannot get Marlex, then it cannot lawfully make its transvaginal mesh that was cleared by the FDA.

14. In 2011, BSC began running out of Marlex. No Marlex meant no transvaginal mesh products, and no $120,000,000 annual revenue.[4] After failing to convince the manufacturer, Phillips, to sell it any more Marlex, BSC made the fateful decision to smuggle counterfeit Marlex out of China. Specifically, beginning in June, 2011 through fall 2012, and specifically including on or about August 16, 2011, May 16, 2012, July 11, 2012 and July 31, 2012, and thereafter, BSC smuggled counterfeit Marlex pellets out of China and into Belgium and the United States. The counterfeit Marlex pellets were then subjected to a manufacturing process.[5] Each step in the process knowingly transformed the counterfeit Marlex pellets into a different form of counterfeit Marlex.

- The counterfeit Marlex pellets (also called resin) were sent to Luxilon's facility in Belgium to produce counterfeit Marlex fibers (filament);
- The counterfeit Marlex fibers were then sent to Proxy in Galway, Ireland to make counterfeit mesh using the counterfeit Marlex;
- The counterfeit mesh was formatted at Proxy to shape and sent to Medventure in Indiana to further shape in preparation for final knitting of counterfeit mesh manufactured with the counterfeit Marlex; and,
- The mesh knitting for the counterfeit mesh was completed at Medventure.[6]

[3] Exhibit 3, BSCM04700050810 - BSCM04700050813; *see also* Exhibit 9, relevant portions of 510(k) submission packet for Advantage line.
[4] Exhibit 6, BSCM13000000033.
[5] Exhibit 4, BSCM11500006055 – BSCM11500006064.
[6] Exhibit 5, BSCM12900000247.

15. Plaintiff and Class Members were implanted with counterfeit mesh made from counterfeit Marlex pellets smuggled out of China and illegally imported into the United States.

II. The Players

a. The Injured Women

16. Plaintiff and Class Members suffer from stress urinary incontinence (SUI) or pelvic organ prolapse (POP), and their condition was treated using transvaginal mesh Products manufactured by BSC. Plaintiff and Class Members suffered damages cause by BSC's transvaginal mesh Products. These women sought to acquire legal, safe, authentic, adequately tested mesh for permanent implantation into their bodies. Defendants marketed their transvaginal mesh Products as such—throughout the United States including New York. Defendants did not deliver such Products. Instead, Defendants provided Plaintiff and Class Members with counterfeit, adulterated Products with unknown or incompatible additives or chemicals. These Products cause a variety of serious health problems including severe pain, bleeding, painful intercourse, worsened incontinence, worsened pain, infections, and punctured organs. Moreover, the Products degrade within the human body. In addition to all of the complications and damage caused by vaginal mesh Products, Defendant Cambridge detected high levels of the toxic element selenium in the counterfeit resin. At this moment, it is unclear what additional complications and damage are being caused by this toxic element in the Products. The Products—which are now Plaintiff's and Class Members' property—is worth far less than bargained. Worse, this counterfeit, adulterated mesh is not just Plaintiff's and Class Members' property, it is permanently part of their bodies. And even worse, the Products are now degrading within their bodies.

b. Boston Scientific

17. BSC has a public face and a private face. Publicly, BSC represents that it's a "leading innovator of medical solutions that improve the health of patients around the world."[7] BSC claims it places its patients first.[8] Caring, it says, is its number one core value.[9] Excellence is inherent is everything we do, it claims.[10] Integrity is a key word it uses to describe itself.[11] BSC claims it is dedicated to women's health – indeed, it claims nothing is more important than women's health.[12] BSC estimates as many as 28 million women suffer from incontinence and prolapse. Capitalizing on these women's medical problems, BSC's own numbers suggest that at least 1,000 women receive BSC mesh products every week. Right now, it is likely another woman is being implanted with Boston Scientific's counterfeit, adulterated mesh.

18. BSC's actions (albeit concealed) speak far louder than its warm words to the public. BSC's public image starkly contrasts its decision to lie to Chinese customs, to U.S. Customs, to the FDA, and to every woman in America who has received a BSC mesh Product since January, 2012. The public image BSC projects differs considerably from the truth of a medical device company that has recalled 793 products since 2003,[13] has operated secret

[7] Exhibit 6A, https://www.bostonscientific.com/en-US/about-us.html
[8] *Id.*; Exhibit 6B, http://www.bostonscientific.com/2014ar/.
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] Exhibit 6C, Search results of recalled Boston Scientific products obtained from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

plants[14] and has been fined hundreds of millions of dollars repeatedly by the U.S. and other governments.[15]

c. Marlex HGX-030-01 Resin

19. To gain FDA clearance, BSC represented to the FDA it used a specific plastic resin, Marlex HGX-030-01 ("Marlex"), to make its mesh. Marlex is the backbone of BSC's transvaginal mesh Products.[16] The FDA cleared BSC's mesh Products based on that representation. Authentic Marlex resin was manufactured by Phillips.[17] Marlex is not a generic name (like "soft drink"). Marlex is a trademarked, specific brand (like "Coke") and is identified in the industry as Marlex HGX-030-01.[18]

20. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene.[19] BSC was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its mesh Products to Plaintiff and Class Members. The MSDS contains the following warning:

> "MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

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[14] Exhibit 7, http://www.boston.com/business/technology/biotechnology/articles/2004/09/27/suit_accuses_stent_maker_of_copying_designs?pg=full.

[15] Exhibit 8, http://www.justice.gov/opa/pr/medical-device-manufacturer-guidant-sentenced-failure-report-defibrillator-safety-problems.

[16] *See* Exhibit 3; *see also* Exhibit 9, relevant portions of Advantage Surgical Mesh 510(k) Pre-Market Notification submission packet.

[17] Exhibit 9A, Marlex HGX-030-01 is now discontinued. It was manufactured for use in products like woven industrial fabric and bags, woven carpet backing, woven bags and rope. Ultimately, unfortunately, BSC sought to permanently implant it into women's bodies. http://www.matweb.com/search/datasheettext.aspx?matguid=33893162c575403e83fab2c6e1fe8042.

[18] Exhibits 1 - 2.

[19] Exhibit 10, Marlex Material Safety Data Sheets from 2004 and 2008; *see also* Exhibit 11, U. Klinge, B. Klosterhalfen, M. Muller, A. P. Ottinger, V. Schumpelick, *Shringin of Polypropylene Mesh in vivo: An Experimental Study in Dogs*, 164 Eur J Surg 965, 965-969 (1998) (discussing how Marlex polypropylene degrades quickly in dogs).

> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES."

(emphasis supplied).[20]

21. In 2005, Phillips terminated its contract with BSC for Marlex HGX-030-01 because the resin was not intended for use in permanent implant devices.[21] In 2005, Phillips only allowed BSC to buy an additional 4,000 pounds of Marlex HGX-030-01. After that, Phillips cut off BSC from getting any more authentic Phillips Marlex from Phillips to permanently implant into women.

22. In 2011, BSC's supply of Marlex resin began to run precariously low.[22] BSC projected it would run out of this product—a critical component for its mesh products—by August/September 2012.[23] If BSC wanted to maintain the $120,000,000 in annual mesh sales, it would need to find more Phillips Marlex resin—and fast. In July, 2011 BSC requested that Phillips make a "special run" of one million pounds of the Marlex resin. From that special run, BSC would take all the resin it needed to continue the current

[20] *See* Exhibit 10.
[21] Exhibit 6, BSCM13000000033.
[22] Exhibit 11A, BSCM06100029374: BSC attempted to accurately forecast its Marlex run out date; Exhibit 11B, BSCM138000009697: BSC only had 700 pounds of Marlex left at Luxilon in Belgium; Exhibit 11C, BSCM13800009673: BSC uses 1,200 pounds of Marlex per year.
[23] Exhibit 12, BSCM06700722580.

production (and profits) and sell the rest. On August 2, 2011, Phillips refused to sell Marlex to BSC "at any price."[24] It seemed that, as far as Phillips was concerned, "no" meant no.

23. Phillips' adamant refusal created a "fire drill" at BSC—an alarm rang out at BSC. The impending Marlex shortage would cripple BSC's mesh profits.[25] The resin supply issue was BSC's "top threat."[26] Quite simply, $120,000,000 per year hung in the balance, not to mention the continued existence of BSC's transvaginal mesh division.[27] BSC feverishly began researching alternative resin products.[28] Time—and authentic, Phillips Marlex—was running short.

III. The FDA Required BSC's Mesh to be Manufactured with Authentic Marlex.

24. BSC's Advantage Mesh, Advantage Fit, and Lynx Systems were cleared for sale by the FDA through its 510(k) process on or about April 2, 2002.[29] To gain clearance under the FDA's 510(k) process, a manufacturer must prove that the product it attempts to put on the market is substantially equivalent to predicate devices cleared by the FDA. BSC specified that the mesh would be made from Marlex HGX-030-01 and that its predicate devices were Tension Free Vaginal Tape ("TVT"), BioSling, Mentor Suspend Sling, and BSC's Trelex Mesh.[30] In 2004, BSC's Obtryx and Prefyx Systems obtained 510(k) clearance (No. K040787) citing Advantage Mesh, Advantage Fit, and Lynx Systems as its predicate

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[24] *Id.*
[25] Exhibit 13, BSCM06700722854.
[26] Exhibit 13A, BSCM06700722558.
[27] Exhibit 13B; Exhibit 13C, BSCM06701713768 - BSC asked Philips to reconsider its decision not to sell the Marlex to BSC. BSC offered Phillips more money for the resin and even indemnity to protect Phillips from any liability which may result from the sale of the Marlex to BSC. However, Phillips told BSC that Phillips would not sell the Marlex resin to BSC at any price. In its desperation, BSC even considered contacting a third party to procure the resin from Philips and give it to BSC. None of these efforts were successful. Exhibit 13D, BSCM06700722572; Exhibit 13E, BSCM11200014918.
[28] Exhibit 6, BSCM13000000033; Exhibit 13F, BSCM07700280242.
[29] Exhibit 3, BSCM04700050810 - BSCM04700050813. Advantage, Advantage Fit & Lynx Systems (K020110) (Boston Scientific) received their class II substantial equivalence designation on 4/3/2002.
[30] *Id.*; *see also* Exhibit 9.

devices.[31] In short, Plaintiff's and Class Members' mesh Products, and all transvaginal mesh Products from BSC, were cleared through the FDA's abbreviated 510(k) process. This process is much cheaper and far easier than the more rigorous approval process. This abbreviated 510(k) process requires a claim of "substantial equivalence" to a prior device. Of course, BSC's prior devices contained Phillips' Marlex, which BSC needed to maintain the facade of its products' "substantial equivalence," including the mesh sold to Plaintiff and Class Members.

25. Once BSC knew it could no longer obtain authentic Marlex from Phillips it considered whether the FDA would approve a mesh made from a different polypropylene. BSC internally concluded taking a new product through the FDA, an agency BSC thought disfavored mesh, would detrimentally impact BSC's profits.[32] Moreover, BSC determined that the FDA had an anti-mesh position and it was highly unlikely to approve any change in material without supporting, clinical data. BSC began to research alternative resin products but concluded that the FDA, in a "backdoor" way to get mesh off the market, would likely not approve an alternative to Marlex.[33] Even if BSC thought the FDA would approve an alternative, approval would have a "long introduction time"[34] – time BSC did not have. BSC decided that its only logical path forward to avoid FDA scrutiny and comply with the law was to somehow buy more Marlex—and fast.[35]

26. BSC scrambled to look for alternative sources to obtain the Marlex, searching worldwide, asking over 25 different distributors, suppliers, third parties, and component manufacturers

[31] Exhibit 14.
[32] Exhibit 13, BSCM06700722854.
[33] Exhibit 12, BSCM06700722580; Exhibit 15, BSCM06700008804.
[34] Exhibit 14A.
[35] *Id.*

if they had any Marlex to sell.[36] No one would sell to BSC at a price that BSC was willing to pay. Faced with a financial catastrophe, BSC turned to its last resort, China—and more specifically, the Guangdong province. In fact, the Guangdong province of China is an area internationally known as a leading counterfeiter in the world. Soon, with BSC's risky entry into the Chinese resin market, the Guangdong province would again live up to that dubious reputation as a world-leading counterfeiter.

27. BSC knew that sourcing Marlex from China was "risky" due to the prevalence of counterfeit products sold in China.[37] But BSC's desperation drove it to ultimately purchase 37,400 pounds of counterfeit Marlex resin from EMAI, a known Chinese distributor of counterfeit resin with offices in the Guangdong province.

IV. Counterfeit Marlex

a. EMAI was a known counterfeiter of resin.

28. China has a well-known, dark history of supplying counterfeit, adulterated products. More specifically, China is known to produce counterfeit mesh. The medical device maker Bard was forced to recall thousands of its mesh products because its distributor used a counterfeit Marlex.[38] BSC considered five potential Chinese sellers of Marlex, all found on alibaba.com (a known counterfeit website[39] that was on the U.S. government's annual "Notorious Market List" until 2012[40]). Ultimately—and fatefully—BSC settled on Defendant EMAI.[41] Defendant EMAI's headquarters sit squarely within the Guangdong province of China—an area of rampant counterfeiting with highly publicized arrests and

[36] Exhibit 13F.
[37] Exhibit 14B at BSCM138000009461.
[38] Exhibit 15A, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm
[39] Exhibit 30A.
[40] Exhibit 30B.
[41] Exhibit 16, BSCM138000008924.

prosecutions doing little to slow down the counterfeiting machine it has become. Ironically, BSC assumed that EMAI had more integrity than BSC. Since the Phillips MSDS warned against medical implantation, BSC instructed its employees not to tell EMAI that the resin would be used for medical implantation, so as to not "scare them away."[42]

29. In June, 2012, BSC's "Women's Health Division" (WHD) received an email from another BSC division. The email was titled **"Counterfeit material from a supplier you use – ACTION REQUIRED,"** and urgently warned that EMAI attempted to sell BSC a counterfeit resin to during the same time as BSC's WHD was procuring the EMAI resin for mesh.[43]

30. Defendant EMAI had sent a sealed bag of resin to the other BSC division,[44] but when that division called the manufacturer (as it should have), the manufacturer told them that the lot number was not valid. The BSC engineer in the other BSC division immediately concluded that the EMAI resin was counterfeit *solely* on the fact that the lot number was invalid and refused to buy from EMAI. Then, the engineer from the other BSC division notified all BSC divisions, but specifically WHD. Despite this, WHD went ahead and completed its shipment of the counterfeit Marlex resin to permanently implant in women's bodies—knowing full well its sister division had just refused to do business with Defendant EMAI.

b. <u>The price of EMAI resin was well below market value.</u>

31. In January 2012, one U.S. distributor offered to sell Marlex to BSC for $67 per pound.[45] BSC was not willing to pay this amount, but admitted that $12 per pound would be a fair

[42] Exhibit 19 at BSCM138000009802.
[43] Exhibit 17, BSCM11500006904 - BSCM11500006906.
[44] *Id.* at BSCM11500006904.
[45] Exhibit 17A, BSCM06700008720.

asking price.[46] BSC found a much more favorable price in China—of course, one would expect a bargain price since counterfeit goods are usually cheaper than the real thing. BSC's internal documents have conflicting information about the exact amount paid for the Chinese resin, but the following per pound figures can be calculated using BSC's documents:

(1) **$1.18 per pound**: Shipping documents for the first 4,400 pounds showed the declared value for U.S. Customs for the 2 tons (2020kg) = $5,200 USD.[47] $5,200 for 4,400 pounds = $1.18 per pound.

(2) **$1.33 per pound:** Final payment for 60% of the 15 tons (15,000kg) of resin = $173,745 CNY.[48] Today, $173,745 CNY = $26,406.82 USD. Payment of $26,406.82 for 60% of 15,000kg means the total for all 15,000kg was $44,011.37. $44,011.37 for 33,000 pounds is $1.33 per pound.

(3) **$1.41 per pound:** Final payment for 60% of the 15 tons (15,000kg) of resin = $173,745 CNY.[49] Internal emails states that this amount translated to approximately $28,000 USD.[50] Payment of $28,000 for 60% of 15,000kg means the total for all 15,000kg was $46,666.67. $46,667.67 for 33,000 pounds is $1.41 per pound.

(4) **$1.21 per pound:** Zhao, BSC Executive and buyer in China, stated that the final payment for 60% of the 15 tons (15,000kg) is $24,000.[51] Payment of $24,000 for 60% of 15,000kg means the total for all 15,000kg was $40,000. $40,000 for 33,000 pounds is $1.21 per pound.

(5) **$0.96 per pound plus tax:** Zhao's first quote from EMAI was $13,900 RBM per ton plus tax.[52] Today, $13,900 RBM = $2,112.61 USD. $2,112.61 for 2,200 pounds (1,000kg) is $0.96 per pound.

32. BSC admitted that $12 per pound was a fair asking price. The Chinese resin at its *highest* price of $1.41 per pound, represented an 85% discount off the U.S. price BSC considered fair. It cost BSC two times more to air ship the 4,400 pounds of Chinese resin to the United

[46] *Id.*
[47] Exhibit 17B at BSCM11500004775.
[48] Exhibit 17C at BSCM13500000768.
[49] *Id.*
[50] *Id.* at BSCM13500000766.
[51] Exhibit 20 at BSCM12900000083.
[52] Exhibit 19 at BSCM13800009804.

States than it cost BSC to actually purchase the 4,400 pounds.[53] This makes one wonder: who would pay to ship Marlex to China in the first place?

c. EMAI had no paperwork documenting that its product was authentic Marlex and lacked import documentation.

33. Although it lacked the necessary paperwork to prove the authenticity of the resin (paperwork demanded by BSC's internal protocols), EMAI claimed its product was indeed Phillips Marlex HGX-030-01.[54] The chain of custody of the EMAI resin could not be documented.[55] EMAI could never show BSC that the Marlex was imported into China. Worse, EMAI could never show BSC a Certificate of Compliance or Certificate of Analysis that, by BSC's own standards, is necessary to accept a product from abroad. As of August 4, 2011, even BSC's Vice President of Operations understood that the "China stuff" was "NG"—presumable, no good.[56]

34. If the EMAI resin were authentic and legally imported to China, upon arrival in China, the Chinese importers would have required a "Certificate of Compliance" (C of C) or Certificate of Analysis (C of A)[57] to ensure authenticity and country of origin.[58] This would ensure that Chinese customs collected the proper import taxes. This certificate details important authenticity information such as the name, the manufacturer, the purchaser, the lot number, product property(ies), test method, value, and unit, purchase order, and packaging information.[59]

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[53] Exhibit 17B at BSCM11500004773- BSCM11500004775. These documents show that it cost BSC approximately $12,000 USD ($93,619.50 HKD) to air ship the 4,400 pounds of Chinese resin from Hong Kong to Boston and the declared value of the resin for customs was $5,200.
[54] Exhibit 18, BSCM135000000010 – BSCM13500000011.
[55] *Id*.
[56] Exhibit 13D at BSCM06700722575.
[57] Certificate of Compliance (C of C) and Certificate of Analysis (C of A) are used interchangeably in BSC's internal emails, depending on the author of the email.
[58] Exhibit 19, BSCM138000009805.
[59] Exhibit 19A, BSCM11800027286, a sample Certificate of Analysis.

35. When goods are brought into China, an import tax must be paid and documentation obtained that prove the goods cleared customs. If those goods are ever exported out of China, import documentation and tax receipts must be produced to Chinese officials to prove that the goods cleared customs upon import and that taxes were paid. If the goods have been modified in China, the Chinese government then charges a value added tax to the increased value of the good when exported and requires the same import documentation and tax receipts in order to calculate the value added tax. Without this documentation, one cannot legally export from China a good that was originally manufactured outside of China. Defendant EMAI could never produce the proper import and tax documentation even though the EMAI resin went through customs in Guangzhou just days after BSC's first inquiry and just weeks before BSC purchased it.[60] This left one BSC employee to wonder "[i]s anyone aware of a method to deal with export of undocumented, imported goods from China?" BSC's answer—smuggle the resin out of China.

36. BSC acknowledged the importance of product authenticity and emphasized to Zhao, BSC Executive and buyer in China, that it was imperative to ensure the EMAI resin was in fact Phillips Marlex made in the United States. BSC repeatedly insisted that EMAI procure the C of C so BSC could ensure its accuracy:

- 7/28/11 – R&D executive Ron Ciulla stressed the need for a C of C to Todd McCaslin. McCaslin acknowledged the need and asked if all would be dead without a C of C.[61]

- 8/5/11 –McCaslin stated that a distributor without a C of C is high risk.[62]

[60] Exhibit 18, BSCM135000000010 – BSCM13500000011; Exhibit 16 at BSCM13800008924 (dated 7/25/11 and stated "they won't know exactly what's in the shipment until the shipment reaches at custom tomorrow in Guangzhou."); Exhibit 35 at BSCM11500006824 (BSC had purchased at least 4,000 pounds of the EMAI resin by 8/15/11).
[61] Exhibit 20A.
[62] Exhibit 13C.

- 8/15/11 –McCaslin stated that they needed to work on getting a C of A.[63]

- 8/15/11 – Zhao sent a picture of the counterfeit Marlex bags containing EMAI resin, showing a lot number. McCaslin told Zhao, "Very nice work!"[64] McCaslin told Zhao to push a bit on getting a C of A.[65]

- 8/15/11 – Using the lot number from the photo that Zhao sent, Ann Charest reached out to a 3rd party and asked that they use their connections at Phillips to obtain a C of C for BSC.[66]

- 8/25/11 – Charles Smith pressed the importance of pursuing all avenues to determine lot number traceability.[67]

- 8/30/11 –McCaslin asked Zhao to continue to work with EMAI to determine the chain of custody and asked again if EMAI had paperwork to show where EMAI bought the material.[68]

37. Amazingly, even though a C of C is essential to prove the authenticity of the resin, Defendant BSC simply accepted the excuse that the C of C was not "available" or lost.[69] They say this even though BSC knew that the Chinese resin was likely procured in bulk by railcar and repackaged.[70] When Defendant Smith told another BSC executive, Robert Mullally, that EMAI did not have the certification to prove traceability, Mullally asked Smith, "[w]hat kind of statement is [that]?" Mullally then asked the same question likely on the mind of each reader, "How did all of this resin end up in China if it was made in Texas?"[71] That crucial question was never answered, nor could it be.

[63] Exhibit 20 at BSCM12900000090; Exhibit 35 at BSCM11500006824.
[64] Exhibit 22A at BSCM06701715875.
[65] Exhibit 20 at BSCM12900000089; Exhibit 35 at BSCM11500006823.
[66] Exhibit 18 at 13500000015.
[67] Exhibit 21 at BSCM07700182056.
[68] Exhibit 35 at BSCM11500006820-BSCM11500006821.
[69] Exhibit 20, BSCM12900000074; Exhibit 27 at BSCM13500000971; Exhibit 20A at BSCM13800008344.
[70] Exhibit 21A at BSCM06701685128; Exhibit 18 at BSCM135000000010; Exhibit 21 at BSCM07700182058.
[71] Exhibit 22, BSCM13500000937.

d. Phillips denied that the EMAI resin was authentic Marlex.

38. Because Phillips refused to deal directly with BSC, BSC enlisted the help of a third party to call Phillips to confirm the lot number and hopefully obtain the critical C of C.

39. Below is a photograph of one of EMAI's counterfeit bags taken by Zhao, BSC's executive in China in charge of purchasing the resin, showing the lot number that needed authenticity verification:

40. Curiously, EMAI requested a photograph of a bag of Phillips Marlex prior to Zhao's visit to EMAI. There is no indication that BSC ever sent EMAI a photograph of an authentic Marlex bag, most likely because BSC had been buying its Marlex in bulk. But EMAI's request for a photograph is highly suspicious as EMAI told BSC that is has just imported Marlex. EMAI would only need a photograph of a Marlex bag if it was going to manufacture a counterfeit product (which it had a history of doing, in the Guangdong area) because EMAI would then need a counterfeit Phillips bag to put it in. One of the counterfeit bags EMAI made is shown above. EMAI made this bag likely using its own plastic resin.

But EMAI had to make up a Phillips lot number. Ironically, this made it easy to detect counterfeit Marlex. Frank Zakrzewski of CPChem testifies by affidavit, for several obvious reasons, including the wrong color and legal entity printed on the bags, and the invalid lot number, that **the bags in which BSC purchased the China Sourced Resin were not Phillips' bags.**[72]

41. Using the lot number on the EMAI photograph sent by Zhao, the third party contacted Phillips to obtain the requested authenticity information. On August 15, 2011, the third party told BSC that an employee in Phillips' quality organization said that the lot number shown on the EMAI bags was not valid.[73] On August 31, 2011, the third party confirmed to BSC that he tried 2 routes to get the information, and received the same answer from both: the lot number on the bags being sold by EMAI was not a lot number in Phillips' system.[74] The lot number was fake. Phillips' lot number system had served its purpose. As designed, Phillips' system showed that the false lot number from the counterfeit bag was fake.[75] In a display of pure greed and rapped with desperation, BSC ignored this conclusive proof that the resin was counterfeit.

e. Summary of facts showing the EMAI resin is counterfeit.

42. At this point in the story, BSC knew that:

- China has a history of selling counterfeit plastics.
- EMAI had no proof the resin was imported into China despite arriving in China days before.
- EMAI had no C of C or C of A proving that the resin was made by Phillips.
- EMAI was a known seller of counterfeit plastic goods with a history of

[72] *See* Exhibit 22A – Affidavit of Frank Zakrzewski.
[73] Exhibit 18 at BSCM135000000014
[74] *Id.* at BSCM135000000010 – BSCM13500000011.
[75] *Id.*.

attempting to sell counterfeit resin to BSC.

- The manufacturer Phillips confirmed that the lot number shown on the EMAI resin was not a Phillips lot number.

f. Despite overwhelming evidence that the EMAI resin is counterfeit, BSC relied on EMAI's dubious assurances that the product was authentic Marlex.

43. BSC, confronted with conclusive proof the lot numbers printed on the bag are fake, still needed Marlex to sustain its multi-million dollar profits. So, Defendant BSC chose to accept EMAI's word that the EMAI resin was Phillips Marlex despite the overwhelming evidence to the contrary. Desperate to use the counterfeit resin, BSC and its employees pointed to the dubious assurances of their co-conspirator as proof of authenticity. Defendant EMAI, a known counterfeiter, assured them that the alleged Marlex was all from the same lot (a lot BSC knew did not exist).[76] Rather than rely on the word of the U.S. manufacturer, Phillips, that this was fake resin and not Marlex, BSC accepted dubious assurances from a known counterfeiter coming to BSC second-hand through emails from China. This stunning refusal to accept the facts and look the other way is documented in an internal email circulated among high level BSC executives.[77]

V. BSC Purchased and Smuggled Counterfeit Marlex out of China in Details Spelled out in BSC's own Documents.

a. Horns of a Dilemma

44. BSC was on the horns of a dilemma. Manufacturing its mesh with something other than Marlex HGX-030-01 created the risk, indeed the certainty in the minds of BSC, that its entire mesh line of products, including those sold and implanted into Plaintiff and Class Members, would be disapproved by the FDA. BSC was even looking to add mesh

[76] Exhibit 23, BSCM129000000085; Exhibit 21 at BSCM07700182056.
[77] *Id.*

manufactured with Marlex to another product line, Pinnacle Biologic, to increase its profit margin, but this would also affect the current Marlex runout date.[78] A failure to secure authentic Marlex HGX-030-01 would cost BSC $120,000,000 in sales each year, would wipe out a division of the company, and would cost lots of people their jobs (including all of those within the mesh division scrambling to find Phillips Marlex).

45. BSC could not find Phillips Marlex HGX-030-01 to purchase despite going to over 25 different distributors, suppliers, third parties, and component manufacturers.[79] The horns of BSC's dilemma bore down hard on them. Phillips would not sell its authentic Marlex to BSC; Phillips' customers would not sell it to BSC; and the FDA would not approve an alternate plastic. The last option—the EMAI resin—clearly was counterfeit.

46. BSC's most profitable choice to keep the lucrative mesh doors open was to purchase the counterfeit EMAI resin and smuggle it out of China and smuggle it into the U.S. and Belgium for production, then design a test that would allow BSC to claim equivalency if it was ever questioned in an attempt to cover up its criminal conduct. The safest choice—the choice to put safety first, as BSC publicly claimed to do—was to walk away from the fake Chinese resin. BSC chose poorly—embracing the counterfeit, Chinese mesh with reckless abandon for patient safety.

b. <u>BSC purchased the EMAI resin it knew was counterfeit.</u>

47. BSC purchased a total of 37,400 pounds of fake Marlex from EMAI. 37,400 pounds is 680 bags that are roughly the size of a fertilizer bag.[80] BSC intended that it would last for 25

[78] Exhibit 23A, BSCM07300046897; Exhibit 24, BSCM06100027516.
[79] Exhibit 13F.
[80] The counterfeit Phillips bag lists a net weight of 25 kilograms or approximately 55 pounds.

years,[81] meaning BSC could continue to implant counterfeit mesh[82] into unsuspecting women through the year 2032. The counterfeit mesh was implanted into Plaintiff and Class Members and will continue to be implanted into hundreds of women daily (including New York women), causing permanent harm to women who will be paying inflated prices for counterfeit, adulterated mesh worth far less than the authentic material. This is certainly not what Plaintiff and Class Members bargained for when they purchased BSC's product.

48. By August 15, 2011, BSC had purchased the first 4,400 pounds of the EMAI resin.[83] This same day, BSC got confirmation from an employee in Phillips' quality organization that the lot number on EMAI's bags was not a valid Phillips lot number.[84] Despite knowing that Phillips did not manufacture the EMAI resin, BSC shipped the 4,400 pounds to the U.S. on August 21, 2011,[85] and paid a 40% deposit to purchase the remaining 33,000 pounds of the counterfeit resin on August 25, 2011.[86] On August 31, BSC had confirmation through two other avenues that the lot number on the EMAI resin was not valid.[87] Subsequently, on or about November 9, 2011, BSC still paid the remaining 60% balance on the 33,000 pounds of counterfeit resin.[88]

49. Now that BSC had secured what it believed was a 25-year supply of counterfeit Marlex, it only needed to get the resin out of China and into the U.S. and Belgium so production could continue and profits could be sustained. To get the counterfeit Marlex out of China, BSC orchestrated a smuggling operation.

[81] Exhibit 25, BSCM12900000228.
[82] A product BSC salesmen referred to as "bullshit." Exhibit 26 at BSCM15100003790.
[83] Exhibit 35 at BSCM11500006824.
[84] Exhibit 18 at BSCM13500000014.
[85] Exhibit 20 at BSCM12900000086.
[86] Exhibit 21 at BSCM07700182056.
[87] Exhibit 18 at BSCM13500000010.
[88] Exhibit 33A at BSCM11500007222.

50. BSC's original plan called for the counterfeit Marlex to be shipped in five shipments:

- 110 pounds or 2 bags for testing shipped by air to the U.S.;
- 4,290 pounds or 78 bags shipped by air to the U.S.;
- 11,000 pounds or about 200 bags shipped by ocean transport to Belgium;
- 11,000 pounds or about 200 bags shipped by ocean transport to the U.S.; and
- 11,000 pounds or about 200 bags shipped by ocean transport to the U.S.

51. BSC's plan was to buy two bags of EMAI resin (about 110 pounds), send it by plane to the U.S., and "test" it to confirm the EMAI resin was authentic Phillips Marlex.[89] Once BSC could "confirm" that the product was authentic, BSC would ship by air 4,290 pounds[90] of the tested product to relieve the impending shortage.[91] Then, BSC would ship another 33,000 pounds[92] via ocean transport.[93] However, even this plan did not fit BSC's condensed timeline and BSC decided to secure the product immediately, getting all 4,400 pounds to the U.S. as soon as possible.[94] Moreover, crucial BSC documents reveal that BSC's WHD had decided to use the 4,400 pounds regardless of the test results.[95] Indeed, by early October 2011, the Chinese resin was already being sent to Luxilon for production runs.[96] The production runs showed the EMAI resin did not perform the same as authentic

[89] Exhibit 28, BSCM13800008329-30.
[90] BSC's internal emails, and Plaintiff's Original Class Action Complaint, often refer to this initial purchase and shipment as 4,000 pounds. However, BSC bought 2 metric tons—2,000kg in 80 bags (25kg/bag). *See* Exhibit 17B at BSCM11500004775. The conversion of 2,000kg is approximately 4,400 pounds.
[91] *Id.*
[92] BSC's internal emails, and Plaintiff's Original Class Action Complaint, refer often to this later purchase and shipment as 30,000 pounds. However, BSC bought 15 metric tons—15,000kg in 600 bags (25kg/bag). *See* Exhibit 35 at BSCM11500006820. The conversion of 15,000kg is 33,000 pounds.
[93] Exhibit 29, BSCM06701716032.
[94] Exhibit 29A, BSCM07700277053: The first 4,400 pounds arrived in the U.S. on 8/26/11. BSC shipped several hundred pounds of this resin to Luxilon in October, 2011. Exhibit 29B at BSCM11500003656.
[95] Exhibit 30, BSCM07300046915; Exhibit 31A
[96] Exhibit 29B at BSCM11500003656; *see also* Exhibit 29C at BSCM04200117214.

Marlex. During the runs, the filament broke multiple times and Luxilon had to adjust the melt temperature because of the differences in the material.[97]

c. The difficulties created by the lack of documentation.

52. The fake Marlex lacked a Certificate of Compliance ("C of C"), despite repeated discussion of the need for, and the absence of, the C of C. The C of C was of paramount importance as it would prove authenticity to U.S. Customs officials. To satisfy FDA concerns that authentic Marlex is being used to produce BSC's mesh, BSC needed to show that authentic Marlex was imported from Phillips into China and then exported out of China (necessitating a C of C to show Chinese Customs) and then imported into the U.S. or into Belgium.

53. Of course, BSC and EMAI could never find the import paperwork because the product was fake, as confirmed by Phillips. BSC could be truthful with Chinese customs and report that it was exporting from China a product made in China, but then BSC would create problems for itself with the FDA. Stated differently, if BSC claimed the EMAI resin was made in China, the product would clear Chinese customs, but BSC would have to notify the FDA of the change in material. The FDA would likely reject the entire BSC mesh product line, costing BSC $120,000,000 its annual revenues. If BSC declared to Chinese customs the EMAI resin is Phillips Marlex then BSC would avoid the FDA problem, but run the risk the Chinese would require proof of import documentation and tax receipts. Resolving the discrepancy would be time-consuming, costly and might lead Chinese customs to confiscate and destroy the EMAI resin.

[97] Exhibit 39A at BSCM07700280497.

d. Smuggling the 4,400 pounds

54. In August, 2011, BSC concocted a scheme to immediately smuggle 4,400 pounds of resin it found on alibaba.com (a known counterfeit website) out of China even though it was found in a warehouse in Guangdong Province, China (a hub for expert counterfeiters[98]) without the C of C and required import paperwork and tax receipts. On August 21, 2011, Zhao, BSC Executive and buyer in China of the counterfeit Marlex, reported to the Global Supplier for BSC that the 4,400 pounds were shipped by air.[99] In order to get past a Chinese customs inspection, the shipper "over-bagged" the counterfeit bag.[100] To over-bag is to put a solid white or brown bag over the counterfeit bags.[101] The solid over-bags contained no markings, and covered up the English on the counterfeit bags.[102] BSC "took a chance"[103] —the amount of product was small, the transport was by air, and the EMAI resin in the counterfeit Phillips bag was over-bagged, so the 4,400 pounds were not "inspected."[104] Put simply, BSC—a medical device manufacturer headquartered in the U.S.—smuggled the 4,400 pounds of counterfeit resin out of China.[105]

55. The deception rose to high levels within BSC. A BSC executive made separate and contradictory reports on the same day about the origin of the resin in order to clear Chinese customs, and then U.S. customs. In bold disregard for the crimes they committed,

[98] Guangdong Province is a hide-out for counterfeiters. *See*, e.g., Exhibit 30B, article identifying hundreds of counterfeiters caught in 2014. http://www.chinadaily.com.cn/china/2014-07/30/content_18217996.htm. Guangdong is in fact the home of the largest counterfeit goods market in the world. http://appv1.linktv.org/videos/genuine-pride-for-knockoff-goods-in-guangzhou. Exhibit 30C.
[99] Exhibit 31, BSCM12900000086.
[100] Exhibit 20, BSCM12900000074.
[101] *See* Exhibit 27 at the final photograph for an example of an over bag.
[102] *Id.*
[103] Exhibit 31B.
[104] *Id.*
[105] BSC actually received photographs of the forgeries and smuggling operation. On December 1, 2011 BSC executive George Vialle, Director of the Global Supply Chain, circulated photographs for the 4,400 pounds of the resin in the original and over bags. Exhibit 27, BSCM13500000971.

Defendants had photographs taken of counterfeit bags and over bags.[106] In a truly shocking move, Defendants brazenly bragged about their criminal activity, openly circulating the photographs of the smuggled bags via email.

56. On August 17, 2011, Rob Mullally, Import Export Coordinator asked Charles Smith, Director of Research and Development, about the Chinese product. Smith reported that it was just a bag of Marlex resin as made by Phillips off the shelf, manufactured in Texas.[107] Mullally then told Smith that he should describe the product as just Marlex being returned to the United States for inter-company use in Marlborough, Massachusetts.[108] Of course, that wasn't true.

57. This information was used for the shipping instructions for import to the U.S. (to satisfy the FDA) and would help the material get through U.S. customs easier.[109] However, Rob Mullally tells the truth in a later email. When shipping the EMAI resin, Mullally tells the Chinese shipper to report that that the product was made by a Chinese manufacturer to "clear" Chinese customs.[110] The Chinese manufacturer was identified as Defendant EMAI from Guangdong Province, China.[111]

58. After BSC safely smuggled the initial 4,400 pounds of counterfeit Marlex out of China, it set in motion its plans to smuggle the remaining resin out of China to protect its $120,000,000 annual sales and the jobs of those BSC directors and officers directing the smuggling operation. No one mentioned protecting the women from the counterfeit resin was soon to infect. BSC leaders were more concerned about the 33,000 pounds of

[106] Exhibit 27 at BSCM13500000971.
[107] Exhibit 36, BSCM11500005993.
[108] *Id.* at BSCM11500005992.
[109] *Id.;* Exhibit 36A at BSCM11500004627.
[110] Exhibit 32, BSCM13500000465.
[111] Exhibit 33, BSCM13500000448.

counterfeit resin still stuck in China.[112] BSC leaders not only smuggled dangerous, counterfeit resin into the United States, they brought that fake product directly into the bodies of unsuspecting women like the Plaintiff and Class Members.

e. Smuggling the 33,000 pounds

59. BSC was left with the remaining 33,000 pounds to get from China to the United States, or from China to Belgium, where the resin would be turned into filament by Luxilon to make the mesh. To get the 33,000 pounds of EMAI resin out of China without the legal paperwork, BSC would have to say the EMAI resin was made in China.[113] Defendant YFL, BSC's shipper, recommended the 33,000 pounds of resin be transferred to different bags with Chinese markings because a large ocean shipment would likely to be inspected by Chinese customs.[114] If Chinese Customs saw "Phillips" bags, the inspectors would believe the resin was a foreign product (which would contradict the paperwork claiming the product was made in China), BSC would be unable to provide paperwork to authenticate the product (C of C), and BSC would "be in trouble."[115] Chinese customs could very well confiscate the 33,000 pounds of resin without returning them to BSC – costing BSC $120,000,000 per year. BSC did not want any problems with Chinese customs, as its previous experience was "painful" and "resource intensive."[116]

60. We know BSC, with the help of YFL, resolved its shipping problem, although the details are a bit murky—as most smuggling operations tend to be. After 19 pages of emails about this problem, George Vialle suggested the issue be discussed on a conference call.[117]

[112] Exhibit 22A, BSCM11500007222 – BSC made its final payment for the remaining 33,000 pounds on November 9, 2011.
[113] Exhibit 34, BSCM11500006030.
[114] *Id.*
[115] *Id.*
[116] Exhibit 34A, BSCM11500006030.
[117] Exhibit 35, BSCM11500006807.

BSC's internal documents reveal BSC's ultimate solution to the problem—it approached this problem like a drug deal. It divided the 33,000 pounds of EMAI resin into three shipments (it had been warned that the bigger the shipment the greater the risk of inspection)[118] and YFL shipped each by sea 3 different dates to the following locations:

5/16/12: 11,000 pounds (5 metric tons) of EMAI resin was shipped by sea from China to Defendant Luxilon in Belgium.[119] This shipment arrived in Wijnegem, Belgium and was then transported by truck to Luxilon.[120]

7/11/12: 11,000 pounds (5 metric tons) of EMAI resin was shipped by sea from China to Seattle, Washington.[121] The final destination of this shipment was a warehouse in Indiana.

7/31/12: 11,000 pounds (5 metric tons) of EMAI resin was shipped by sea from China to Seattle, Washington. The final destination of this shipment was a warehouse in Indiana.

61. BSC's internal documents reveal the counterfeit Marlex cleared Chinese customs by claiming it was made in China.[122] The counterfeit Marlex cleared U.S. customs by claiming it was made in the U.S.[123] BSC did not advise the FDA about the lack of authenticity of the resin. Plaintiff and Class Members were sold and implanted with the adulterated, counterfeit, EMAI resin despite paying a premium price for genuine Marlex resin. Codefendants openly conspired to commit criminal activity in BSC company emails.

62. Smith, the executive in charge of this project for BSC, wanted to use the same over-bagging approach for the 33,000 pounds (15 metric tons) of fake Marlex that it had used to smuggle

[118] Exhibit 20, BSCM12900000074. Zhao, the BSC buyer in China, explicitly discussed that the preferred course was to split the ten tons into two containers and have 5 tons in each in case of any accidents. One thing that might have happen was that BSC gets caught and admittedly, BSC would be in trouble. One kind of trouble was that the material would be confiscated, meaning the $120,000,000 would be lost, the division would close and people would lose their jobs. *See also* Exhibit 20B.
[119] Exhibit 36B at BSCM07700186099.
[120] Exhibit 35A, BSCM11500007399; BSCM11500007458.
[121] Exhibit 36C at BSCM11500006533.
[122] Exhibit 32, BSCM13500000465.
[123] Exhibit 36, BSCM11500005992

out the 4,400 pounds via air because BSC completely evaded detection by customs on the first 2 tons air shipped. However, more intricate plans were necessary to ship the larger amounts of EMAI resin purchased. Zhao, BSC Executive and buyer in China, discussed with BSC executives his conversation with YFL, and the need to conceal the containers from the inspectors by repacking the full inventory in different bags so Chinese customs did not catch them smuggling the alleged Marlex out of China without the proper paperwork.[124] Zhao goes on to talk about the trouble that will happen if they are caught by Chinese customs.[125]

63. Smith responded that they could just "over-bag" the products again.[126] However, Plaintiff believes, based on emails from the Indiana storage facility,[127] and emails and photos regarding the shipment to Belgium,[128] that BSC, at YFL's suggestion, packed or repacked the full inventory in different bags, in order to avoid the risk of confiscation by Chinese customs if the counterfeit "Phillips" bags were discovered.

64. At least eight (8) high level BSC executives were included on these emails and allowed these laws to be brazenly broken. A medical device company's high-level executives and employees were openly discussing smuggling adulterated, counterfeit resin from one of the leadings counterfeiting provinces in China—Guangdong—and they each stayed at least willfully blind to the blatant legal violations.

65. It is incredible that BSC employees shamelessly laid out details on how to complete the smuggling operation and finalize their criminal enterprise in company emails. BSC

[124] Exhibit 20, BSCM12900000074.
[125] *Id*.
[126] *Id*.
[127] Exhibit 36E at BSCM13500000085.
[128] Exhibit 36F at BSCM13500000733, BSCM13500000734, BSCM13500000735.

discussed bribing Chinese officials to get the counterfeit Marlex out of China. When Michael Zhao, BSC Executive and buyer in China, had difficulty finding a distributor in China to provide the exact Marlex that BSC needed, BSC management encouraged Zhao to bribe the distributors and suppliers for the resin. Helge Batz, BSC Director of Materials Management, emailed Zhao and asked whether Zhao offered the distributor money to obtain the information he wanted. Batz told Zhao it was necessary to pull all strings possible.[129]

66. BSC even lied to the Chinese about the intended use of the counterfeit Marlex, making the conscious choice not to tell EMAI that the product would be medically implanted into women so as to not "scare them away."[130] Surely, Defendant EMAI would not want attention paid to its fake plastic—something that might very well happen if the fake Marlex was used to make medical devices inserted into the human body in violation of the explicit warnings from Phillips. BSC concealed the truth from EMAI about the intended use for the resin—and BSC did that because it desperately wanted that Chinese resin.[131]

67. BSC thought nothing about misleading women about the mesh they were purchasing and implanting in their bodies—mesh marketed as BSC-manufactured and lawful, quality-tested, authentic, and FDA-approved mesh. It wasn't. It was adulterated, counterfeit mesh made from raw materials found in China in the possession of a known counterfeiter of plastics. BSC knew this—Plaintiff and Class Members did not. Plaintiff and Class Members were implanted with this mesh made from counterfeit Marlex without knowing any of these facts—facts which should have been disclosed not only to them, but to the

[129] Exhibit 20A, BSCM13800008343.
[130] Exhibit 22 at BSCM138000009802
[131] *Id.*

proper authorities including the FDA, U.S. Customs, and Chinese Customs. Now, these same women must be informed so they can make a decision, together with their doctors, what to do. Do they risk further complications by further attempts to remove the mesh and its remnants, or do they leave it in despite now knowing it is a counterfeit, Chinese made resin? It is a difficult decision—one that should not be controlled by BSC. If Plaintiff or Class Members consider further mesh "revisions" or surgery (as they are), they must gamble that the next medical device permanently implanted into their bodies is an adulterated, counterfeit device for which they paid far too much money—just like the Boston Scientific mesh they unfortunately bought.

f. Safety Concerns Based Upon What Can't be Disputed

68. Assume for the moment that BSC conjures up paperwork to somehow contradict its own internal emails showing it worked with known counterfeiters from the known counterfeit capitol of the world—internal emails showing BSC sought this product with a history of being counterfeited squarely within this counterfeit capitol of the world. Jump past the lack of documentary proof that the product was imported into China (legally or otherwise). Jump past Phillips' confirmation that the counterfeit Marlex in fact, didn't come from Phillips. Jump past the open discussion about smuggling, over-bagging, bribery, and deceiving the FDA, the injured women, and the doctors and the hospitals. Jump past BSC's declaration that women are its number one priority, that caring is its watchword, that passion for excellence is its guiding beacon. Jump past all that.

69. Beyond all these hurdles, BSC knows that even authentic Marlex is subject to degradation due to exposure to bacteria in the air, UV rays, sea air, water, salt water, bacteria, heat, cold, and to warehouse varmints like insects, rodents, and other unsanitary conditions.

Degradation of Marlex causes BSC products to become deformed, rigid, shrink, break into pieces, and inflicts significant pain and horrible injures upon these women. Protecting Marlex against exposure to the known elements that cause degradation is crucial. The need to protect Marlex increases considering that degradation and exposure to contaminants is not immediately evident and, in fact, may not become evident for years. Add atop these requirements lies BSC's fiduciary responsibility to protect the EMAI resin from such exposure and degradation before permanently implanting it into unsuspecting women—something that should be paramount for BSC's stated goal of protecting women.

70. Contrast this need to protect these women—and the EMAI resin from China—with the facts. For the sake of argument, let's indulge BSC's outlandish claim that the resin is authentic Marlex, despite every piece of evidence, direct and circumstantial, to the contrary. BSC represented to the FDA that the shelf life of Marlex HGX-030-01 is ten years.[132] Assuming that this is correct, and that EMAI resin is truly Phillips Marlex (that was for some reason sitting in a warehouse in an area of China known as a leading counterfeiter), at a minimum BSC bought the resin without knowing the following:

- The date the EMAI resin was manufactured;
- The lot number of the EMAI resin;
- How or when Phillips transported the product to China (or to somewhere else, ending up in China);
- How or when the product was transported in China to the first storage point, the number of times the EMAI resin was moved in China (at least once);[133]
- How or when the product was transported from the last storage point in China to Chinese Customs;

[132] Exhibit 38B at BSCM05100041157.
[133] Exhibit 37 at BSCM11500006880.

- How or where the EMAI resin was stored (inside, outside, on the floor, in a bag, in the heat, in the cold, in the rain? Was it bagged? Were they plastic bags?);

- How the EMAI resin was handled, exposed, or contaminated during any of its mysterious history or "re-bagging" designed to evade customs officials.

71. Further, BSC's internal documents show that BSC intended that the EMAI resin last for 25 years.[134] How could that be if the shelf life is ten years?

VI. "Testing" Is BSC's Cover Up

72. In furtherance of their enterprise, Defendants conspired to cover up their illegal and fraudulent actions by designing a test plan that would quickly allow the specious claim of "equivalence" to authentic Marlex.[135] Of course, Defendants did this despite the alarming evidence already in their possession that the EMAI resin was, in fact, counterfeit. To carry out their fraudulent and criminal scheme, Defendants manipulated the tests, used some wrong tests, and even failed to perform the tests to ASTM standards. Despite Defendants' remarkably transparent efforts to transmogrify existing tests (and ignore others), the EMAI resin still failed Defendants' phony tests.

a. Changes in BSC's Experimental Method: Why BSC tested only one bag.

73. Within BSC's own documents there are seven (7) different drafts of BSC's internal "equivalency" report (the "Burrill Report"). In the end, the Burrill Report is an amalgamation of Defendants remarkable manipulation of tests and standards—a hodge-podge of tweaked testing and subtle cover-up that evolved over several months. At critical junctures, Defendants changed the Burrill Report to fit the pre-determined conclusion that

[134] Exhibit 25, BSCM12900000228.
[135] Exhibit 14B at BSCM13800009461.

Defendants knew they must reach—equivalency.[136] Just as Defendants' manipulative testing evolved through the various iterations of the Burrill Report, so, too, did the report itself. Indeed, the only thing that stayed the same was the pre-destined conclusion of "equivalency"—equivalency, it seems, of a product Defendants already knew was rejected by the manufacturer (through the phony lot number) as being counterfeit. Initially, the Burrill Report stated that "[s]amples from both lots will be randomly selected."[137] Soon, that method changed because, it seemed, commercial manufacturing processes are large; such processes typically generate thousands of pounds per hour, and, so it went, the nature of the material bagging operations and material property variations from bag to bag were not expected.[138] Thus, instead of samples from both lots being randomly selected (something that would seem quite reasonable), samples would now be selected from only a single bag from each different lot.[139] The problem with this is that BSC knew that the EMAI resin was not bagged by ISO certified[140] Phillips; instead, BSC knew the EMAI resin was packaged in some other country, by some unknown bagger, in some unknown warehouse, under some unknown conditions, by some unknown personnel.[141] With such remarkable uncertainty, Defendants could no longer credibly make their convenient assumption of homogeneity. Yet, Defendants did so anyway to justify their carefully manipulated testing methods and, of course, to cover up their illegal actions.

74. From the first 4,400 pound resin purchase from China, BSC tested pellets from just **one bag**. This one, Chinese bag was then compared to what was supposed to be two, known

[136] 7 versions are attached hereto as Exhibits 37A, 37B, 37C, 37D, 37E, 37F, 37G, and 40.
[137] Ex. 37A at BSCM07700276852.
[138] Ex. 37D at BSCM07700280389.
[139] *Id.*
[140] ISO develops international standard to ensure products and services are safe, reliable, and of good quality. ISO certification is issued to products that meet specific requirements.
[141] Exhibit 21 at BSCM07700182058

Marlex samples—all so BSC could claim equivalency. After reviewing 10,000,000 pages of BSC information and multiple inquiries to BSC, there is no indication that any of the pellets from the 33,000-pound purchase were ever tested. Assuming BSC is being forthright in its production and responses, the only logical conclusion is that **none of the pellets from the 33,000 purchase were ever tested.** There's more. The pellets sent to Belgium for production runs appear to be in different bags.[142] That is, BSC knew it had different bags in its possession, but chose to test only one from the 4,400 shipment—and not a single one from the 33,000 pound purchase. BSC's single-bag test for equivalency was nothing more than a don't test / don't tell strategy to shoe-horn Chinese resin into manipulated tests with predetermined conclusions.

b. BSC and Cambridge used the wrong tests.

75. Authentic Marlex HGX-030-01 requires at least eight (8) separate tests to ensure its qualities and properties. Phillips, the Texas-based manufacturer of authentic Marlex, actually published this testing data necessary to identify its product. In fact, Phillips' protocol should have been attached to the final Burrill Report identifying the following tests: Density, Melt Flow Rate, Tensile Strength, Flexural Modulus, Notched Izod Impact Strength, Heat Deflection Temperature, Rockwell Hardness, and Shore D Hardness.[143] In fact, Phillips' test protocol is attached to the original redline draft of the Burrill report but is not followed.[144] Indeed, Defendants expressly dropped that test protocol from the attachments, and abandoned all but one of those eight (8) tests. Cambridge, BSC's so-called "independent lab,"[145] performed only one of these required tests set forth by Phillips:

[142] Exhibit 36F at BSCM13500000733, BSCM13500000734, BSCM13500000735.
[143] *See* Exhibit 1.
[144] Exhibit 37A at BSCM07700276854.
[145] Exhibit 37D at BSCM07700280392.

Melt Flow Rate. The single test (and limited one at that) used a general plastics testing standard and not the testing standard specific to Marlex HGX-030-01. Unexpectedly, Sample 3, which was supposed to be authentic Marlex, fails even that wrong test. Remarkably, this surprising result is never addressed by BSC. Of course, it didn't matter to BSC because, as BSC remarkably claimed, Defendants were testing for "equivalency, not goodness."[146] BSC, testing for a medical product to be permanently implanted in women's bodies, didn't seem to care about the "goodness" of its product—just the bare minimum to get it out of China and into their bodies without interrupting their $120,000,000 per year revenue.

c. BSC and Cambridge did not perform the tests to the ASTM standards.

76. ASTM International develops and publishes technical standards for a wide range of materials testing, including those for plastics like polypropylene. Even after cherry-picking ASTM standards they thought the purported "Marlex" would pass, Defendants did not perform those tests to the standards set out by ASTM International. For example, an insufficient sample size was used by Defendant Cambridge for the reported oxidation introduction time (OIT). ASTM D 3895-98,[147] Section 10.2.7 states, "***As a minimum requirement, samples should be tested in duplicate with the mean value reported***."[148] BSC, using its not-so-independent lab, Cambridge, only tested one specimen for each of the three samples,[149] which fails the minimum requirements of the applicable ASTM. The Cambridge report also states that "Oxidation induction time (OIT) was

[146] Exhibit 37E at BSCM07700283781.
[147] BSC used an outdated version of this ASTM standard. Since 1998, there were 5 subsequent revisions. *See* Exhibit 37G for Historical Versions of D3895.
[148] Exhibit 37H at p. 3, Section 10.2.7, Line #s 45-47.
[149] Exhibit 39 at p. 3, Section 3.2, Line # 39; Exhibit 38, BSCM11500006926 – BSCM11500006930.

determined…according to ASTM D3895-98" which simply is not true.[150] Of course, BSC was following its don't test, don't tell strategy.

d. The Chinese resin failed BSC's own, phony tests.

77. Even though BSC specifically designed its testing protocol to ensure the Chinese resin met BSC's arbitrary "equivalency" standards, the Chinese resin failed the tests, too. BSC's testing cover-up unfurls when all versions of the Burrill Report are laid next to the Cambridge Report.

78. The "testing" of the Chinese resin was substandard. Defendants' tests were designed at the outset to ensure the product met "equivalency" standards arbitrarily set by BSC. In fact, when the Chinese resin did not meet BSC's original, arbitrary acceptance standard, BSC simply changed it. For OIT expected results, the Burrill Report originally stated that "[t]ypically differences greater than 20% are considered significant."[151] When the Cambridge test results came back showing differences greater than 20%, BSC simply changed the acceptance standard and inserted a 75% standard, nearly quadruple the original standard. Worse, BSC claimed this arbitrary 75% standard was, in fact, the "ASTM" standard.[152] It's not. Indeed, BSC's phony ASTM standard does not even exist. While BSC mused this was a "clever solution" to the glaring problem, the Chinese resin failed even this standard arbitrarily set by BSC for its own test.[153]

79. Setting aside the Defendants' manipulation of Phillips' testing protocols and widely accepted ASTM standards, the test results themselves showed remarkable discrepancies that make no sense. For example, the results show:

[150] Exhibit 39 at p. 3, Section 3.2, Line # 38-39.
[151] Exhibit 37D at BSCM07700280389, BSCM07700280392.
[152] Exhibit 38A, BSCM11500006589; Exhibit 37D.
[153] Exhibit 38A, BSCM11500006589

- **Weaker fibers with molecular variations.** The test results showed different molecular strings, different string lengths, and a wider variation in the bell curve, indicating a different and/or substandard manufacturing process;[154]

- **Control sample fails the test.** Sample 3, which was supposed to be the control, did not even pass the melt rate standard for Marlex;[155]

- **High levels of selenium.** Selenium is a rare, toxic element.[156] Selenium reacts with hydrogen peroxide to form selenic acid, a strong oxidant, which attacks polypropylene, resulting in the rapid degradation of the mesh implanted in Plaintiff and Class Members. All three (3) samples tested by Cambridge, both Legacy Sourced (prior to purchase in China) and China Sourced Resin, showed selenium which Cambridge itself described as a rare and toxic substance.[157] Cambridge issued its original report on October 13, 2011, [158] and specifically noted:

4.7 Inductively Coupled Plasma (ICP) Spectroscopy

The data for the inductively coupled plasma spectroscopy of all samples is summarized in Table 7. There are some common elements between the three samples, however sample 11440-1 showed a larger array of trace metals than the other two samples. All the samples showed high levels of selenium. As this is a rare and toxic element, this result is unusual and should be verified using another technique, such as SEM-EDS.

Either BSC verified the selenium results and has never provided the test results to Plaintiff or her counsel, or BSC never verified the toxicity of the resin it is using to currently manufacture its mesh Products. Either way, BSC had a conference call with Cambridge on October 18, 2011 to review its initial report and determine the next steps,[159] and three days later, on October 21, 2011, Cambridge issued an amended report **removing** the statement above that selenium is rare and toxic, and **deleting** its suggestion for additional testing. BSC's remarkable re-write is just below:[160]

[154] Exhibit 39, Cambridge Polymer Group Testing Data (BSCM07300068256).
[155] *Id.*
[156] *Id.* at page 21, paragraph 4.7
[157] *See* Exhibit 39.
[158] *Id.*
[159] *See* Exhibit 42.
[160] *See* Exhibit 43.

4.7 Inductively Coupled Plasma (ICP) Spectroscopy

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The first page of Cambridge's Report #11440-2 states that the report supersedes report 11440-1 (which contains the warning and recommendation regarding selenium), and the only description of a change to the report states, "Data was added to the extraction portion of the report."[161] The note regarding changes to the report omitted the *only other change* Cambridge made to the report: the removal of its warning that selenium is a rare and toxic element, and the result was unusual and should be verified using another technique. It wasn't because BSC pursued its don't test, don't tell strategy to rush the Chinese resin into production.

80. There are several other major discrepancies in the test results and reports from BSC and Cambridge.

81. The test results were so inconsistent that they should have never even been published by Cambridge to BSC. Cambridge should not have even performed the tests that it knew would produce false results. Cambridge knew the limited testing was not all of the required testing and that the tests it performed were not Marlex-specific. Cambridge knew the testing were not performed to the ASTM standards. No truly independent lab would have agreed to produce these results. BSC even mocked the "independence" of Cambridge, stating, "I really like the 'independence' of our lab."[162] A comment which, of course, BSC deleted. Two hundred women a day continue to be implanted with BSC's Chinese resin.

[161] *Id.*
[162] Exhibit 37D at BSCM07700280392.

82. Cambridge, Luxilon and Proxy did performance and production runs on the Chinese resin using BSC's arbitrary protocol; each were aware that the results showed significant differences in the Chinese material compared to certified, Phillips Marlex. During a production run, Luxilon informed Proxy and BSC that the filament broke at the spinneret when using the Chinese resin, and that the temperature had to be adjusted.[163] Despite this, Luxilon and Proxy knowingly used the substandard, counterfeit Marlex in the manufacturing of the mesh components for BSC. Evidence shows that products are delayed because it was taking new products over a week to complete multiple production runs and still the products were not meeting acceptance criteria.[164]

83. BSC omitted facts and findings from its internal equivalency testing report written by BSC. Most frighteningly, the internal equivalency testing report omits the grave finding of high levels of toxic selenium noted in Cambridge's first report. BSC simply ignored Cambridge's concern and suggestion that the presence of the toxic element should be verified. BSC's internal emails do not show that any further verification or testing was performed. Don't test, don't tell.

84. Further, section 4 of the Burrill Report entitled "Materials / Traceability" originally describes the lot number as a Phillips Lot number.[165] Once Burrill received the email that the lot numbers did not match any authentic Phillips lot number,[166] he omitted the reference to Phillips in his subsequent drafts and describes the lot as a "new lot of HGX030-01 obtained from distributor Emai Plastic Raw Material (Dongguan) Inc" in an effort to

[163] Exhibit 39A at BSCM07700280496.
[164] Exhibit 39B at BSCM06100185310.
[165] Exhibit 37A at BSCM07700276852.
[166] Exhibit 21 at BSCM07700276857- BSCM07700276858.

conceal the truth about the counterfeit resin.[167] That bears repeating—BSC knew the lot number was phony, but christened this batch of resin as a "new lot" with, apparently, an improper lot number the manufacturer already confirmed was phony. BSC didn't care about protecting women from substandard, dangerous product from China. BSC cared about protecting BSC's $120,000,000 in revenue.

85. The adulterated, counterfeit, Chinese mesh repeatedly failed BSC's and Cambridge's own phony tests—so BSC just lowered the standards and waved it on through, then omitted findings from its internal equivalency report.[168] No just didn't mean "no" to Defendants. Defendants simply changed the testing to fit the pre-determined conclusion they needed to sustain BSC's $120,000,000 annual revenue. Thus, BSC decreed, without adequate and authentic testing: **THIS IS MARLEX.** It most certainly is not.

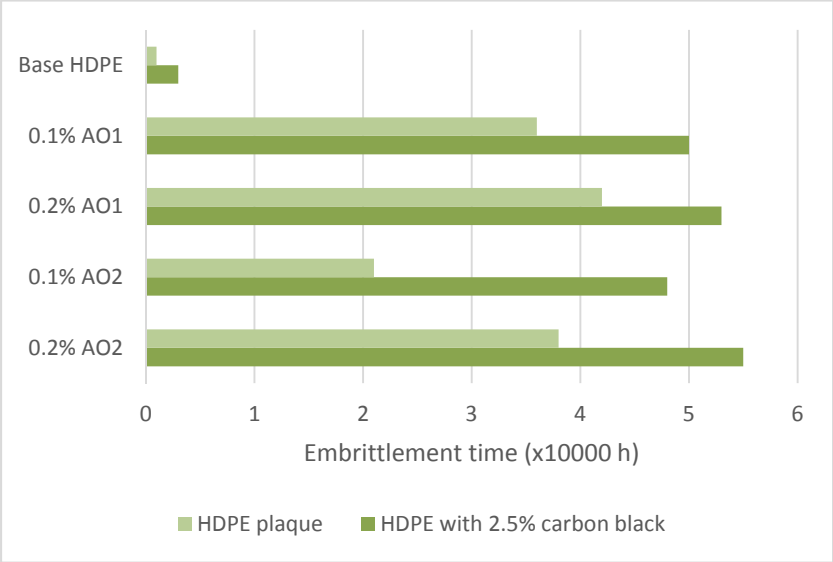
e. Fingerprint Testing and Importance of Additive Packages

86. At its melt temperature, polypropylene is not stable and degrades at room temperature.[169] "More than any other polymer used to prepare fibers, polypropylene owes its existence as a fiber-former to stabilizers used to overcome its deficiencies."[170] Different manufacturers add different stabilizers to polypropylene through additive packages that can vary for specific grades of polypropylene produced by the same manufacturer.

87. Over the life of a polymer, heat-induced degradation can cause loss of multiple mechanical properties and make the materials brittle.[171] Of course, embrittlement of polypropylene used as a permanently implantable medical device inside the human body is not conducive

[167] Exhibit 37B at BSCM07700277050.
[168] Exhibit 40, BSC Engineering Report, BSCM11500005941.
[169] Menachem Lewin, *Handbook of Fiber Chemistry* 174 (3rd ed. 2007).
[170] *Id.* at 178.
[171] Michael Tolinski, *Additives for Polyolefins, Getting the Most out of Polypropylene, Polyethylene and TPO*, 21, Figure 3.3 (2nd ed. 2015).

to continued functioning of that device, let along human health. All additive packages for polypropylene consist of at least a primary and secondary antioxidant (AO) which helps sustain the mechanical properties over time. The table below compares long term heat aging of heat-stabilized materials with an unstabilized base polymer. The table demonstrates that various AO, or additive packages, and carbon black filler extend time to embrittlement of these materials.[172]



88. Autoxidation has obvious damaging property effects to polymers.[173] Certain AOs, or additives, can extend the stability of polypropylene fibers longer than other additives. The table below demonstrates that the use of certain AOs will maintain the stability of the mechanical properties for many more days than other AOs.[174]

Heat Stability of Multifilament Yarn (8000/396)[175]

	Days at 120º to embrittlement
Goodrite 3114 (0.10%)	14

[172] *Id.*
[173] Michael Tolinski, *Additives for Polyolefins, Getting the Most out of Polypropylene, Polyethylene and TPO*, 19 (2nd ed. 2015).
[174] Menachem Lewin, *Handbook of Fiber Chemistry* 17, Table 3.13 (3rd ed. 2007). This book is also cited by BSC in reference to the shelf life of polypropylene monofilament yarn at BSCM19800000037.
[175] *Id.*

Irganox 1010 (0.10%)	20
CR 144 (0.10%)	47
0.25%CR144+0.1%Goodrite 3114	83
0.25%CR144+0.1%Irganox 1010	86
0.25%CR144+0.1%Weston 618	82

89. The correct additive package must be determined with consideration of the end-use for the intended fibers. In this circumstance, BSC advised Zhao, its employee working in China, not to tell the Chinese distributors where the "Marlex" would be used because it might "scare them away."[176] This leads to the crucial question of the chemical composition and physical properties of the China Sourced Resin. If the manufacturer of the resin doesn't know the intended use of its resin, it cannot fashion and apply the appropriate AOs or additive packages to prepare that product. Manufacturing polypropylene with AOs or additive packages for carpet backing (a common use of it) is far different than manufacturing it for the permanent implantation into the human body. Worse, with the China Sourced Resin having an unknown origin and manufacture, the body's reaction to it (and whatever cocktail of additives were added) is simply unfathomable for this unidentified, contaminated Chinese resin.

90. Although additive packages are proprietary to certain manufacturers, they are commonly reverse engineered. The standard, commonly used test to detect the additive package used for any given grade of Marlex (or other polymer) is High Performance Liquid Chromatography (HPLC). Defendant Cambridge, which tested the counterfeit Marlex BSC sourced from China ("China Sourced Resin") in October 2011,[177] did not perform HPLC testing, even though BSC's equivalency testing protocol originally included this

[176] *See* Exhibit 19 at BSCM13800009802.
[177] *See* Exhibits 39 and 42.

specific fingerprint testing to determine the additive package.[178] After BSC learned the lot number on the bag was not a valid lot number for Marlex HGX-030-01,[179] the HPLC testing was removed from the equivalency testing protocol,[180] purposefully omitting testing for the unique fingerprint of Marlex HGX-030-01. Don't test, don't tell.

91. On April 25, 2016, BSC received a report from Polymer Solutions, Inc. ("Polymer Solutions") that purports to test the same lot of Marlex HGX-030-01 Cambridge tested in Sample 1 and China Sourced Resin Cambridge tested in Sample 2.[181] However, the results are clearly different. One need not look any further than BSC's own testing performed by Polymer Solutions to determine that **the China Sourced Resin is not Marlex**.

92. The Polymer Solutions testing[182] shows results for samples as follows:

- A1 and B1 are authentic Marlex HGX-030-01 ("Legacy Sourced Resin") which has a Certificate of Analysis tracing the resin pellets back to Phillips Lot No. 2951877;
- C1, D1 and I1 are China Sourced Resin with no Certificate of Analysis;
- E1, F1 and H1 are product samples made from China Sourced Resin; and
- G1 is a product sample from Legacy Sourced Resin.[183]

93. If the China Sourced Resin was manufactured by Phillips, or even chemically identical or equivalent to Marlex HGX-030-01, the polypropylene comprising the resin pellets would contain the same additives in the same quantities. However, the following chart taken from Polymer Solutions' HPLC testing report reveals a very different result:

[178] *See* Exhibit 37A.
[179] *See* Exhibit 19 at BSCM07700182058.
[180] *See* Exhibit Ex. 37B.
[181] Both Cambridge and Polymer Group purported to test Phillips Marlex HGX-030-01, Lot No. 2951877.
[182] *See* Exhibit 44 – Polymer Solutions, Inc. Report
[183] *Id.* at Addendum, page 13.

G. HPLC Analysis of Resin Samples and Product Samples

High performance liquid chromatography was performed on resin samples and product samples to determine the concentrations of low molecular weight constituents that are soluble but are not volatile enough to be detected by the GC-MS method.

Table 8. Chemicals that were detected in the resin samples.

Identification	Antioxidant Concentration in Sample (ppm)					
	A1	B1	C1, Prep. 1	C1, Prep. 2	D1	I1
2,4-Di-tert-butylphenol	ND	ND	173	173	154	157
Irganox 3114	685	684	ND	ND	ND	ND
Irganox 1330	ND	ND	487	488	453	445
Irgafos 168 (oxidized)	95	84	9	9	7	10
Irgafos 168 (non-oxidized)	663	676	54	54	54	51

ND = Not Detected

94. The first additive, the primary AO, that Polymer Solutions detected in the China Sourced Resin is Irganox 1330. That's startling, because Phillips never used Irganox 1330 to manufacture Marlex HGX-030-01, as proven by the non-detection of this additive in the Legacy Sourced Resin.[184] Irganox 1330 is highly susceptible to UV degradation, and neither BSC, nor Plaintiff, can know if the China Sourced Resin was subject to UV rays because of the unknown manufacturer, unknown storage conditions, and unknown transportation methods. BSC failed to control the process or obtain this crucial information.

95. The second additive, the secondary AO, Polymer Solutions detected in the China Sourced Resin – Irgafos 168 – was detected in significantly low amounts compared to the Legacy Sourced Resin. This result is crucial because this secondary AO is designed to decompose hydroperoxides created by the reaction of autoxidation by oxidizing themselves (taking oxygen from the hydroperoxides). "Used in combination with primary AOs, secondary AOs are often referred to as 'synergists,' because their interaction with primary AOs

[184] Green and red boxes have been added to the chart to emphasize these differences.

greatly enhances the protection the polymer receives."[185] Irgafos 168 is designed to slow the rate of degradation of Marlex caused by peroxides. In the small amounts found in the China Sourced Resin, Irgafos 168 will be unstable and ineffective to slow the natural degradation of the polypropylene or fight the naturally produced peroxides in the resin and the body. This formulation has no known record of use at all, and most importantly, no record of use in the human body.

96. Polymer Solutions' report clearly shows that the additive package used to manufacture the China Sourced Resin is different than the additive package used by Phillips to manufacture the Legacy Sourced Resin. Stated differently, the resins clearly have different fingerprints. Not only does this prove that the China Sourced Resin is not Marlex HGX-030-01, but the different primary additive and significantly different quantities of the secondary additive will impact the ability of these additives to act synergistically. And that stated differently, is that none of these women can truly know for sure what foreign additives and chemicals are currently degrading in their bodies.

97. Polymer Solutions' report demonstrates other opposite results between the China Sourced Resin and the Legacy Sourced Resin, as detailed below, proving that the China Sourced Resin is not Marlex HGX-030-01. Specifically, these differences include (1) differences in metal content, and (2) the existence of over a dozen chemicals, most "unidentified," in the China Sourced Resin and BSC products made with China Sourced Resin which are not present in the Legacy Sourced Resin or BSC products made with Legacy Sourced Resin.

i. Differences in Metal Content

[185] Michael Tolinski, *Additives for Polyolefins, Getting the Most out of Polypropylene, Polyethylene and TPO*, 23 (2nd ed. 2015).

98. Polymer Solutions' testing shows that *none* of the Legacy Sourced Resin samples contains aluminum or zinc and *all* of the China Sourced Resin samples contain aluminum and zinc in significant quantities of over 300ppm. The testing also shows that all of the Legacy Sourced Resin samples contain magnesium, and the China Sourced Resin does not.[186]

Table 2. Concentration (ppm) of chemical elements detected in Samples using ICP-OES.

Element	Resin A1	Resin B1	Resin C1	Resin C1 (duplicate)	Resin D1	Resin I1
Aluminum (Al)	Not Detected	Not Detected	50	50	50	60
Magnesium (Mg)	50	50	Not Detected	Not Detected	Not Detected	Not Detected
Zinc (Zn)	Not Detected	Not Detected	330	330	310	340

ii. Unidentified Chemicals

99. Polymer Solutions' Gas Chromatography-Mass Spectroscopy (GC-MS) results, used to separate and define the extractables profile for the resin and the BSC products, also show clear distinctions between the Legacy Sourced Resin and China Sourced Resin.

100. The results also show that all samples of the China Sourced Resin contain over 300 parts per million of Pentylparaben, a synthetic hormone not present in the Legacy Sourced Resin, as demonstrated in the chart below:

[186] Colors added to chart for emphasis.

Table 6. Chemicals that were detected in the resin samples.

	Samples					
	A1	B1	C1	C1	D1	I1
Most Probable ID	16431-01	16431-02	16431-03a	16431-03b	16431-04	16431-09
Phenol, 4-(2-propenyl)-, acetate	-	-	39	31	25	50
Unspecified cyclic compound	369	388	-	-	-	-
2,4-Di-tert-butylphenol	-	-	390	381	301	378
Unspecified aromatic compound	-	-	57	57	56	97
Pentylparaben	-	-	346	356	352	491
Irgafos 168	1,232	1,273	103	100	68	92
Oxidized Irgafos 168	84	171	-	-	-	-
Total	1685	1832	935	925	802	1108
Count	3	3	5	5	5	5

101. Polymer Solutions' GC-MS results on the BSC Products made with China Sourced Resin detect over a dozen chemicals, most of them "unidentified," which are not present in the Legacy Sourced Resin. The differences between Product Samples E1, F1, and H1, purportedly BSC products made with China Sourced Resin, also show that sample to sample, products made with China Sourced Resin "from the same lot" are different. *None* of the chemicals detected in G1, purportedly a BSC product made with Legacy Sourced Resin, are found in the products made with China Sourced Resin. Likewise, *none* of the chemicals detected in product samples E1, F1, or H1, purportedly BSC products made with China Sourced Resin, are found in G1, the product made with Legacy Sourced Resin.

Table 7. Chemicals that were detected in the product samples.

	Samples			
	E1	F1	G1	H1
Most Probable ID	**16431-05**	**16431-06**	**16431-07**	**16431-08**
Unidentified	-	-	53	-
2,4-Di-tert-butylphenol	61	39	-	-
Isopropyl laurate	277	140	-	-
Unspecified octanoic acid ester	124	195	-	-
Unspecified fatty acid ester	143	227	-	-
Unidentified	136	225	-	-
Unidentified	48	66	-	-
Unidentified	184	261	-	-
Unidentified	177	256	-	31
Unidentified	190	256	-	-
Flexol 4GO	188	261	-	39
Unidentified	233	241	-	-
Flexol 4GO	153	197	-	-
Unidentified	161	252	-	-
Irgafos 168	-	-	77	-
Unidentified	162	184	-	-
Unidentified	-	-	85	-
Unidentified	-	156	-	-
Flexol 4GO	129	99	-	-
Total	2364	3054	216	70
Count	15	16	3	2

102. The Polymer Solutions testing shows clear differences between the Legacy Sourced Resin and the China Sourced Resin, and the Products made from each of these resins. Despite the obvious differences, BSC still claims that both the Legacy and China Sourced Resin are "authentic Marlex." The differences are either ignored or glossed over. The lack of any scientific analysis or evidence showing the safety of China Sourced Resin, with different additives, different metal content, and different chemicals (including parabens and multiple unidentified chemicals), is simply overwhelming. Don't test, don't tell.

103. In fact, there is *no evidence* showing how polypropylene using the additive package in the China Sourced Resin, and the extra unidentified chemicals and parabens, performs when used as a permanent human implant—not in any part of the body, not in any application. It is impossible to know if polypropylene with these AOs and chemicals have ever been safely used in the human body. Polymer Solutions' conclusions do not address the end-

use application of this product as a medical device nor the effects of the unidentified chemicals, which could even be banned phthalates. BSC has provided no evidence demonstrating the safety of its products made with China Sourced Resin. It can't.

f. The quality of the counterfeit Marlex is irrelevant.

104. Even if the counterfeit Marlex was identical to authentic Marlex (which BSC's own limited testing confirmed it is not) the argument is a red herring. A perfect copy of a $100 bill is still counterfeit. A perfect replica of a Rolex watch is still counterfeit. Advantage mesh made with counterfeit Marlex is still not approved by the FDA and is still counterfeit. It's just that, unlike a $100 bill or Rolex, this product—BSC's transvaginal mesh—is being permanently implanted into women's bodies at an inflated price costing them both physically and financially. For counterfeiting purposes, the quality of the counterfeit Marlex is irrelevant. *See United States v. Farmer*, 370 F.3d 435, 441 (4th Cir. 2004) "One of the rights that a trademark confers upon its owner is the 'right to control the quality of the goods manufactured and sold' under that trademark. *For this purpose the actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain." Id.* at 441 (internal quotation marks and citations omitted) (emphasis added).

105. Despite Defendants' knowledge that the Chinese material was counterfeit, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL continued with the purchase, smuggling, distribution, manufacturing, advertising, packaging, labeling and selling the counterfeit mesh, along with the counterfeit bagging and/or marking, which resulted. By November 8, 2012, BSC had already used over 3,000 pounds of the counterfeit resin to manufacture its products because on that day, the calculated amount of the Chinese resin still on hand

was only 34,294 pounds.[187] BSC never told anyone, let alone the Plaintiff or these Class Members. What had been—all along—a solid "no" about the authenticity of the EMAI resin became a BSC yes. Yes to $120,000,000 in continued annual revenue. Yes to saving the jobs of those at BSC. And sadly, yes to implanting Plaintiff and Class Members with counterfeit, substandard mesh, made with counterfeit resin smuggled out of China.

RICO ALLEGATIONS

I. The Boston Scientific Enterprise

106. BSC is a "person" within the meaning of 18 U.S.C. §1961(3).

107. Based upon Plaintiff's current knowledge, the following persons constitute a group of entities associated in fact that Plaintiff refers to as the Boston Scientific Enterprise: (1) BSC, (2) EMAI, (3) Proxy, (4) Luxilon, (5) Cambridge, and (6) YFL.

108. The Boston Scientific Enterprise is an ongoing organization which engages in, and whose activities affect, interstate commerce. The members of the Boston Scientific Enterprise function as a continuing unit as described below and share the common purpose of smuggling counterfeit Marlex out of China and manufacturing mesh products with the counterfeit Marlex for their individual and collective economic gain.

109. While BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL participate in and are members of the Boston Scientific Enterprise, they also have an existence separate and distinct from the enterprise. The common goal was to smuggle adulterated and/or counterfeit "Marlex" out of China, circumvent import/export laws of China and the U.S. to "pass" the counterfeit mesh as authentic Marlex, and to avoid the scrutiny of the FDA and termination of the

[187] Exhibit 41 at BSCM07700287137.

many mesh sales to Plaintiff, Class Members, and other women throughout the U.S. This generated profits for the enterprise as a whole and for participating individuals.

110. In order to successfully defraud Plaintiff and Class Members in the manner set forth above, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL needed a system to obtain and smuggle counterfeit Marlex out of China and manufacture mesh products using the counterfeit Marlex. Additionally, Defendants stood to benefit directly from the sales of tens of thousands of mesh products each year made with the counterfeit Marlex. BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL participated in the scheme to avoid a loss of over $120,000,000 per year. EMAI, Proxy, Luxilon, and Cambridge also participated in the scheme to avoid the loss of business from BSC.

111. BSC controls and operates the Boston Scientific Enterprise as follows:

(a) By purchasing the counterfeit Marlex from EMAI even after it was confirmed that the lot number on the product did not match a Phillips lot number;

(b) By colluding with shipper YFL to purchase, over-bag, conceal, ship, and smuggle the resin out of China and into the United States and Belgium;

(c) By developing a protocol to test the counterfeit Marlex that ensures that if the Marlex is in fact counterfeit, it will still meet "industry standards;" this included, but is not limited to, reducing standards or protocols to improperly "pass" the Chinese resin as authentic, Marlex mesh or approved product, or directing testing to so find;

(d) By colluding with Proxy, Luxilon, and Cambridge to ensure that the counterfeit Marlex "passed" the equivalency and performance tests pursuant to BSC's protocol; and

(e) By marketing and selling its mesh products which it knows were manufactured using counterfeit Marlex.

112. As set forth above, the Boston Scientific Enterprise has an ascertainable structure separate and apart from the pattern of racketeering activity in which BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL engage.

II. Predicate Acts

113. Section 1961(1) of RICO provides that "racketeering activity" includes any act indictable under 18 U.S.C. §1341 (relating to mail fraud), 18 U.S.C. §1343 (relating to wire fraud), and 18 U.S.C. §2320 (relating to trafficking in goods or services bearing counterfeit marks). As set forth below, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have and continue to engage in conduct violating each of these laws to effectuate their scheme.

114. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations, or promises, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL, in violation of 18 U.S.C. §1341, placed in post offices and/or in authorized repositories matter and things to be sent or delivered by the Postal Service, caused matter and things to be delivered by commercial interstate carrier, and received matter and things from the Postal Service or commercial interstate carriers, including but not limited to counterfeit products, counterfeit bags or marks, invoices, correspondence, payments, lab or test results, samples, and false written materials regarding the mesh Product being sold.

115. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations or promises, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL also in violation of 18 U.S.C. §1343, transmitted and received by wire things which include but are not limited to counterfeit product, emails, invoices, correspondence, payments, lab or test results, samples, photographs or descriptions of counterfeit bags or marks, and false written materials regarding the mesh product being sold.

116. The matter and things sent by BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL via the Postal Service, commercial carrier, wire or other interstate electronic media include, inter alia, counterfeit Marlex which was smuggled out of China and into the United States, and false information regarding the mesh products implanted into Plaintiff and Class Members.

117. Other communications sent through or received from the Postal Service, commercial carrier, or interstate wire transmission by BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL included information or communications in furtherance of or necessary to effectuate the scheme.

118. For the purpose of executing and/or attempting to execute the above described scheme to defraud or obtain money by means of false pretenses, representations, or promises for financial gain, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL violated 18 U.S.C. § 2320 by intentionally trafficking in goods and knowingly using a counterfeit mark on or in connection with the goods.

119. EMAI intentionally sold BSC 37,400 pounds of counterfeit Marlex for financial gain. The counterfeit markings on the bags intentionally sold to BSC were identical to, or substantially indistinguishable from, Phillips' mark, which is registered in the United States Patent and Trademark Office (USPTO), and in use. The counterfeit marks were applied and used in connection with the goods for which the mark is registered in the USPTO. Additionally, BSC's and EMAI's use of the counterfeit marking on the bag is likely to cause confusion, mistake, or to deceive. Defendant BSC's and EMAI's creation and duplication of Phillips' bags and Proxy's, Luxilon's, and Cambridge's knowledge of or willful blindness to these unlawful acts constitutes counterfeiting.

120. BSC intentionally purchased at least 33,000 pounds of the counterfeit Marlex, despite having knowledge that the lot number on the counterfeit label was not a lot number recognized by Phillips.

121. After purchase of the counterfeit Marlex, BSC contracted with Cambridge, Proxy and Luxilon to test the product knowingly obtained from China. The test results and production runs performed by Cambridge, Proxy and Luxilon showed that the Chinese Marlex was not in fact Phillips Marlex and the material did not perform the same. Cambridge knowingly performed the wrong tests, and deviated from the standards used to adequately test Marlex HGX-030-01. Despite having knowledge that the resin product from China was counterfeit Marlex, Luxilon intentionally manufactured mesh fibers using the counterfeit Marlex. Despite having knowledge that the resin product from China was counterfeit Marlex, Proxy intentionally wove mesh sheets using the filament that was manufactured with the counterfeit Marlex.

122. Despite having knowledge that the resin product from China was counterfeit Marlex, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL fraudulently imported, exported, tested, manufactured, marketed, and sold mesh Products which were manufactured with the counterfeit Marlex, but represented to Plaintiff, Class Members, and others that authentic Phillips Marlex was used to manufacture the mesh products.

123. BSC's, EMAI's, Proxy's, Luxilon's, Cambridge's, and YFL's overt acts of fraud, misrepresentations, acts of concealment, and failures to disclose were knowing and intentional, and made for the purpose of deceiving Plaintiff and Class Members and for the purpose of financial gain from products made with the counterfeit Marlex which were sold to and implanted in Plaintiff and Class Members.

124. BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL either knew, recklessly disregarded, or were willfully blind to the fact that the cheating, misrepresentations and omissions regarding the authenticity of the Marlex described above were material and would be relied upon by Plaintiff and Class Members. Plaintiff and Class Members were defrauded as a result of the misrepresentations and omissions as set forth above.

125. As a result, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have fraudulently imported, exported, and manufactured, marketed and distributed the counterfeit mesh products sold and implanted to Plaintiff and Class Members. These Defendants were able to charge for services based upon their participation in fraudulently importing, exporting, manufacturing, marketing, and selling mesh Products made with the counterfeit Marlex.

126. Defendants' introduction into interstate commerce medical devices, specifically counterfeit transvaginal mesh, which were misbranded in that the product labeling contained false and misleading information identifying the devices as authentic transvaginal mesh manufactured with Marlex, when in reality the mesh was not made with Marlex, is criminal conduct pursuant to §§ 21 U.S.C. 331(a), 331(a)(1), and 352(a).

127. Defendants devised, engaged in, condoned, and/or ratified the above-described open-ended and unlawful "representational" and "cheating" schemes to (i) cheat and defraud Plaintiff and Class Members to obtain money, funds, credits, assets, and/or other property from Plaintiff and Class Members by means of false or fraudulent pretenses and/or (ii) fraudulently and intentionally misrepresent to Plaintiff and Class Members the counterfeit and adulterated quality of the Product purchased and permanently implanted in their bodies. Alternatively, Defendants fraudulently and intentionally failed to disclose to

Plaintiff and Class Members that the mesh Products purchased and implanted in their bodies was counterfeit and adulterated.

128. In addition to their personal-injury damages, Plaintiff and Class Members have been injured in their business or property by Defendants' overt acts of mail fraud, wire fraud, and intentionally trafficking goods bearing counterfeit marks.

III. Pattern of Racketeering Activity

129. BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in a "pattern of racketeering activity," as defined by 18 U.S.C. § 1961(5), by committing or aiding and abetting in the commission of at least two acts of racketeering activity, *i.e.*, indictable violations of 18 U.S.C. §§1341, 1343, and 2320, as described above, within the past ten years.

130. BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have committed multiple acts of racketeering activity. BSC's purchase of the counterfeit Marlex and wire payment for the product occurred on two separate dates, the illegal export of the polypropylene from China bearing counterfeit markings occurred on at least four different dates, the illegal import of the counterfeit Marlex bearing counterfeit markings occurred on at least four separate dates, all proving separate and definable predicate acts of racketeering activity. Additionally, Plaintiff's and Class Members' mesh implants manufactured from counterfeit Marlex were manufactured, sold, and transported interstate on different dates, proving separate and definable predicate acts of racketeering activity. The Boston Scientific Enterprise provided false information regarding the mesh Products implanted into Plaintiff and Class Members through mail or interstate wire transfer on many different dates, proving separate and definable predicate acts of racketeering activity. Each act of

racketeering activity was related, had a similar purpose, involved the same or similar participants and method of commission, had similar results, and impacted similar victims, including Plaintiff and Class Members.

131. The multiple acts of racketeering activity which Defendants committed and/or conspired to commit, or aided and abetted acts, were related to each other and amount to and pose a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity" as defined in 18 U.S.C. § 1961(5).

CLASS ACTION ALLEGATIONS

132. Plaintiff brings this action against Defendants on her own behalf and, pursuant to Rules 23(a) and (b) of the Federal Rules of Civil Procedure, as a class action on behalf of a class of persons similarly situated which include the following:

> **All persons who were implanted with a Boston Scientific Corporation transvaginal mesh product after January, 2012.**

133. Excluded from the Class are Defendants, any entity in which one or more of the Defendants has a controlling interest or is a parent or subsidiary of said Defendants, any individual or entity already represented by counsel for these offenses, any entity that is controlled by one of more of the Defendants and any of their officers, directors, employees, affiliates, legal representatives, heirs, predecessors, successors and assigns, this Court and any of its immediate staff.

134. Upon information and belief, there are thousands of members of the Class. Accordingly, the Class is so numerous that joinder of all members is impracticable. The Class is ascertainable, as the names and addresses of all Class Members can be identified in business records maintained by hospitals or doctors to whom BSC's transvaginal was sold, as well as Defendants' sales and other records.

135. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual Class Members. Such common questions include, *inter alia*:

a. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in a scheme to smuggle counterfeit Marlex out of China and into the United States and/or Belgium;

b. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in a scheme to manufacture mesh Products made from counterfeit Marlex;

c. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in mail and wire fraud;

d. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in trafficking of goods bearing counterfeit marks;

e. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have engaged in a pattern of racketeering activity;

f. Whether BSC's, EMAI's, Proxy's, Luxilon's, Cambridge's, and YFL's overt and predicate acts in violation of 18 U.S.C. § 1962(c) proximately caused injury to Plaintiff's and Class Members' business or property;

g. Whether BSC's, EMAI's, Proxy's, Luxilon's, Cambridge's, and YFL's overt acts in violation of 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(a) proximately caused injury to Plaintiff's and Class Members' business or property;

h. Whether BSC's, EMAI's, Proxy's, Luxilon's, Cambridge's, and YFL's, overt acts in violation of 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c) proximately caused injury to Plaintiff's and Class Members' business or property;

i. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL constitute an enterprise within the meaning of 18 U.S. C. § 1961(4);

j. Whether BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL made intentional or negligent misrepresentations in connection with the testing, manufacturing, production, marketing, advertising, packaging, labeling, distribution, and/or sale of BSC mesh products containing the counterfeit Marlex.

k. Whether BSC's, EMAI's, Proxy's, Luxilon's, Cambridge's, and YFL's practices in connection with the manufacturing, production, marketing,

advertising, packaging, labeling, distribution, and/or sale of BSC mesh products containing the counterfeit Marlex unjustly enriched Defendants at the expense of, and to the detriment of, Plaintiff and Class Members.

l. Whether Defendants' conduct as set forth above injured consumers and if so, the extent of the injury.

136. Plaintiff's claims are typical of the claims of the Class Members because they originate from the same illegal, fraudulent, and confiscatory practices of Defendants. Defendants acted in the same way toward Plaintiff and Class Members.

137. Plaintiff will fairly and adequately protect the interests of the Class Members, is committed to the vigorous prosecution of this action, has retained counsel competent and experienced in class litigation and has no interests antagonistic to or in conflict with those of the Class. As such, Plaintiff is an adequate Class representative.

138. The prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for the party opposing the Class.

139. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Further, the expense and burden of individual litigation make it impossible for all the Class Members individually to redress the wrongs done to them. There will be no difficulty in the management of this action as a class action. To the extent any defendant or this Honorable Court deems the proposed class as un-certifiable, then Plaintiff submits that subclasses can be applied to rectify any legitimate concern for certification.

CAUSES OF ACTION

COUNT I: VIOLATION OF 18 U.S.C. § 1962(c)

140. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

141. This claim for relief arises under 18 U.S.C. §1962(c). As set forth above, BSC, EMAI, Proxy, Luxilon, Cambridge, and YFL have violated 18 U.S.C. §1962(c) by conducting or participating, directly or indirectly, in the conduct of the affairs of the Boston Scientific Enterprise through a pattern of racketeering.

142. As a direct and proximate result, Plaintiff and Class Members have been injured in their business or property by the predicate acts which make up Defendants' patterns of racketeering activity through the Boston Scientific Enterprise.

143. Specifically, Plaintiff and Class Members have been economically injured in their business or property by purchasing counterfeit Products which were medically implanted in their bodies as a result of the scheme.

COUNT II: VIOLATION OF 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(a)

144. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

145. Each Plaintiff and each Class Member is a "person" within the meaning of 18 U.S.C. §§ 1961(3), 1964(c).

146. Defendants are each a "person" within the meaning of 18 U.S.C. §§ 1961(3) and 1962(a).

147. Defendants are an "enterprise" within the meaning of 18 U.S.C. §§ 1961(4) and 1962(c) and, at all relevant times, were engaged in, and the activities of which affected, interstate commerce within the meaning of 18 U.S.C. §§ 1961(4), 1962(c), 1962(d).

148. BSC conspired with Defendants and other persons and/or entities, the identities of whom are known only to BSC at this time and await discovery, within the meaning of 18 U.S.C. § 1962(d) to violate 18 U.S.C. § 1962(a); that is, BSC and its co-conspirators conspired to receive income derived, directly or indirectly, from a pattern of unlawful activity in which BSC and its co-conspirators participated as principals within the meaning of 18 U.S.C. §§

1961(1)(B), 1961(5), and 1962(a)—to wit, the above-described open-ended, unlawful and fraudulent schemes to manage and operate the Boston Scientific Enterprise and cheat and defraud Plaintiff and Class Members to obtain money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members by means of false or fraudulent pretenses and/or intentional misrepresentations. Alternatively, Defendants fraudulently and intentionally failed to disclose to Plaintiff and Class Members the adulterated and counterfeit nature of the Products.

149. As a direct and/or proximate result of BSC's above-described multiple and repeated acts of interstate wire fraud, mail fraud, and intentionally trafficking goods bearing counterfeit marks, Plaintiff and Class Members have suffered (and will continue to suffer) damages to their businesses and/or property, and other injury and harm in the form of, *inter alia,* (i) loss of money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members due to purchasing a counterfeit, adulterated product, and (ii) loss of money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members due to costs associated with revision surgeries necessitated by the purchase of the counterfeit adulterated Products.

150. BSC and its co-conspirators intentionally participated in a conspiracy to engage in the above-described interstate wire fraud, mail fraud, intentionally trafficking goods bearing counterfeit marks, unlawful and intentional schemes, wrongful actions, inaction and/or omissions for Defendants' financial benefit and to Plaintiff's and Class Members' financial detriment in violation of 18 U.S.C. §§ 2, 1343 and 1344. All members, time and place of this complex, multi-party conspiracy are known only by Defendants at this time and await discovery.

151. Defendants used or invested (and continue to use or invest), directly or indirectly, such income, or the proceeds of such income, in their ongoing participation in the Boston Scientific Enterprise and/or the creation and/or operation of one or more other BSC-owned stand-alone enterprises, all of which are engaged in, or the activities of which affect, interstate commerce.

152. As described above, BSC and its co-conspirators managed and/or operated the Boston Scientific Enterprise in such a way as to engage in the above-described multiple predicate acts of interstate wire fraud, mail fraud, and intentionally trafficking goods bearing counterfeit marks for the purpose of increasing Defendants' profitability and return on investment to Plaintiff's and Class Members' financial detriment.

153. Defendants knew, or should have known, their unlawful and intentional conspiracy and commission of the above-described interstate wire fraud, mail fraud, intentionally trafficking goods bearing counterfeit marks, wrongful actions, inaction and/or omissions were fraudulent, misleading and illegal, and would directly and/or proximately cause Plaintiff and Class Members to suffer the above-described damages. All of Plaintiff's and Class Members' damages were reasonably foreseeable by Defendants and/or anticipated as a substantial factor and a natural consequence of its pattern of unlawful activity.

COUNT III: VIOLATION OF 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)

154. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

155. Defendants conspired, within the meaning of 18 U.S.C. § 1962(d) to violate 18 U.S.C. § 1962(c); that is, BSC and its Defendant co-conspirators conspired to manage and operate the Boston Scientific Enterprise, and conduct and/or participate in the business and financial affairs of the Boston Scientific Enterprise through a pattern of unlawful activity

within the meaning of 18 U.S.C. §§ 1961(1)(B), 1961(5), and 1962(c)—to wit, the above-described open-ended, unlawful and fraudulent schemes to cheat and defraud Plaintiff and Class Members to obtain money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members by means of false or fraudulent pretenses and/or intentional misrepresentations. Alternatively, Defendants fraudulently and intentionally failed to disclose to Plaintiff and Class Members the adulterated and counterfeit nature of the Products.

156. As a direct and/or proximate result of Defendants' above-described multiple and repeated acts of interstate wire fraud, mail fraud, and intentionally trafficking goods bearing counterfeit marks, Plaintiff and Class Members have suffered (and will continue to suffer) damages to their businesses and/or property, and other injury and harm in the form of, *inter alia*, (i) loss of money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members due to purchasing a counterfeit, adulterated Products, and (ii) loss of money, funds, credits, assets, and/or other property owned by, or under the custody or control of, Plaintiff and Class Members due to costs associated with revision surgeries necessitated by the purchase of the counterfeit adulterated Products.

157. Defendants and their co-conspirators intentionally participated in a conspiracy to engage in the above-described interstate wire fraud, mail fraud, intentional trafficking of goods bearing counterfeit marks, unlawful and intentional schemes, wrongful actions, inaction and/or omissions for Defendants' financial benefit and to Plaintiff's and Class Members' financial detriment in violation of 18 U.S.C. §§ 2, 1343 and 1344. All members, time and

place of this complex, multi-party conspiracy are known only by Defendants at this time and await discovery.

158. As described above, Defendants and their co-conspirators managed and/or operated the Boston Scientific Enterprise in such a way as to engage in the above-described multiple predicate acts of interstate wire fraud, mail fraud, and intentional trafficking of goods bearing counterfeit marks, for the purpose of increasing Defendants' profitability and return on investment to Plaintiff's and Class Members' financial detriment.

159. Defendants knew, or recklessly should have known, their unlawful and intentional conspiracy and commission of the above-described interstate wire fraud, mail fraud, intentional trafficking of goods bearing counterfeit marks, wrongful actions, inaction and/or omissions were fraudulent, misleading and illegal, and would directly and/or proximately cause Plaintiff and Class Members to suffer the above-described damages. All of Plaintiff's and Class Members' damages were reasonably foreseeable by Defendants and/or anticipated as a substantial factor and a natural consequence of its pattern of unlawful activity.

COUNT IV: NEGLIGENCE

160. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

161. Defendants had a duty to individuals, including Plaintiff and Class Members, to use reasonable care in designing, manufacturing, testing, shipping, storing, marketing, labeling, packaging and selling the Products.

162. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, testing, shipping, storing, marketing, labeling, packaging and

selling the Products. Defendant(s) breached their aforementioned duty by, among other things:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff and Class Members;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff and Class Members;

c. Failing to use reasonable care in the testing of the Products and the resin used to make the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the Plaintiff and Class Members;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff and Class Members;

e. Failing to use reasonable care in shipping and storing the resin used to make the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff and Class Members;

f. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff and Class Members;

g. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Products;

h. Failing to use reasonable care in studying the Products to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

i. Otherwise negligently or carelessly designing, manufacturing, testing, shipping, storing, marketing, labeling, packaging and/or selling the Products.

163. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of collagen upon the female pelvic tissue; and

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

164. Defendant BSC also negligently failed to warn or instruct Plaintiff and Class Members, and/or her health care providers of subjects including, but not limited to, the following:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation and/or creep;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. The need for corrective or revision surgery to adjust or remove the Products;

j. The severity of complications that could arise as a result of implantation of the Products;

k. The hazards associated with the Products;

l. The Products' defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

165. As a direct and proximate result of Defendants' negligence, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

COUNT V: STRICT LIABILITY – DESIGN DEFECT

166. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

167. The Products implanted in Plaintiff and Class Members were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals and/or human cadavers;

k. The harshness of collagen upon the female pelvic tissue, and the hardening of the Products in the body;

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

m. The use of polypropylene material in the products and the failure to provide adequate directions for use (DFU) and training.

168. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members

have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

169. Defendants BSC is strictly liable to Plaintiff and Class Members for designing, manufacturing, marketing, labeling, packaging, and selling the defective Products.

COUNT VI: STRICT LIABILITY – MANUFACTURING DEFECT

170. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

171. The Products implanted in Plaintiff and Class Members were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendant BSC's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff and Class Members.

172. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

173. Defendant BSC is strictly liable to Plaintiff and Class Members for designing, manufacturing, marketing, labeling, packaging and selling defective Products.

COUNT VII: STRICT LIABLILTY – FAILURE TO WARN

174. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

175. The Products implanted in Plaintiff and Class Members were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendant BSC did not provide sufficient or adequate warnings regarding, among other subjects:

a. The Products' propensities to contract, retract, and/or shrink inside the body;

b. The Products' propensities for degradation, fragmentation, disintegration and/or creep;

c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. The risk of chronic infections resulting from the Products;

g. The risk of permanent vaginal or pelvic scarring as a result of the Products;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. The need for corrective or revision surgery to adjust or remove the Products;

j. The severity of complications that could arise as a result of implantation of the Products;

k. The hazards associated with the Products;

l. The Products' defects described herein;

m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Products.

176. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

177. Defendant BSC is strictly liable to Plaintiff and Class Members for designing, manufacturing, marketing, labeling, packaging and selling defective Products.

COUNT VIII: BREACH OF EXPRESS WARRANTY

178. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

179. Defendant BSC made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

180. Plaintiff and Class Members and/or her healthcare provider chose the Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

181. Plaintiff and Class Members, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes. Defendant BSC breached these express warranties because the Products implanted in Plaintiff and Class Members were unreasonably dangerous and defective as described herein and not as Defendant(s) had represented.

182. Defendant BSC's breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective products in the body of Plaintiff and Class Members, placing said Plaintiff's and Class Members' health and safety in jeopardy.

183. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

COUNT IX: BREACH OF IMPLIED WARRANTY

184. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

185. Defendant BSC impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

186. When the Products were implanted in Plaintiff and Class Members to treat her pelvic organ prolapse and/or stress urinary incontinence, the Products were being used for the ordinary purposes for which they were intended.

187. Plaintiff and Class Members, individually and/or by and through her physician, relied upon Defendant BSC's implied warranties of merchantability in consenting to have the Products implanted in her.

188. Defendant BSC breached these implied warranties of merchantability because the Products implanted in Plaintiff and Class Members were neither merchantable nor suited for their intended uses as warranted.

189. Defendant BSC's breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Products in the body of Plaintiff and Class Members, placing said Plaintiff's health and safety in jeopardy.

190. As a direct and proximate result of Defendant BSC's breach of the aforementioned implied warranties, Plaintiff and Class Members have experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not

limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

COUNT X: INTENTIONAL MISREPRESENTATION

191. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

192. Defendant BSC has represented to the public, including Plaintiff and Class Members, as well as the FDA, through promotion, marketing, informational materials, application for approval, packaging, labeling, and other means that its mesh Products had characteristics and qualities, that they did not have, specifically, that the products were manufactured using authentic, certified Marlex, that they met certain standards and grades as described herein, and that they were safe to use in permanently implantable devices.

193. Defendant BSC's representations were false in that the mesh products manufactured with counterfeit Marlex, not made with certified Phillips Marlex as represented and approved by the FDA and were not safe for use in the human body.

194. Defendant BSC made the misrepresentations alleged herein intentionally to deprive Plaintiff and Class Members of property or otherwise causing damage.

195. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its transvaginal mesh Products, and in justifiable reliance thereon, purchased the BSC Product.

196. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on counterfeit products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendant BSC, and thereby lost money by purchasing Products that were not what it was represented to be,

which was worth less that they paid for, and which they would not have purchased but for the misrepresentations.

197. Plaintiff and Class Members, in purchasing and being implanted with BSC's mesh Products as alleged herein, did rely on Defendant BSC's misrepresentations, all to their detriment. As a direct and proximate result of Defendant BSC's misrepresentations, Plaintiff and Class Members also experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

COUNT XI: NEGLIGENT MISREPRESENTATION

198. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

199. Defendant BSC has represented to the public, including Plaintiff and Class Members, as well as the FDA, through promotion, marketing, informational materials, application for approval, packaging, labeling, and other means that its mesh products had characteristics and qualities, that they did not have, specifically, that the products were manufactured using Marlex and that they were safe to use in permanently implantable devices.

200. Defendant BSC's representations were false in that the mesh products manufactured with counterfeit Marlex, not made with certified Phillips Marlex as represented and approved by the FDA and were not safe for use in the human body.

201. Defendant BSC made the false representations alleged herein with the intention of inducing Plaintiff and Class Members to purchase and/or use BSC mesh Products.

202. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its transvaginal mesh Product, and in justifiable reliance thereon, purchased the BSC Product.

203. At the time Defendant BSC made the misrepresentations alleged herein, Defendant BSC has no reasonable grounds for believing the representations to be true.

204. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on counterfeit products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendant BSC, and thereby lost money by purchasing Products that were not what it was represented to be, which was worth less that they paid for, and which they would not have purchased but for the misrepresentations.

205. Plaintiff and Class Members, in purchasing and being implanted with BSC's mesh Products as alleged herein, did rely on Defendant BSC's representations, all to their detriment, including economic damage. As a direct and proximate result of Defendants' misrepresentations, Plaintiff and Class Members also experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future; additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

COUNT XII: FRAUD

206. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

207. BSC is liable to Plaintiff and Class Members for fraud. Under New York law a Defendant is liable for fraud if: (1) the defendant knowingly committed a fraudulent act; (2) the act was material, false, and plaintiff's reliance on the act was justifiable; and (3) plaintiff was damaged as a result of her reliance on defendant's act. *See Global Minerals & Metals Corp. v. Holme*, 824 N.Y.S.2d 210, 214 (1st Dep't 2006).

208. Defendants smuggled counterfeit Marlex HGX-030-01 resin into to the United States and Belgium.[188] Zhao, a BSC executive, discussed with other BSC executives his conversation with the shipper, Defendant YFL, as well as the need to conceal the containers from the inspectors by repacking or over-bagging the full inventory. Repacking or over-bagging was necessary so that Chinese customs did not catch BSC and its cohorts, including Defendant YFL, smuggling the alleged Marlex out of China without the proper paperwork. Indeed, BSC and its cohorts discussed what would happen if they are caught by Chinese Customs.[189]

209. BSC used this counterfeit product as the base material shipped to Proxy and Luxilon—base material subsequently manufactured into all mesh Products relevant herein. The FDA requires device manufacturers to submit a new application for clearance if the manufacturer changes any material within a permanent implant device. BSC failed to submit a request for clearance of the counterfeit material in its mesh Products. Rather, BSC deceptively promoted, marketed, packaged, labeled, sold and distributed this mesh as being manufactured with authentic Marlex and approved by the FDA. BSC's specific, fraudulent

[188] Exhibit 20, BSCM12900000074.
[189] Exhibit 20, BSCM12900000074.

statements (in addition to its marketing, product, and instruction materials) are further contained, *inter alia*, within the exhibits attached to this complaint.

210. Plaintiff, Class Members, and their healthcare physicians believed and relied on Defendants' promotion, marketing, advertising, packaging, and labeling of its Products to their detriment, and in justifiable reliance thereon, purchased the BSC product.

211. BSC sold mesh manufactured with counterfeit Marlex to Plaintiff and Class Members under the false premise that the product(s) were cleared by the FDA. BSC's goal was to maintain its $120,000,000 revenue per year.[190]

212. As a proximate result of these acts, Plaintiff and Class Members were induced to spend an amount to be determined at trial on BSC products manufactured, promoted, marketed, advertised, packaged, labeled, distributed and sold by Defendant BSC, and thereby lost money by purchasing Products that were not what they were represented to be, which were worth less than they paid for them, and which they would not have purchased but for the fraud. As a direct and proximate result of Defendants' misrepresentations, Plaintiff and Class Members also experienced significant physical and mental pain and suffering, physical impairment, physical disfigurement, permanent injury, and mental anguish, all both in the past and in the future. Additionally, Plaintiff and Class Members have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, medical bills, lost income, and other damages, all both in the past and future.

[190] Exhibit 6.

COUNT XIII: UNJUST ENRICHMENT

213. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

214. Defendant BSC has benefited from its unlawful acts by receiving excessive revenue derived from the sales of mesh products represented as being manufactured with Marlex. Defendant BSC appreciated and/or knew the benefit of the receipt of such excessive revenue. This excessive revenue has been received by Defendant BSC at the expense of Plaintiff and Class Members, under circumstances in which it would be inequitable for Defendant BSC to be permitted to retain the benefit.

215. Plaintiff and Class Members are entitled to the establishment of a constructive trust consisting of the benefit conferred upon Defendant BSC in the form of its excessive revenue derived from the sale of mesh products manufactured with counterfeit Marlex from which Plaintiff and Class Members may make claims on a pro rata basis for restitution.

TOLLING OF THE STATUTES OF LIMITATION

216. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

217. **FRAUDULENT CONCEALMENT AND DISCOVERY RULE.** Defendants took active steps to conceal that they wrongfully, improperly, illegally, and repeatedly smuggled counterfeit Marlex out of China and used it to manufacture adulterated Products that were implanted in Plaintiff and Class Members. The details of Defendants' efforts to conceal their above-described unlawful conduct are in their possession, custody, and control, to the exclusion of individual plaintiffs, and await further discovery. Plaintiff exercised due diligence by thoroughly investigating the situation, retaining counsel, and pursuing her claims. Defendants fraudulently concealed their above-described wrongful conduct. Should such be necessary, therefore, any applicable statutes of limitation are tolled under the fraudulent

concealment doctrine. Additionally and/or in the alternative, Plaintiff exercised reasonable diligence to bring suit within the applicable time frame such injury should have been discovered and/or brought suit within a reasonable amount of time after which she reasonably discovered such injury.

218. **EQUITABLE ESTOPPEL.** Defendants took active steps to conceal that they wrongfully, improperly, illegally, and repeatedly smuggled counterfeit Marlex out of China and used it to manufacture adulterated Products that were implanted in Plaintiff and Class Members. The details of Defendants' efforts to conceal their above-described unlawful conduct are in their possession, custody, and control, to the exclusion of individual plaintiffs, and await further discovery. Plaintiff exercised due diligence by thoroughly investigating the situation, retaining counsel, and pursuing her claims. Defendants fraudulently concealed their above-described wrongful conduct. Should such be necessary, therefore, all applicable statutes of limitation (if any) are tolled under the doctrine of equitable estoppel.

219. **EQUITABLE TOLLING.** Defendants took active steps to conceal that they wrongfully, improperly, illegally, and repeatedly smuggled counterfeit Marlex out of China and used it to manufacture adulterated Products that were implanted in Plaintiff and Class Members. The details of Defendants' efforts to conceal their above-described unlawful conduct are in their possession, custody, and control, to the exclusion of individual plaintiffs, and await further discovery. Plaintiff exercised due diligence by thoroughly investigating the situation, retaining counsel, and pursuing her claims. Defendants fraudulently concealed their above-described wrongful conduct. Should such be necessary, therefore, all applicable statutes of limitation (if any) are tolled under the doctrine of equitable tolling.

RELIEF REQUESTED

220. Plaintiff incorporates by reference as if fully set forth herein all preceding paragraphs.

221. **ACTUAL, CONSEQUENTIAL, AND/OR INCIDENTAL DAMAGES.** As a direct and/or proximate result of the above-described unlawful and intentional schemes to cheat and defraud, wrongful actions, inaction and/or omissions engaged in by Defendants, Plaintiff and Class Members have sustained (and will continue to sustain) actual, consequential, incidental, and/or statutory damages to their businesses and/or property, and other injury and harm in the form of, *inter alia*, (a) ascertain the true nature of their BSC mesh product from the date of implant and whether it is of counterfeit origin; (b) consult with medical providers to determine whether to leave the BSC, counterfeit mesh inside them, or have it removed, (c) schedule and pay for surgeries to remove BSC's counterfeit, Chinese mesh, (d) seek medical monitoring or other redress to monitor their physical health regardless whether the Chinese, counterfeit mesh remains or is explanted (since it is of unknown origin and manufacture); and (e) recover the difference in value between what was paid for the BSC mesh (misrepresented to contain authentic Phillips Marlex), and what was actually received (Chinese, counterfeit mesh of lesser value) for which Plaintiff and Class Members are entitled to compensation. Alternatively, Plaintiff and Class Members are entitled to equitable relief in the form of restitution and/or disgorgement of BSC's revenues, profits, and/or earnings from sale of the counterfeit products, and all other amounts by which BSC, and any other Defendants, have been unjustly enriched. All of the damages, injury, and harm sustained by Plaintiff and Class Members were reasonably foreseeable by Defendants. All conditions precedent to Plaintiff's and Class Members' claims for relief have been performed and/or occurred.

222. **PUNITIVE DAMAGES.** The above-described unlawful and intentional schemes, wrongful actions, inaction and/or omissions engaged in by Defendants were committed intentionally, willfully, wantonly and/or with reckless disregard for Plaintiff's and Class Members' rights and interests. Accordingly, Plaintiff and Class Members are entitled to punitive damages from Defendants as punishment, and to discourage such wrongful conduct in the future. All conditions precedent to Plaintiff's and Class Members' claims for relief have been performed or occurred.

223. **TREBLE DAMAGES.** Plaintiff and Class Members also are entitled to automatic treble damages for the above-described unlawful and intentional schemes to cheat and defraud, wrongful actions, inaction and/or omissions engaged in by Defendants under 18 U.S.C. § 1964(c).

224. **ATTORNEYS' FEES, LITIGATION EXPENSES AND COSTS.** Plaintiff and Class Members also are entitled to recover their attorneys' fees, litigation expenses, and court costs under, *inter alia*, 18 U.S.C. § 1964(c), Federal Rule of Civil Procedure 26(h), and state statutory and/or common law. All conditions precedent to Plaintiff's and Class Members' claims for attorneys' fees, litigation expenses, and court costs have been performed and/or occurred.

WHERFORE, Plaintiff, for herself and Class Members, respectfully request that (i) Defendants be cited to appear and answer this lawsuit, (ii) this action be certified as a class action, (iii) Plaintiff be designated the Class Representative, and (iv) Plaintiff's counsel be appointed as Class Counsel. Plaintiff, for herself and Class Members, further requests that upon final trial or hearing, judgment be awarded against Defendants in their favor for:

(a) With respect to Counts I–III (violations of 18 U.S.C. § 1961, *et seq.*)--

(i) threefold the actual, consequential and/or incidental damages sustained by Plaintiff and Class Members, along with attorneys' fees, litigation expenses,

and court costs, all pursuant to 18 U.S.C. § 1964(c), together with pre- and post-judgment interest at the highest legal rates;

(ii) equitable relief, as may be appropriate, pursuant to 18 U.S.C. § 1964(a) or other law, including an equitable accounting for all benefits, consideration, and revenues, profits, and/or earnings received, directly or indirectly, by Defendants from sales of the counterfeit and adulterated products, the disgorgement of all ill-gotten revenues, profits, and/or earnings, and/or all amounts by which Defendants have been unjustly enriched;

(b) With respect to Counts IV–XIII:

(i) actual, consequential, incidental, and/or statutory damages to be determined by the trier of fact;

(ii) punitive and/or exemplary damages;

(iii) all amounts by which Defendants have been unjustly enriched;

(iv) an equitable accounting for all benefits, consideration, and revenues, profits, and/or earnings received, directly or indirectly, by BSC from the sale of adulterated, counterfeit mesh products, the disgorgement of all ill-gotten revenues, profits, and/or earnings, and/or all amounts by which Defendants have been unjustly enriched;

(v) pre- and post-judgment interest at the highest legal rates;

(vi) attorneys' fees, litigation expenses and costs of suit incurred through the trial and any appeals of this case; and

(c) For all Counts, such other and further relief the Court deems just and proper.

JURY DEMAND

225. Plaintiff hereby requests a trial by jury.

DATED: November 14, 2016

THE MOSTYN LAW FIRM

/s/ J. Steve Mostyn
J. Steve Mostyn
Texas State Bar No. 00798389
Mark C. Sparks
Texas State Bar No. 24000273
3810 West Alabama Street
Houston, Texas 77027
(713) 861-6616 (Office)
(713) 861-8084 (Facsimile)
Pending Pro Hac Vice

LAW OFFICES OF SHAWN J. WALLACH

/s/ Shawn J. Wallach
Shawn J. Wallach
SW5611
52 Duane St, 7th Floor
New York, NY 10007
(646) 848-5400 (Office)
Wallach.shawn@gmail.com

ATTORNEYS FOR PLAINTIFF AND CLASS MEMBERS