March 31, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MC 20852

"How did all of this resin end up in China if it was made in Texas?"[1]

[2]

"Counterfeit material from a supplier you use-ACTION REQUIRED[3]"

CITIZEN PETITION

Teresa Stevens ("Mrs. Stevens" or "Petitioner"), by and through her undersigned attorneys Mike Hull and Amber Anderson Mostyn (the "undersigned") respectfully submits this petition (the "Citizen Petition") under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, federal and state laws governing smuggling and counterfeit products, all applicable rules and regulations of the FDA governing medical devices, all laws and regulations concerning the use of counterfeit, smuggled products as the primary component of medical devices designed for permanent implant inside the human body, and any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs. Petitioner respectfully asks the Commissioner of Food and Drugs to take the administrative actions requested in Section A below, including an immediate Class I recall of all Boston Scientific Corporation ("BSC") products made with counterfeit, Chinese resin.

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[1] Exhibit 1. This question was asked by BSC's Import/Export Coordinator, Robert Mullally.
[2] The photo above is the business located at 22 Xianwei Road, Dongguan, Guangdong, China 523000. This is the location of the distributor from which BSC purchased the resin it is permanently implanting into women. *See also* Exhibit 2 at BSCM13500000448.
[3] Exhibit 3. This is a statement made to BCS's R&D Director, Charles Smith regarding the distributor who sold BSC the resin it is currently using to manufacture its mesh products for permanent implant.

This Citizen Petition is also filed at the insistence of United States District Court Judge Goodwin.[4] Petitioner respectfully reserves the right to amend, modify or supplement this Citizen Petition as additional facts become known or their significance further understood.

The Citizen Petition tracks the Bard recall and seeks nothing more than what the Food and Drug Administration ("FDA") has already ordered Bard to do when it was selling counterfeit mesh, that is:

Bard	Boston Scientific
Counterfeit Bard Marlex mesh is being sold to the public.	BSC mesh that is counterfeit because it is not using Marlex HGX-030-01 as advertised is being sold to the public.
The counterfeit mesh may not meet the authentic product's specifications, including strength and clinical performance.	The counterfeit mesh may not meet the authentic product's specifications, including strength and clinical performance.
The packaging of the counterfeit samples is different from that of the authentic mesh.	The packaging of the Marlex HGX-030-01 is counterfeit and adulterated.
No specific harm had been conclusively proven.	Specific harm has not yet fully manifested.

Despite the absence of specific harm the Bard mesh was given an immediate Class I recall. The possibility that the Bard counterfeit mesh might be unsafe or ineffective was enough to trigger a recall. The FDA has not yet recalled the counterfeit BSC mesh despite having proof for months that the BSC mesh is counterfeit. The Citizen Petition implores the FDA to take action, just like it took action with Bard, before more women are hurt. The injury from defective mesh can take months or even years to manifest and if the FDA waits until thousands of women are suffering from unacceptably high rates of morbidity including infection, shrinkage with tissue contraction, mesh erosion, pelvic, rectal, and bladder pain, debilitating dyspareunia, or selenium toxicity[5] because they were implanted with defective mesh made with "[G]od knows"[6] what, which could have been prevented then the FDA will have protected the medical device companies and will have monumentally failed to protect the very women it should have helped.

A. Action Requested

Petitioner requests that the FDA take the following administrative actions, which are more fully described in the paragraphs below:

[4] Exhibit 4, Judge Goodwin's Memorandum Opinion and Order at 15, *Teresa L. Stevens v. Boston Scientific Corporation et. al.*, No. 2:16-cv-00265 (S.D.W.V. Jan. 26, 2016), ECF No. 35 ("The FDA is in the best position to determine whether Boston Scientific's mesh device is in compliance with the FDA's own statutes, regulations, and directives."). Petitioner waited to file this petition until documents BSC improperly marked as confidential were de-designated so that Petitioner could properly support her Citizen Petition.
[5] Exhibit 5, BSCM07300068256 at page 21, paragraph 4.7.
[6] Exhibit 3, BSCM11500006904.

1) issue an immediate Class I recall of all BSC products made with counterfeit, Chinese resin (including but not limited to Lot Number 6020105), that is, the material smuggled and exported out of China on or about August 2011, May 2012 and July 2012 by or on behalf of BSC;
2) issue warnings to purchasers, end users and recipients of mesh made from counterfeit Chinese resin; and
3) take other actions consistent with the Orders the FDA issued in the substantially similar situation involving counterfeit Bard mesh.

The limited nature of this request is important, and is perhaps best explained by identifying what is **not** requested in this Citizen Petition. Petitioner is not requesting the removal of all mesh, from whatever source, from the market. Petitioner is not even requesting the removal of all BSC mesh from the market. Petitioner is not requesting, in this Petition, that the 510(k) for Advantage mesh made from authentic Marlex mesh be revoked (although the question is left open here since the order should be revoked given the dangers represented by polypropylene mesh as recognized by the FDA in its reclassification of all pelvic organ prolapse products). Indeed, the request is not to prohibit BSC from producing and selling mesh made from authentic Marlex HGX-030-01, or from submitting a 510(k) if a change in materials is preferred to Marlex. Instead, this request is limited to recalling all BSC mesh products on the market made with the counterfeit, smuggled Chinese resin and prohibiting BSC from making products from the counterfeit Chinese resin.

Please note that BSC (by filing its Opposition to Plaintiffs' Motion for Sanctions)[7] has conceded that the counterfeit resin is sourced in China and is not Marlex (what it calls "certified Marlex").[8] Instead, the Opposition contends the Chinese resin it now admits using is the equivalent of Marlex (called in an extreme predictive close "uncertified Marlex") because of certain ISO 10993 testing that BSC did not do or use.

Most critically, however, the undersigned requests the FDA order BSC to quit making and selling any product with the Chinese resin. Each day that BSC continues to make this product with Chinese resin, is another day that approximately 200 women are permanently implanted with the counterfeit, unsafe material.

Alternatively, and additionally, Petitioner asks the FDA issue a warning letter to BSC asking BSC to quarantine the Chinese resin and all products made from the Chinese resin, requesting BSC cease making products with the Chinese resin, and asking BSC to permit the FDA to inspect and test the Chinese resin and all products made from it, preserve the Chinese resin as it is and where it is, and warn all purchasers and end users of products made with the resin of this application and the FDA warning letter.

In light of the serious and immediate threat to public health, if the FDA refuses to order a recall of mesh made from counterfeit resin then the undersigned requests that the FDA require

[7] Defendant Boston Scientific Corporation's Memorandum in Opposition to Plaintiffs' Motion for Sanctions and to Strike All "Confidential" Designations from Defendant's Documents, *In Re: Boston Scientific Corp., Pelvic Repair System Products Liability Litigation*, Case 2:12-md-02326 (S.D.W.V. 2016), ECF No. 1306 at 5.
[8] BSC in its Court filing refers to the counterfeit resin as the China Sourced Resin or is substantially equivalent to Marlex. BSC does not claim the counterfeit resin is Marlex.

BSC to warn all purchasers of BSC products made with the Chinese resin against their use. Each day, approximately 200 more women are implanted with this Chinese, counterfeit mesh. Worse, the decision to implant BSC's mesh is a permanent one, with permanent consequences. At the very least, these women (and their medical providers) should be given the information about the medical devices being permanently implanted into their bodies. The warnings should be similar to and consistent with the FDA required warnings about the counterfeit Bard mesh.[9]

A Class I recall is the appropriate response to a medical device being implanted into the human body and coming into contact with tissue and bone for thirty or more days when the device is made from counterfeit Chinese resin smuggled into the United States without any manufacturing or environmental history that is causing damage to the women who are implanted with it.

The Health Hazard Evaluation Worksheet

The Health Hazard Evaluation Worksheet (Attachment D Recall Procedures in Chapter 7 of the Regulatory Procedures Manual (October 2013) (the Worksheet)) asks a reviewer a series of questions to evaluate the health hazard. Applying the Worksheet to the counterfeit Chinese resin leads to the unavoidable conclusion that the products must be recalled. After collecting basic identifying information in questions 1-3, the Worksheet asks:

4. (a) Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

[ ] No
[x **] Yes - Attach copies or explain**

The answer is yes. The undersigned has been advised about numerous reports of adverse reactions and injuries associated with the use of Chinese resin, including the complaints of Mrs. Stevens, the injured party who filed the matter in West Virginia to remove the tainted mesh from the market.

Further, the possibility of harm was enough to cause a recall order in a very similar fact situation involving Bard counterfeit mesh.

(b) Have any adverse reaction reports or other indication of injuries or diseases been reported for similar situations?

[ ] No
[x **] Yes - Attach copies or explain**

Again, the answer is yes. Numerous women implanted with mesh made from Chinese resin are complaining about injuries post-implant.

Here, mesh made from counterfeit product is currently being marketed and implanted into over one thousand women every week—a situation not dissimilar to the Bard recall where counterfeit mesh was recalled on order of the FDA.

[9] *See* Exhibit 6, from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm204199.htm

(c) Is the problem easily identified by the user?

[x **] No**
[ ] Yes

Here the problem of defective mesh is unknowable by the women at the time of the implant because BSC refuses to alert doctors, hospitals and patients that all of its mesh products made in the last several years are made from counterfeit, Chinese resin.[10] Moreover, BSC compounds the problem by improperly designating, in bad faith, all documents "confidential" - documents that should be immediately released to this agency and the general public who have a right to know about this immediate threat to health.

5. What is the risk to the general population?

Two hundred women receive the defective mesh implants every business day. Over 2,000 women have been implanted with defective mesh since this matter was first brought to the attention of the FDA on February 19, 2016. This mesh - made from counterfeit Chinese resin - is permanently implanted into these women.

(a) For products not bearing dosage information, what is the normal consumption of the product by the general population and the population most at risk.

All women receiving a BSC mesh product will be implanted with a product made from counterfeit, Chinese resin.

6. What segment(s) of the population is most at risk and why? [e.g. entire population(animals/species), infants, children, elderly, pregnant women, women of child bearing age, nursing mothers, surgical patients, immune suppressed, clinical situations, food producing animals, non-food producing animals, other].

All women are at risk.

(a) Is there any known/accepted off labeled use(s) that would increase or change the population at risk.

No. The only way to reduce the risk is to warn people who have already been implanted, warn people not to use the defective mesh, recall the unused mesh, inform the general public about this imminent risk, stop making products from the counterfeit resin, and stop distributing the adulterated mesh to the public.

7. Within the population at risk, could individuals suffering from any particular conditions or diseases be more or less at risk and if so, why? [e.g. Immune system debilities, diabetes, cardiac problem, concomitant medications, etc.]

All women with stress urinary incontinence ("SUI") or pelvic organ prolapse ("POP") are at risk.

[10] In fact, BSC affirmatively asserts the counterfeit resin is safe. *See* Exhibit 31.

8. What is the hazard associated with use of the product? Explain and cite literature references when applicable.

A Class I Recall is mandated if the hazard:

> ***Could be Life-Threatening (death has or could occur); or***
>
> ***Could result in permanent impairment of a body function or permanent damage to a body structure; or***
>
> ***Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function.***

Here, the use of mesh made from counterfeit Chinese resin has, and is, and in the terminology of the Worksheet "could" cause permanent impairment and damage to the bodies of women who receive the implants. Moreover, these women require surgical intervention to remove the mesh and are suffering nerve and liver damage before the offending product can be removed. Further, because the composition and environmental history of the Chinese resin is unknown, these women face additional risks that cannot be quantified or predicted until after the damage has already occurred.

9. What is the probability of an adverse event occurring?

There is a reasonable probability of an adverse event occurring each time an implant made with counterfeit Chinese resin occurs.

The adverse events (in the worksheet) are italicized and in bold. Every time a woman is implanted with counterfeit mesh - 200 times every day - there is a probable and increased risk of an adverse event occurring.

The Worksheet next asks whether a recall would cause a major disruption in the treatments currently available. Absolutely not. There are many mesh products on the market—products from manufacturers who chose not to source counterfeit resin from China. Moreover, there are alternative mesh products and alternative procedures to mesh that treat the same symptoms.

The Worksheet concludes with an action plan. The difference between a Class I and a Class II hazard is the limited or permanent nature of the harm and the degree of risk. Since the hazards from counterfeit mesh are serious and permanent (and not temporary or medically reversible), and because the use of the product both could and in fact there is a reasonable probability of adverse health consequences related to the use of the product, a Class I recall is mandated.

Conclusion: the degree of seriousness of the hazard [real or potential] to the population at risk?

[x] The product is volatile and there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death. (Class I)(Market Withdrawal).

Please recall this product immediately so the ongoing harm to women can be stopped, and so that those women whom have already been harmed can be informed about the current danger that is permanently implanted into their bodies.

B. Statement of Grounds[11]

Summary

"How did all of this resin end up in China if it was made in Texas?"[12]

As explained in detail below, the simple answer to this question is that the resin used by BSC in its mesh products did not end up in China from Texas. The resin was never in Texas because it was not made by Phillips/Sumika ("Phillips"), the manufacturer of certified Marlex HGX-030-01 ("Marlex").

"Counterfeit material from a supplier you use-ACTION REQUIRED[13]"

Instead, BSC sought and obtained counterfeit Marlex which Petitioner believes was manufactured in Guangdong, China, the counterfeit capital of the world, by a known counterfeiter, and smuggled into the United States for use in BSC's permanently implantable mesh products. BSC performed bogus testing on the counterfeit resin, specifically designed by BSC so that it could quickly claim equivalence of the counterfeit resin to certified Marlex to avoid detection by the FDA and sustain its $120,000,000 annual profits gained from sales of its mesh products to unsuspecting women.

Grounds

1. Petitioner has a BSC mesh implant made from counterfeit Chinese resin.

Teresa Stevens was implanted a BSC mesh product — the Obtryx-Halo Urethral Sling System. Her implant is supposed to use Advantage mesh, a BSC product cleared by the FDA in 2002.

Mrs. Stevens implant date was October 27, 2014. BSC emails indicate the counterfeit Chinese resin was being used to make mesh as early as 2011.[14] BSC admits to using the counterfeit

[11] In ongoing, multi-district, mesh litigation in the Southern District of West Virginia, BSC, marked virtually all of its production (millions of pages) as "confidential" without a good-faith basis. The documents it calls confidential include newspapers and articles in medical journals. BSC refused to allow Mrs. Stevens to give the FDA or the public the documents that demonstrate that BSC is selling mesh made from counterfeit, plastic resin smuggled from China—resin containing medically significant levels of toxic selenium.

Only after a motion was filed in the MDL and only after two orders from Judge Goodwin did BSC finally agree to waive confidentiality for a handful of documents. The remaining millions of documents remain confidential.

BSC claims, in its Opposition, that it will share with the FDA anything they want. The FDA should have immediate, unfettered access to the thousands of pages of documents where BSC secretly discusses the undisputable facts it purchased counterfeit Chinese resin, smuggled the resin into the United States and Belgium in counterfeit bags and is now selling adulterated products.

This Petition is limited by BSC's document production and Petitioner reserves the right to amend it.

[12] Exhibit 1. *See* footnote 1, *supra*.

[13] Exhibit 3. *See* footnote 3, *supra*.

[14] BSCM07700285346, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

Chinese resin in 2013.[15] Therefore, Mrs. Steven's implant must be made from mesh manufactured with the counterfeit Chinese resin. Imagine thinking you have a permanently implanted medical device supposedly made according to the specifications in the 510(k) application and then learning that you might or might not have a mesh product that is a counterfeit mesh originating from the top counterfeiting location in China, sold by a known counterfeiter, that was illegally exported out of China and illegally imported into the United States.

2. Advantage mesh, the general name of BSC's mesh that should have been implanted into Mrs. Stevens, should be made specifically, and exclusively, from Phillips Marlex HGX-030-01 as represented by BSC and approved by the FDA for use in Advantage mesh, a Class II medical device.

BSC mesh products were approved for use by the FDA with Marlex as the primary component of the mesh. *See* K020110.[16] The 510(k) application for Advantage mesh received FDA clearance on April 3, 2002.[17] The use of Marlex HGX-030-01 is at Exhibit 7 of the application. No other polymer is identified by BSC as being the prime material component for the mesh. No other material was approved by the FDA for the BSC mesh products. The 510(k) application included several documents of significance:

1. The MSDS sheet for Marlex;
2. The Phillips performance and technical specifications for Marlex;
3. A Certificate of Analysis from Phillips confirming by lot number that a particular batch of Marlex had been made and confirming the run date, run amount, and the name, address and phone number of a person with Phillips to contact if questions arose; and
4. A letter of confirmation from Phillips that the particular product the BSC distributor had was, in fact, Marlex.

Marlex is a distinct polypropylene manufactured in La Porte, Texas by Phillips. Marlex is a specific, unique type of polypropylene, similar to a "Coke" being a specific, unique type of soft drink. Different grades of polypropylenes display different degrees of flexibility and susceptibility to oxidation and degradation. They also display differences in other qualities including weight and pore size. Marlex is certified by Phillips as being Marlex.[18]

BSC concedes it is using a Chinese resin that is not certified by Phillips as being Marlex. In fact, BSC knows Phillips has specifically denied that the Chinese resin is Marlex. BSC has never produced a Certificate of Analysis from Phillips or from any other manufacturer for the Chinese resin. There is no one to call to confirm a lot number, date or production, amount of

[15] BSC has admitted to using the resin from China, but not conceded the resin is counterfeit. It simply refers to the resin as the China Sourced Resin, a phrase that originated after litigation commenced and the counterfeiting issues was raised by Mrs. Stevens. However, BSC does admit the China Sourced Resin was in used in 2013. *See* BSC Opposition, referenced in footnote 7, *supra*.
[16] Exhibit 8, Relevant portions of FDA 510(k) Pre-Market Notification Surgical Mesh K020110.
[17] *See* the Advantage 510(k) application at K020110. A summary of the application is publicly available from the FDA.
[18] Marlex resin is used for carpet backing. Marlex is used to make plastic for hula hoops. In fact, if you are holding, touching, or viewing a plastic product the odds are decent that you are looking at a Marlex product.

production or disposition of the production. BSC instead says it is using something it calls "China Sourced Resin." This marketing term never appears in BSC internal documents but first appeared in court filings as a term of litigation. Whatever the "China Sourced Resin" is, it is not Marlex HGX-030-01 made by Phillips in La Porte Texas. If it was, Phillips would be quick to identify the lot number (Phillips has denied that the China Sourced Resin has a legitimate lot number), BSC would have the Certificate of Analysis from Phillips (it doesn't), and it would have Chinese import documents such as a Country of Origin certificate and prove that import (into China) taxes were paid (it doesn't).

Today (and tomorrow, and the day after that) BSC is manufacturing its Advantage mesh with counterfeit Chinese resin smuggled out of China—not authentic, certified Marlex. The Advantage mesh is used in all BSC devices used to treat SUI and POP. The FDA has not approved the use of counterfeit Chinese mesh smuggled out of China—for good reason. The FDA has only approved Advantage mesh made from authentic Marlex certified by Phillips. BSC doesn't know when the Chinese resin was made (relevant to its shelf life), how it was made (relevant to the chemical properties of the product), who made it (relevant to the manufacturing standards), the conditions under which it was made (relevant to the quality and consistency of the resin), whether the Chinese resin comes from one manufacturer or many (relevant to the quality and consistency), or how the product(s) were stored to protect against environmental and contamination damage (including, *inter alia*, oxidation); and since no assumption of homogeneity can be made, BSC, as well as consumers, know absolutely nothing about over 17 tons of Chinese resin that was never subjected to any test, including a visual test. For example, polypropylene degrades at an accelerated rate when exposed to UV rays, meaning, Chinese resin stored in sunlight will degrade faster and hurt more women sooner than will mesh made from authentic Marlex that is properly stored. BSC also doesn't know whether the May and July, 2012 lots come from a same or different production run than the August, 2011 shipment. BSC knows nothing about the chemical properties of the May and July, 2012 shipments. BSC does not know anything about any of the Chinese resin derived from running ISO 10993 tests.

This Citizen Petition asks the FDA to order BSC, in every reasonably effective manner, to warn purchasers and end users to stop using BSC mesh products made with counterfeit, smuggled, improperly tested, and falsely documented plastic resin from China. The petition also asks BSC to warn all users of the product to quit using the product, and to seek medical attention, in addition to other relief, contained in the "Relief Requested" section.

3. <u>In 2004, Phillips publicly announced that Marlex HGX-030-01 was not safe for permanent use in the human body.</u>

OSHA regulations require a manufacturer of a product like Marlex to produce a Manufacturers Safety Data Sheet (MSDS) to accompany the product. The MSDS is supposed to warn about and warn against particular hazards associated with the use of the product and describe limitations for the use of the product.

In 2004, Phillips amended its MSDS sheet to prohibit the use of Marlex in any medical device that was to be permanently implanted into the human body. In particular, the 2004 MSDS sheet for Marlex produced by Phillips states:

> **MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.**[19]

The significance of the Phillips statement must be emphasized. Phillips was not simply a manufacturer of a component part of a mesh product. Phillips held the original patents on polypropylene mesh[20] and every polypropylene mesh product on the market today has Phillips at its origin. Thus, Phillips, as the originator of polypropylene mesh, and the first patent holder in the field, and the maker of the principle component of the mesh, declared without equivocation that Marlex was not safe for use inside the human body.

4. Phillips refused to sell additional Marlex to BSC in 2005.

As the Advantage mesh began to move through the 510(k) process and BSC anticipated its need for Marlex would increase, BSC went to Phillips in 2005 to purchase additional Marlex for its inventory. Phillips would not supply additional Marlex to BSC for medical use.[21]

BSC ultimately offered an indemnity agreement to Phillips in exchange for an agreement to sell Marlex to BSC, but Phillips refused supply the Marlex for medical use.[22] BSC eventually purchased Marlex from a distributor, Channel Prime Alliance, who itself required an indemnity agreement from BSC.[23]

5. BSC ran short of Marlex in 2011, creating a fire drill[24] inside BSC.

In 2011, BSC began to run out of Marlex which threatened its annual $120 million revenue stream from the sale of mesh products made with Marlex and the jobs of the executives of the Women's Health Division. BSC determined that Phillips quit making Marlex at least by 2008.[25]

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 production (and profits), then sell the rest. Phillips refused to sell additional Marlex to BSC absent confirmation the Marlex would not be used in the human body. BSC refused to give that

[19] Exhibit 9, 2004 MSDS for Marlex.
[20] Amid, Parviz K. "Polypropylene prostheses." In *Abdominal Wall Hernias*, pp. 272-278. Springer New York, 2001; Francis C. Usher, herniologist of the twentieth century, History, Hernia; September 199, Volume 3, Issue 3, pp. 167-171.
[21] BSCM07400031600, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.
[22] *Id.*
[23] Exhibit 10, BSCM06701713798.
[24] Exhibit 11, BSCM06700722854. One reason for the fire drill is within the Women's Health division, the loss of Marlex impacted the BSC mesh products Pinnacle, Uphold, Obtryx, Lynx, Prefyx, Advantage, Advantage Fit and future products. The loss of Marlex also affected other products in other divisions including its Trelex mesh.
[25] Exhibit 12, BSCM13000000033.

assurance to Phillips, but promptly offered to grant indemnity and offer more money.[26] Phillips refused, and told BSC it simply wasn't interested in selling Marlex to BSC "at any price."[27]

6. BSC contends[28] that it attempted to, but failed, to find an authorized distributor who would sell Marlex to BSC.

BSC could find no suppliers of authentic Marlex who would sell product to BSC due to the MSDS warning;[29] BSC went so far as to draft a Model Indemnification/Insurance agreement to provide to sellers of Marlex but never found a willing seller.[30]

7. BSC looked to other options to replace its Marlex needs.

BSC's annual sales from mesh totaled about $120 million.[31] To protect its $120 million in annual mesh sales, BSC needed Marlex HGX-030-01 because BSC believed the FDA would need to approve a change in materials and believed the FDA would be unlikely to approve a change in materials, or approve a change before the existing supply of Marlex was depleted.[32]

BSC also looked at changing the chemical resin used to create the mesh. BSC freely acknowledges in its concealed emails that a change of materials to a new resin would require BSC to submit a new 510(k) to the FDA. This plan ultimately failed because BSC didn't have enough resin in stock to continue manufacturing Advantage mesh with Marlex until it could attempt to gain approval of the new mesh from the FDA. BSC believed approval of a new resin would have a long introduction time and that its current stock of Marlex would be depleted before mesh made from a new material could be on the market.[33]

BSC also looked at ways to stretch its use of the current (authentic) resin, including using Marlex scraps used to create Advantage products.[34] But that was a temporary reprieve at best. The authentic, Phillips Marlex was running precariously low, and BSC was getting desperate. Indeed, BSC's Women's Health Division began developing arguments why it should get the existing supplies of Marlex in preference to other BSC divisions who also used Marlex, like the division that created Trelex Surgical Mesh from HGX-030-01.

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[26] Interestingly, BSC paid far less than the market price for Marlex located in the United States for the counterfeit resin located in China that had to be smuggled out of China and into the United States.
[27] Exhibit 13, BSCM06701713768; Exhibit 14, BSCM04700235069.
[28] BSC has consistently taken the stance that it could not find Marlex from an authorized distributor. It did find 1,300 pounds of a product that was supposed to be Marlex but turned out to be another product or to be defective. *See* BSCM06701685127. It appears that BSC may have used the wrong material or the defective material, or both. *See also* Exhibit 15 at BSCM13800009461- BSC employee Charlie Smith writes that the tests that will be used on the Chinese resin and "on the US based Gaylord that has been partially used as well."
[29] *See, e.g.*, BSCM07700280242, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.
[30] Exhibit 16, BSCM13000000037.
[31] Exhibit 17, BSCM11200014917.
[32] Exhibit 13, BSCM06701713768.
[33] *Id., see also* Exhibit 18 at BSCM05700089221.
[34] BSCM14700006847, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

8. BSC turned to a known Chinese counterfeiter to satisfy its Marlex needs.

Since an approved, known supplier of authentic Marlex could not be found, BSC instead chose to begin its search in China by using the search engine alibaba.com,[35] which is notorious for producing counterfeit good.[36] Purchasers of foreign goods have been repeatedly warned by U.S. trade officials about its massive counterfeiting problem. Remarkably, after using the alibaba.com search engine, Michael Zhao, a BSC employee located in China, found five potential sellers of Marlex.[37] BSC just happened upon thousands of pounds of Marlex that made its way from La Porte, Texas, to the Guangdong province of China—an international hub for counterfeiting. Perhaps even more striking is that a Chinese counterfeiter just happened to have the resin when twenty-six reputable suppliers in the U.S. had no Marlex to sell to BSC.

As Zhao searched the Alibaba finds which were located in the heart of the counterfeiting capitol of the world, Zhao was advised by BSC to hide the intended purpose of the Marlex because the information might scare away the Chinese sellers.[38] BSC was itself aware of the risk of purchasing counterfeit resin as its internal emails show that it discussed whether there were tests to confirm whether the resin was counterfeit or contaminated.[39] Of course the first easy test is whether the resin has a Certificate of Analysis from the manufacturer (which the purchased Chinese resin did not have).

Ann Charest, the Manager of Global Sourcing for BSC, noted that the Chinese seller would need to supply BSC with a photo of the material packaging, a copy of the certificate of compliance,[40] the MSDS sheet, pictures of the actual resin and other requirements.[41] In the end, as discussed below, BSC only ever received a photo of the material packaging and Phillips confirmed that the lot number on the Marlex bag in the photo was invalid.

BSC ultimately settled on the Alibaba-sourced distributor identified in some of the BSC records as EMAI, a distributor in China known to BSC to be a counterfeiter of plastic goods.[42]

EMAI claimed to have sufficient Marlex HGX-030-01 to satisfy all of the needs of BSC. Remarkably, EMAI subsequently attempted to sell counterfeit plastic to another division of BSC. The memo below is from John Kummailil. John is the Senior Engineer for Corporate Engineering. The subject of the email is:

RE: Counterfeit material from a supplier you use-ACTION REQUIRED

John then writes:

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[35] Exhibit 19 at BSCM13800009803; Exhibit 20, BSCM13800008924.
[36] *See* Exhibit 21, "There's no end in sight for Alibaba's counterfeit problem" published in Fortune Magazine at http://fortune.com/2015/05/18/theres-no-end-in-sight-for-alibabas-counterfeit-problem/; *see also* http://appv1.linktv.org/videos/genuine-pride-for-knockoff-goods-in-guangzhou
[37] Exhibit 20, BSCM13800008924.
[38] Exhibit 19 at BSCM13800009802.
[39] Exhibit 15 at BSCM13800009461.
[40] BSC uses Certificate of Analysis, Certificate of Compliance, and Certificate of Authenticity somewhat interchangeably throughout internal documents.
[41] Exhibit 19, BSCM13800009800.
[42] Exhibit 5 at BSCM11500006906.

> We were looking for Nylon 12 in China and came across possibly counterfeit material form [sic] a distributor **(Emai)** who you use for Carbothane(?) or **Marlex**-not sure which.[43]

Charles Smith with BSC then responds:

> Thxs, we will review. Our material was in sealed bags and we tested **as we had no certification (trail back to Marlex on lot#).**[44]

John responded that his counterfeit plastic from EMAI was in sealed bags and looked pristine.[45]

A simple reason to recall the BSC mesh is that once one knows the material is not Marlex and that the manufacturer of the product is unknown then the process used to make the resin is unknown and the materials used to make the process is unknown. John Kummailil nailed this problem in the same email chain. John is asked how he knew his plastic was counterfeit. His response:

> We did not run any tests. The lot numbers in the pic were Evonik lot numbers for a different grade, per Evonik's VP.
>
> The hypothesis is that they re-bagged god know what grade, or even recycled materials, in bags that have the grade # we were looking for.[46]

9. <u>BSC elected to go to production with EMAI despite it being a known counterfeiter of plastic resin.</u>

BSC had only one positive response across the entire world for a distributor who claimed to have Marlex in the volume being sought by BSC. EMAI, that distributor, originally told Zhao that it had Marlex on hand. But then, on July 25, 2011, EMAI reported that it sold its remaining inventory of Marlex to another distributor.[47] But fortunately, a new batch of Marlex might arrive from the harbor the following day, July 26, 2011.[48]

On July 26, 2011 Zhao reported that EMAI had been in contact with him and the shipment contained no Marlex. EMAI offered to help BSC find the resin in China.[49] EMAI required a $15,000 RMB finder's fee from BSC and notes that it cannot provide a receipt to BSC for the payment.[50] BSC agreed to EMAI's terms but not before Ron Ciulla, Manager of the Urology and Women's Health Research and Development Division emphasizes the need for a Certificate of Compliance.[51] Todd McCaslin, the Global Sourcing Director for BSC, responded to Ciulla:

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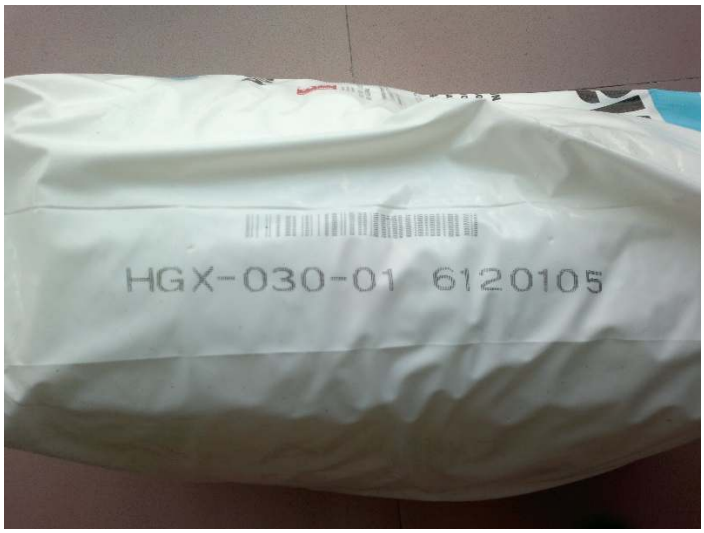
[43] *Id*. (emphasis added).
[44] *Id*. at BSCM11500006905 (emphasis added).
[45] *Id*.
[46] *Id*. at BSCM11500006904.
[47] Exhibit 19 at BSCM13800009801.
[48] Exhibit 20 at BSCM13800008924.
[49] Exhibit 22 at BSCM13800008345.
[50] *Id*.
[51] *Id*.

> I know…this is the "higher risk" option.
>
> If there is no C of C available at all is this dead? I wonder if we could get a lot # from the bag and contact Phillips (who does not seem to want to talk to use).[52]

As will be noted below, BSC did elect the higher risk option, and no C of C was available. The deal should have been dead at that time. Instead, BSC used an intermediary to contact Phillips about the lot number as McCaslin suggested. As discussed below, Phillips reported the lot numbers on the EMAI bags were invalid.

Curiously, Zhao requested a photograph of a bag of Phillips Marlex prior to his 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 Zhao and/or 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. EMAI likely made this bag using its own plastic resin. EMAI had to make up a Phillips lot number. Ironically, this made it easy to detect counterfeit Marlex.

BSC then obtained photographs of one of the EMAI bags containing the Chinese resin. The photographs showed the lot number on the bags, as demonstrated by the following picture:



BSC confirmed that all of the lot number for the entire purchase of 37,400 pounds was the same - 6120105.[53] BSC sent the lot number to Phillips to determine whether the lot number were valid. BSC has to use an intermediary at this point because Phillips would not discuss Marlex with BSC. BSC turned to Prasad Puttagunta, an AK Plastics employee. AK Plastics is an authorized distributor of Marlex. Puttagunta, after checking on the validity of the lot number supplied by EMAI, wrote:

[52] *Id.*
[53] Exhibit 23 at BSCM06701715874.

> I have been told by someone in the quality organization at Phillips Sumika that **the lot number below is not valid.** Can you send me a picture of the bag and the lot number. I will check again.[54]

After receiving a photo of the lot number (like the photo above), Puttagunta confirmed:

> We tried two routes to get this information . . . Unfortunately we received the same answer. **The lot number on the bag is not a lot number in their system.**
>
> As I mentioned in a separate email, I have been unable to discover who the Chinese distributors[55] are and, Phillips Sumika will not take responsibility for the material sold their [sic].[56]

10. <u>The EMAI resin is clearly counterfeit.</u>

Below is a list of documents that should accompany the Marlex issued by Phillips and a list of documents that should be available to prove the Marlex was imported into China, compared to what BSC actually has for the Chinese resin:

Phillips Documents	Chinese Import Documents	What BSC actually has
Certificate of Analysis		None
Performance and Technical Specifications		None
Letter from Phillips confirming Sale to an authorized Distributor		None
	Shipping Waybill (air or ship) How did Marlex get to China?	None
	Electronic Export Information	None
	Commercial Invoice	None
	Pro Forma Invoice	None
	Packing List	None
	Certificate of Origin	None
	Price List	None
	Purchase Order	None

In addition to above, we can add the facts that the resin was found using alibaba.com, that the seller was known to try to sell counterfeit plastic goods to BSC, that all of the paperwork it should have was missing, BSC was aware of the lack of paperwork, and that BSC checked with

[54] Exhibit 24 at BSCM13500000014.
[55] It is of note that the undersigned believes there are multiple distributors.
[56] Exhibit 24 at BSCM13500000010.

Phillips on three separate occasions about the validity of the lot numbers and on three separate occasions Phillips said the lot numbers were not in the Phillips system.[57]

As further confirmation that BSC knew the bags were counterfeit, after Phillips rejected the lot number on three separate occasions, Prasad wrote:

> My guess is that the material was repackaged in China from a bulk container and given a new lot number that may mean something to the Chinese distributor.[58]

And to further show that BSC knew the material itself was counterfeit, Prasad wrote:

> As I mentioned in an earlier email I have been unable to discover who the Chinese distributors are …[59]

EMAI further was unable not provide a receipt, which BSC required:

> Since service is not part of his company's scope, he can't provide a receipt which we will need.[60]

At this point, BSC elected to purchase the Chinese resin. However, Janice Courtois, the Senior Quality Engineer for the Women's Health Division, wrote that BSC would need to do testing on the Chinese resin (discussed below), conduct accelerated aging studies (which was not done), determine the source of the resin (which was never done), determine the storage conditions in China of the resin (which was never completed), determine how the product was packaged (which was never done) and obtain a Certificate of Compliance (which never happened).[61]

Despite all of these clear signs the product was counterfeit, the pressure of losing $120 million in annual sales was just too great and BSC purchased 37,400 pounds of counterfeit Chinese resin.

11. <u>BSC had to smuggle the Chinese Resin out of China and into the U.S. and Belgium.</u>

BSC purchased 37,400 pounds of the counterfeit Chinese resin, a purchase made knowing the resin was counterfeit and knowing the bags containing the resin were counterfeit. The lack of paperwork (that is, no Certificate of Analysis, no import papers and no payment of an import tax—all the things a prudent manufacturer would require) created quite the dilemma for BSC. How does it get the counterfeit resin out of China and into the United States (for use and storage by BSC) and Belgium (to Luxilon, BSC's mesh component manufacturer for production)? And in doing so how does it address the Chinese/FDA dilemma?

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[57] *Id.*
[58] *Id.* Once the pictures of the counterfeit bags were obtained, BSC inexplicably decided that the existence of the counterfeit bags proved that the Marlex had not been in a railroad car and proof that Phillips packaged the product. *See* Exhibit 25, BSCM07700157280.
[59] Exhibit 24 at BSCM13500000010.
[60] Exhibit 22 at BSCM13800008345.
[61] BSCM13800008865, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

*a. The Chinese/FDA dilemma created a need to **smuggle** the counterfeit resin out of China.*

Before progressing further, it is important to acknowledge BSC's ridiculous conduct and the importance of FDA action. BSC has counterfeit Marlex, 37,400 pounds of it, confirmed by prior experience and Phillips (the manufacturer of real Marlex), in counterfeit bags as confirmed by comparing authentic bags made by Phillips, from a known counterfeiter with financial motive to sell the cheapest plastic it can find (or make), from the global heart of counterfeit goods, and the emails (that have presumably been supplied by BSC to the FDA) that discuss how to smuggle the resin out of China and into the United States. How does one explain to women injured by the counterfeit resin the conduct of BSC or inaction by the FDA?

The FDA dilemma has two prongs: the Chinese prong and the FDA prong. The Chinese prong required BSC to show to Chinese Customs that the resin was made in China. The resin had to be made in China (when exporting from China) because otherwise BSC, to export the resin from China, needed all of the import paperwork (that it didn't have) to show Chinese Customs when the U.S. made product was imported into China (including a statement of the Country of Origin and a receipt for the payment of the import tax).

The FDA prong is that BSC believed using a change of materials to manufacture its mesh would require FDA approval.[62] Therefore once the resin left Chinese Customs (as polypropylene made in China, and not as Marlex made in Texas) the resin had to somehow become Marlex when it was being imported into the U.S. to demonstrate to BSC's Quality Assurance department and to the FDA that the product was Marlex HGX-030-01 so that no change of materials 510(k) application had to be filed with the FDA.

BSC solved its dilemma by declaring that the Chinese resin was **made by Dongguan Sunmei Plastic Raw Material Co., Ltd.**, **a Chinese company, to clear Chinese customs**[63] (to get around the fact EMAI had no import papers or record of paying an import tax) and declaring to the relevant U.S. and Belgium authorities the product was Phillips Marlex made in Texas (Marlex HGX-030-01 made by Phillips only in Texas—never anywhere else, and certainly never China).[64] Or stated differently, if the product is Marlex then BSC lied to the Chinese. But since it isn't Marlex, BSC lied to U.S. Customs, to its Quality Assurance department (unless QA was in on the fraud), and to the FDA, the public, and ultimately to Mrs. Stevens.

b. BSC concealed the counterfeit bags to solve the Chinese/FDA dilemma split the shipments of the Chinese resin to reduce the chances of detection and reduce the consequences if caught.

The 37,400 pounds of Marlex were split up and shipped on four separate dates in different containers, by different methods (one by air and three by ocean transport). The first shipment was for 4,400 pounds and it was shipped by air. The product had a declared value of $5,200. BSC paid

[62] Exhibit 13, BSCM06701713768.
[63] Exhibit 26, BSCM13500000465.
[64] Exhibit 27 at BSCM11500004627.

$93,000[65] in Hong Kong dollars to ship the product. (Leading one to ask not only how the product got to China but also why it was in China and who paid for it?).

Zhao described the first shipment in an email discussing the remaining shipments and openly discussed the smuggling operation:

> Just to give you a heads up. Last time due to it's by air and small amount, the 2 tons was not "inspected" by the custom. The shipper basically put a blank bag over the original bag.[66] This time since it has 3 containers and by sea, likely custom will inspect them. The shipper told me that the inspector is pretty good at their job and we will need to "re-pack" all 600 bags. I have not seen them by myself yet, but if it is the same bag as previous 2 tons we bought, they all have details about where it was produced originally on the outside of the bag. Per import/export law in China, it is very hard to export stuff out if it was produced from oversea without the original and correct paperwork. For this material, **we have lost all of the original paperwork so we can't prove that was legally imported in the country.** and if we don't get rid of the original bags or the writing on the bags when we claim they are from China(we have to say they are from China since we don't have the original paperwork attached), **if it is caught by custom, we will be in trouble**. Therefore the shipper told me it is better to consider to re-pack all of them or find a way to get rid of all of the words/writing on the bags.[67]

Charles Smith quickly responded to Zhao and stated:

> We can over bag, but we should not open bags and repack.[68]

Zhao also stated that that on the first shipment by air, BSC "took a chance, the shipper who handled it was not 'over-cautious', it was a different person."[69]

The counterfeit resin was purchased at two separate times, 4,400 pounds purchased in August, 2011, and 33,000 pounds purchased in November, 2011. Even though BSC's chance of being audited was low,[70] BSC played it safe and split the resin into 4 separate shipments: the 4,400 pounds were shipped by air in August, 2011, to avoid detection; the second purchase was shipped in three ocean transport shipments which occurred in May and July 2012. All 600 bags were over-bagged to fool Chinese customs.

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[65] Approximately $12,000 US dollars depending on the conversion rate.
[66] This is a process called "over-bagging." If a Chinese customs official had looked at the bags in the first shipment the official would have seen blank bag (white plastic or brown paper). This visual presentation is consistent with the appearance of a bag contain product manufactured in China. Then, once the product cleared Chinese customs, the blank bag could be removed revealing the counterfeit Marlex bag underneath to create the illusion that the counterfeit Marlex bag contained real Marlex.
[67] Exhibit 28 at BSCM12900000074 (emphasis added).
[68] *Id.*
[69] Exhibit 29, BSCM11500006697.
[70] Exhibit 30, BSCM11500006979.

12. <u>The use of counterfeit resin mandates that the products made with the counterfeit resin must be recalled for the following reasons:</u>

a. There is no independent determination that the counterfeit mesh is safe and effective for permanent implantation into women;
b. BSC failed to comply with statutory law and FDA rules and regulations that require a new 510(k) application with a change of material that come into contact with tissue and bone in a permanent implant;
c. BSC created and falsified its internal "equivalency" and mechanical testing repots in violation of FDA rules and regulation;
d. BSC failed to comply with Guidance letter G95-1 regarding biocompatibility testing of a change in materials and also failed to comply with ISO 10993;
e. BSC failed to comply with FDA standards, its own internal policies, and dozens of its own Standard Operating Procedures; and
f. BSC is violating medical device export law by exporting mesh made from counterfeit resin to other countries.

a. *There is no independent determination that the counterfeit mesh is safe and effective for permanent implantation into women.*

Before proceeding too far down the statutory and regulatory path, one can begin with the simple proposition that BSC should only be placing products that are safe and effective on the market. BSC is very careful to extol its virtues in that regard, since it claims…

BSC places its patients first;

Caring, it says, is its number one core value;

Excellence is inherent is everything we do, it claims;

Integrity is a key word it uses to describe itself;

It is dedicated to women's health; and

Nothing is more important than women's health.

BSC has never publicly acknowledged that it has changed from Marlex resin to a counterfeit resin. There is no peer reviewed study of any kind evaluating the use of counterfeit mesh in SUI/POP products. There is no record of the age of the resin. The resin may exceed the shelf life of Marlex or of the resin itself.[71] It appears from review of other women's medical records that there is a higher incident of complications reported after BSC began using the Chinese resin in its products.

[71] BSCM05100041157, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

Given that BSC and the FDA have an obligation to the public to only allow safe and effective medical devices on the market, the mesh should be recalled until it can be proven safe and effective. This is the exact position the FDA took with the counterfeit Bard mesh. Mrs. Stevens asks for no less but also no more than that.

BSC should advise patients, the FDA, the hospitals who buy mesh, and the doctors who permanently implant it into women, that it stopped using a FDA-approved polypropylene and started using counterfeit resin from China (with no history as to when it was made, how it was made, who made it, no title, and was smuggled out of China in four shipments into two countries in a series of transactions mimicking an international drug deal).

Even if BSC felt no moral obligation to the safety of the women using its products, BSC certainly has legal obligations to report the change. No matter, because BSC, threatened with losing $120,000,000 in annual revenue, breached all its duties without batting an eye.

b. BSC failed to comply with statutory law and FDA rules and regulations that require a new 510(k) application with a change of material that comes into contact with tissue and bone in a permanent implant.

Using Chinese Resin is a "Change" of Materials

Mrs. Stevens received an Obtryx implant. BSC represents on its website that her implant is made from Advantage mesh.[72] The 510(k) submitted by BSC to the FDA for Advantage mesh specifically included the warranty that Marlex HGX-030-01 resin would be used to create the Advantage mesh.

As the above discussion shows, whatever the counterfeit Chinese resin is, it certainly is not Marlex HGX-030-01. Here is a summary of facts that support the conclusion that Advantage mesh was made from Marlex HGX-030-01 and is now being made from counterfeit Chinese mesh.

Authentic, Certified Marlex	Counterfeit Chinese Resin
Certificate of Analysis	None
Performance and Technical Data from Manufacturer	None
Identify of Manufacturer is Known	None
MSDS Sheet	None
Confirmation letter from Phillips re the particular lot	Lot Number is Invalid
Verifiable Chain of Possession	None

[72] http://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/sling-systems/obtryx-II/Obtryx_II_Brochure.pdf

Known Environmental History, that is, Knowledge of how material was stored	None, except BSC stated the material was stored in railroad cars, in less than ideal conditions.
All pellets from a single distributor	Unknown; BSC assumed the resin came from multiple sources
Lot Number	Invalid Lot Number
Authentic Marlex bag	Counterfeit bag
Not Smuggled	Smuggled out of China and into the U.S. and into Belgium
Approved by the FDA	Not Approved by the FDA
Manufactured in La Porte, Texas	Unknown

Further, as discussed below, the Chinese resin does not comply with ASTM standards, despite BSC's claims otherwise. As BSC's senior engineer said, "[G]od knows" what is in the changed resin.

The FDA defines a "change" of materials or chemical composition as a change or modification that could affect the health and safety of a device, something that "could" present a serious threat of adverse health consequences including death, and does present an immediate and serious public health risk. *See* 21 CFR 807.81(a)(3)(i).

The FDA standards for change lean, as they should, in favor of protecting the public. So if the difference could pose a risk then the difference is a "change" within the meaning of the FDA Statutes and Regulations.

BSC never satisfied its burden to negate the proposition that using counterfeit Chinese resin could significantly affect the safety and effectiveness of the device. Indeed, BSC conducted no testing at all on 37,400 pounds (minus one pellet) of the counterfeit product, conducted no testing on any shipment in 2012, and conducted no testing on any resin smuggled by ocean transport.

BSC violated its own policies because it purchased the counterfeit Chinese resin even though it lacked a Certificate of Analysis. BSC also violated its own policies on four separate occasions by smuggling the counterfeit Chinese resin out of China and into the U.S. and Belgium. Of course, BSC violated a litany of laws and regulations, too.

<u>Because the Chinese Resin constitutes a "change," a new 510(k) was and is required.</u>

Because the counterfeit Chinese resin represents a change of materials and chemicals, FDA statutes and regulations require BSC to submit a new 510(k) application. To quote the FDA,

> Under 21 CFR 807.81(a)(3), a 510(k) must be submitted when "the device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes that require a premarket notification:
>
> (i) A change or modification in the device **that could** significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, **material, chemical composition,** energy source, or manufacturing process.[73]
>
> Further, the 2014 Report states:
>
> *All changes*, regardless of the manufacturer's reason for making them, *need to be assessed* according to the regulation – *could they significantly affect the safety or effectiveness of the device*, or are they a major change or modification in intended use? FDA has also observed that manufacturers sometimes rely on testing to demonstrate that a change or modification to a medical device does not affect safety or effectiveness, as opposed to showing whether it could affect device safety or effectiveness. Each of these misinterpretations of the regulatory language could lead to modified medical devices being marketed without appropriate FDA oversight (emphasis added).

BSC never attempted to satisfy its burden that using counterfeit resin smuggled into the U.S. from China with all of the deficiencies noted here could significantly affect the safety of the device and the women into whom the devices are permanently implanted.

The Advantage mesh currently being sold by BSC is a Class II medical device made from counterfeit resin and therefore is unlicensed. Because the current Advantage mesh is materially changed from the mesh approved by the FDA, a new 510(k) is still required.

<u>The FDA 510(k) Memorandum K97-1 requires BSC to submit a new 510(k).</u>

The FDA 510(k) Memorandum K97-1 is entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device." K97-1 applies here since the counterfeit Chinese resin represents a change to Advantage Mesh which is an existing device. The letter accompanying K97-1 gives us important information. For example, the Guidance (K97-1 is called a Guidance) covers "changes in materials." Here, the counterfeit Chinese resin is a change of materials.

Here, the basis for comparison should have been the Advantage 510(k) with the Marlex specifications submitted with the application. Instead, BSC compared the Chinese resin to two sample resins, one of which failed its own equivalency study.

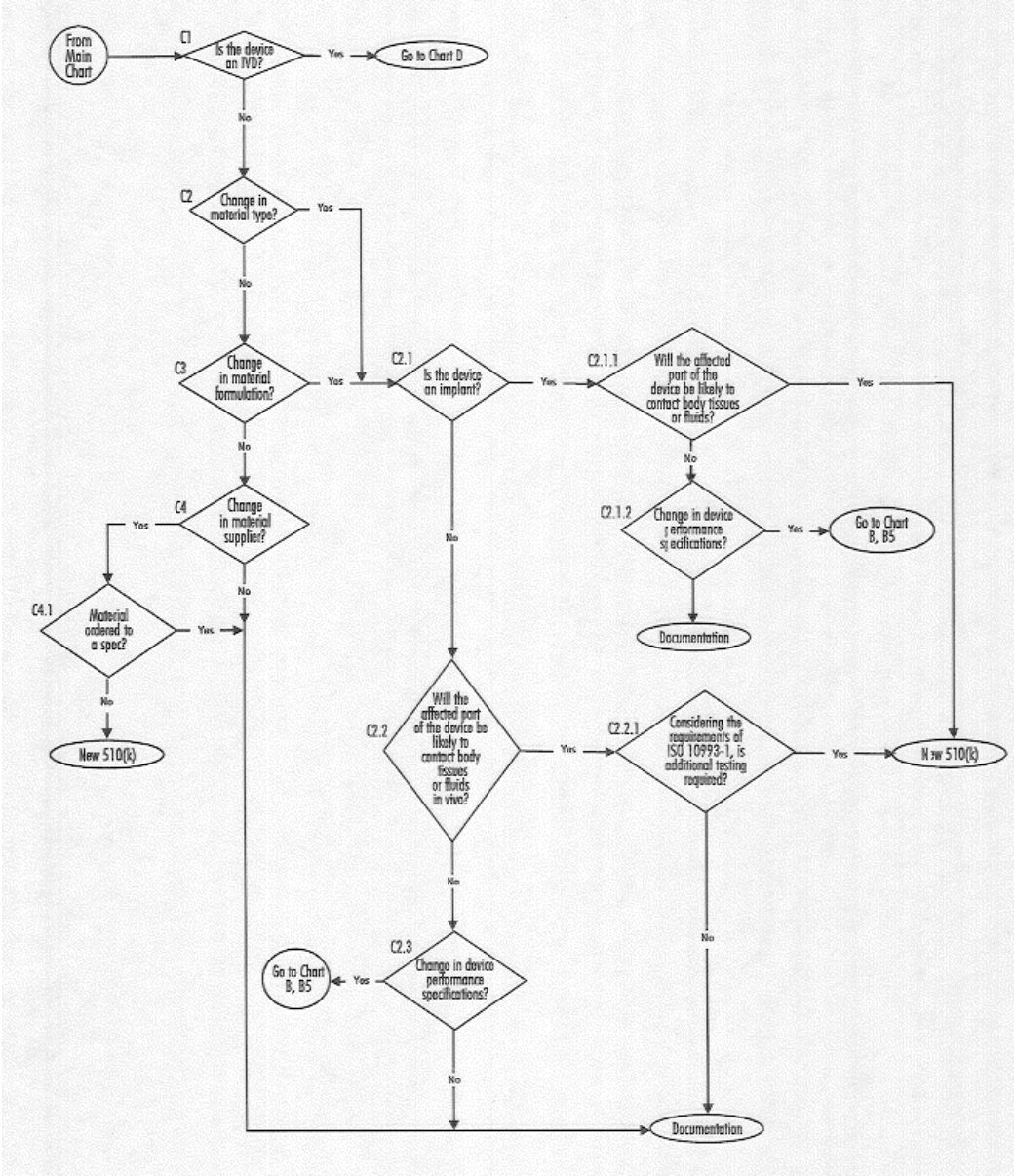
A new 510(k) **is required** when a change "**could** significantly affect the safety or effectiveness of the device." The key word here is "could." "Could" says Merriam-Webster is to

[73] The FDA 2014 Report to Congress Regarding the FDA's Policy for… Modifications to Medical Devices (the 2014 report).

say that "something is possible." The quoted standard comes from 21 CFR 807.81 (a) (3). Here, BSC's failure to submit a new 510(k) thus violates Guidance and CFR.

The Guidance letter doesn't actually require substantial interpretation. The Guidance letter provides "flow charts" to guide those deciding whether to submit a new 510(k). As the Guidance letter says, if use of the Flow Chart leads to the conclusion "new 510(k)," the reader should **"strongly consider submitting a 510(k)."** (Emphasis supplied in the original).

Flowchart C governs materials changes (p. 31). Flow Chart C is reproduced below and quickly leads to the conclusion that a new 510(k) is required.



To remove any and all doubt, if any could remain, the reader need only go to the text in Section C regarding material changes.

> Question C-1 (all of these questions correspond to the above Flowchart C) asks whether the device is *in vitro. In vitro* relates to products used to diagnosis a disease or other condition, not for permanent implant into the human body. A "no" answer takes us to Question C-2.
>
> Question C-2 asks whether this is a change in the type of material from which the device is manufactured. Going from a known Marlex product with a substantial chemical and environmental history from a recognized manufacturer to a chemical substance the recognized manufacturer won't acknowledge *with* an unknown chemical history and unknown environmental history is, indeed, a change in the type of material being used.
>
> Question C-2-1 then asks whether the device is an implant, that is, one that will be in the body for more than thirty days. Since Advantage mesh is intended to be a permanent implant, the answer, again, is yes.
>
> A "yes" answer then takes the reader to Question C-2-1-1 which asks whether the material of the implant is likely to contact body fluids or tissues. Since the answer is "yes" the Flowchart quickly takes the reader straight to "510(k) required."

The Guidance text goes further by stating:

"Manufacturers should submit a new 510(k) for a change in implant material where the material contacts tissue (including bone tissue) or body fluid."

BSC completely failed to document its decision that no new 510(k) was required. The CFR's require BSC to conduct a detailed analysis of whether a new 510(k) was required when it started using the Chinese resin. The BSC "analysis" is both flawed and inadequate.

c. BSC created and falsified its internal "equivalency" and mechanical testing repots in violation of FDA rules and regulation.

Equivalency Testing

Because the Chinese resin is not Marlex, BSC decided to conduct "testing" to determine whether the counterfeit Marlex is similar to authentic Marlex. BSC failed to meet its fundamental obligation of keeping the women's health its number one priority, an obligation met by only offering to sell safe and effective product. BSC knew before it purchased the Chinese resin that it could lay out a bogus test that would allow BSC to claim equivalency pretty quickly.[74]

Despite BSC's claim that it ran samples of the Chinese resin "through a thorough and rigorous battery of chemical tests prior to its use to ensure that it was the same grade of Philips

[74] Exhibit 15 at BSCM13800009461.

Sumika-produced Marlex resin,"[75] BSC simply took the results of inadequate testing performed by Cambridge Polymer Group ("Cambridge)[76] and BSC Executive Dan Burrill interpreted the results and drafted an internal report (the "Burrill Report") claiming the Chinese resin was equivalent to Phillips Marlex.[77] The Burrill Report for equivalency was changed and deeply flawed. The Burrill Report is nothing more than a farce—a rubber stamp on a known, counterfeit product. This report may be a clever attempt by BSC executives to avoid prison and make at least an effort to ostensibly develop some of the data required by the standards—but certainly not the important data.

The Burrill Report becomes report number 90708859.[78] It claims to be a summary of eight chemical tests conducted by Cambridge. Even a casual reader untrained in science can detect immediate problems with the report. For example:

If a scientist were to compare equivalency, he would compare the test sample (the Chinese resin) against published performance data issued by Phillips about Marlex. BSC has the data, it is attached to the Advantage 510(k) and appears in numerous places in the BSC's data set. Rather than use this confirmed data about Marlex, BSC compares the counterfeit resin against a sample obtained from two of its component manufacturers who may lose their contracts with BSC if the test results are poor:

- BSC compares only one pellet from the 4,400 pounds against the two BSC contract component manufacturers (Luxilon and Proxy);
- BSC conducts its tests only one time; there is no effort to determine whether the test results are repeatable;
- One of the standards being tested fails to meet Phillips standards;
- BSC never tests any pellet in the remainder of the 4,400 pound shipment in August 2011;
- BSC never tests any pellet of the roughly five tons shipped in May 2012;
- BSC never tests any pellet of the roughly five tons shipped in early July 2012;
- BSC never tests any pellet of the roughly five tons shipped in late July 2012;
- BSC has no proof each shipment originated from the same manufacturer and internally speculates the resin came from multiple manufacturers;

[75] Exhibit 31.
[76] Exhibit 5, BSCM07300068256.
[77] Exhibit 32, BSCM11500005941.
[78] *Id.*

- The Burrill report attempts to justify testing one pellet one time by assuming homogeneity among all products because the Chinese resin all contains the same lot number and a bag bearing the Phillips markings. Remarkably, BSC's assumption is being made even though BSC knows the lot number is counterfeit, and even though BSC knows EMAI created counterfeit bags. Indeed, BSC's own employee warned these BSC engineers not to buy from EMAI, which had just tried to sell BSC counterfeit plastic. It seems this time EMAI succeeded, but only because desperate BSC staff blindly waved its shoddy product on through;

- The counterfeit resin test results show the presence of titanium which should not be present at the end of the manufacturing process;

- The counterfeit resin contains high amounts of selenium, a toxic element. Selenium, when exposed to hydrogen peroxide (which mesh is exposed to when inserted into a woman's body), turns into selenic acid which accelerates degradation of the mesh and causes tissue and nerve damage;

- The test results of the two samples and the Chinese resin do not match or fall within an acceptable range of deviation;

- The molecular weights of the two samples are inconsistent with the published data for Marlex;

- Cambridge recommended that additional testing be performed which the Burrill Report ignored;

- Burrill changed observations made by the Cambridge;

- Burrill creates a standard to validate the test results for ASTM D3895 that is not found in the standard; and numerous other errors.

Despite all of these flaws, BSC then relied on this pre-destined "Equivalency Assessment" to conclude that no Biocompatibility test was required. The Burrill report failed the testing requirements in numerous ways as noted above. BSC's response was simply to change the scores needed to pass the test. Burrill went so far as to say that "[t]here never was an acceptance criteria" — a critical decision since the OIT results don't meet the expected results.[79]

Mechanical Testing

BSC's manipulation continues with the mechanical testing of the Chinese resin.[80] The introduction to the Mechanical Testing report is riddled with the false and deceptive assumptions:

[79] Exhibit 33 at BSCM11500006589.
[80] Exhibit 34, BSCM11500006055.

1. "Phillips Sumika has discontinued production of Marlex HGX-030-01, a Polypropylene Homopolymer grade. Therefore, BSC obtained the **same polymer** . . ."

BSC had done no such thing. Indeed, BSC was conducting this testing to reach that conclusion (albeit fraudulently).

2. This "scientific approach" begins with the various assumptions the test is designed to address. For example, it fancifully concludes the resin comes "from a second source (material distributor). While the material has been supplied in the **correct Phillips Sumika bag . . ."**

In fact, the bag was not correct. The bag bears a counterfeit lot number, which BSC knew. Indeed, all the bags bore a counterfeit lot number. Also, the bags represent that the contents come from Phillips Sumika Polypropylene Company, LP. BSC must have suspected EMAI (or someone in China) had printed the bags and that the bags did not come from Phillips because until seeing the bags, BSC had presumed the resin was purchased in bulk and transported/stored in a rail car, and not in bags.[81] Further, Phillips is not an LP.

3. The Chinese resin came "with an **identifiable lot number."**

The lot number is not identifiable. It is counterfeit.

4. "there was no CoA supplied with this lot and the distributor is not able to **reproduce** the CoA. …"

In fact, the distributor is not supposed to "reproduce" a Certificate of Analysis. It is supposed to have one, as required by the even BSC's own internal standards.

5. This document outlines the strategy for the mechanical testing that BSC will [sic] conducted to **ensure the *new* lot of Marlex HGX-030-01.**

Again, BSC assumes the Chinese resin is in fact Phillips Marlex from La Porte, Texas, when, in fact, it knows that conclusion is false.

6. …**is equivalent** to the **existing lot of Marlex obtained from Channel Prime Alliance**.

The issue is not whether the counterfeit Chinese resin is equivalent to a Channel Prime Alliance product. It is a change in materials requiring submission under 510(k). Further, the issue, even if one concedes the validity of "equivalency" testing, is not whether the Chinese resin is identical to Phillips Marlex. A fake Rolex is still counterfeit even if it is identical to a genuine Rolex watch.

[81] Exhibit 25, BSCM07700157280; *see also* BSCM06701685127, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

BSC has the Marlex standards from Phillips. It didn't need to test the Channel Prime Alliance product and then compare those results against the Chinese resin. It simply needed to compare the mechanical testing of the Chinese resin against the known data for Marlex. BSC didn't follow this protocol so it could feign "equivalence" that simply doesn't exist. The experimental design and the actual testing samples are flawed, as such, all results of the test are unreliable.

The "testing" never addresses the relevant standard of whether the Chinese resin could pose a risk to the safety of the device.

While BSC was busy concocting a bogus equivalency packet it never addressed the fundamental question, could the Chinese resin pose a risk to the safety of the device to the women who are implanted with it.

d. BSC failed to comply with Guidance letter G95-1 regarding biocompatibility testing of a change in materials and also failed to comply with ISO 10993.

Guidance G95-1 and ISO 10993

FDA Guidance G95-1 concerns the "Biological Evaluation of Medical Devices". The Guidance relates to appropriate tests for medical devices being considered for approval via the 510(k) process. BSC should have, but failed to, comply with Guidance G95-1 and ISO 10993. The Guidance begins by clarifying that "biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body."

AK Plastics, the entity which confirmed with Phillips that the Chinese resin lot number was counterfeit, offered to test one pound of the counterfeit resin. It is worth noting that AK Plastics would be unable to confirm the counterfeit resin characteristics even after testing one pound of the counterfeit resin.[82] BSC tested one pellet from one shipment.

The Guidance goes on to state the obvious — that device materials should not "directly or through the release of their material constituents" produce "adverse local or systemic effects." To achieve this goal the Guidance clarifies that "evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials."

The focus of the Guidance is on the appropriate testing that should be done to ensure the new material does not produce "adverse local or systemic effects." The Chinese resin is "new" as it has never been tested and did not come with any Certificate of Analysis or any toxicology profile—the types of things good manufacturers typically demand before purchasing, let alone using, these products.[83]

[82] BSCM07700158425, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.
[83] Since BSC was smuggling counterfeit resin into the United States it decided to conduct a "material equivalency" test, to justify using resin it had already decided to use and may have already been using Marlex. *See* Exhibit 35,

The Guidance contains a helpful flowchart to show which tests should, at a minimum, be conducted. The Guidance also clarifies that its list is neither exhaustive nor exclusive and that additional testing specified in ISO 10993 might be required.

The Guidance uses two tables to identify which tests should be conducted when new material is used that has no toxicology profile. Table 1, the "Initial Evaluation Tests of Consideration" include the: 1) ISO test for Cytotoxicity; 2) the ISO test for sensitization; 3) the ISO test for Genotoxicity; 4) the ISO test for Implantation; 5) the System Toxicity (Acute) test; and 6) the Sub-chronic toxicity (sub-acute toxicity) test.

In addition, the Table 2 "Supplementary Evaluation Tests for Consideration" include: 1) the ISO test for Chronic Toxicity; and 2) the ISO test for Carcinogenicity.

ISO 10993 has additional tests that should be conducted on new materials. ISO 10993 clarifies that its primary aim is the protection of human being from potential biologic risks arising from the use of medical devices. The ISO combs all available resources to be the international standard to ensure the "safety in use" of the device. The ISO focuses on "the effects of medical devices on tissue" [not the profit margin of the seller and not the job security of the sales force].

Section 4 of ISO 10993 focuses heavily on the risk management plan that should be used to determine if a material is safe for use. Section 4 is adamant that a person should document the physical and chemical characteristics of a material, any history of clinical use or human exposure data, and any existing toxicology or existing biological data on the materials. It is especially emphasized that the data should be about the material itself and about the use of the material in the particular device. Here, EMAI supplied no physical or chemical characteristics data about the material, the Chinese resin has no known history of clinical use and no known human exposure data, and EMAI supplied no toxicology or biological data on the Chinese resin.

The entire BSC plan is flawed from the outset. The extruded resin breaks so the manufacturing standards had to change[84] and the limited and flawed testing that was done revealed differences between the single pellet of the counterfeit resin and material purchased from Channel Prime Alliance in 2005.[85] BSC apparently never compared the counterfeit resin, not even one pellet of it, against the technical data supplied by Phillips for actual Marlex which was contained in the FDA 510(k) packet for Advantage mesh.

Section 4.3 then lists a series of data points needed to assess the product. The list is extensive and BSC gathered none of the required data. It is especially noteworthy that section 4.3 requires information about degradation of the product. One might think that BSC would be especially interested in gathering information about the degradation of the product and yet this requirement was also ignored.

BSCM07300046915. Unfortunately, an early test of the filament made from the counterfeit resin broke on the spinneret. *See* Exhibit 36 at BSCM07700280497.

[84] Exhibit 36 at BSCM07700280497.

[85] Exhibit 37 at BSCM07300073861; Exhibit 5, BSCM07300068256.

Section 4.4 discusses the environmental history of the product including "the conditions of exposure as well as the nature, degree, frequency, and duration of exposure of the medical device *or its constituents* to the body." (Emphasis added). The environmental history of the Chinese resin is unknown.

Section 4.6 requires that the test results be reproducible, a feat BSC did not even attempt to achieve since it only tested one pellet from the first purchase.

Section 4.7 requires new testing if there is any change in the source of the materials. Section 4.7 also requires new testing if there is "***any*** evidence that the product may produce adverse effects when used in humans." (Emphasis added). Certainly every sane person must concede the existence of "any" evidence that the mesh may produce adverse effects when used in humans. Indeed, these adverse effects resulted in thousands of lawsuits being filed in the Southern District of West Virginia—the Court that ordered review by the FDA of these claims.

ISO 10993 specifies additional testing that should be accomplished, a list that closely mirrors the FDA Guidance letter. The tests include at a minimum:

1) ISO test for Cytotoxicity;

2) The ISO test for Sensitization;

3) The ISO test for Genotoxicity;

4) The ISO test for Implantation;

5) The System Toxicity (Acute) test;

6) The Sub-chronic toxicity (sub-acute toxicity) test;

7) The ISO test for Chronic Toxicity; and

8) The ISO test for Carcinogenicity.

However, BSC conducted none of these tests. Instead, BSC prepared a bogus Biocompatibility Analysis that listed ISO tests, WuXi chemical tests, and a solvent test. It then concluded the ISO tests didn't need to be performed.

BSC did NO Biocompatibility tests on the Chinese Resin.

BSC claimed, without any authority, in its "Biocompatibility Assessment" that because Equivalency Testing was performed (the Cambridge/Burrill reports discussed below which tested to ASTM standards) no biocompatibility testing needed to be performed, with one exception noted below.

BSC then filled in the Biocompatibility form with data taken from a known sample of Marlex bearing a Certificate of Analysis. This is really a remarkable statement. To determine from a biocompatibility standpoint whether the counterfeit resin is equivalent to Marlex the test authors

simply assumed the Chinese resin was Marlex based on the Burrill Report, that is, based upon flawed results from a different assessment using different tests.

The one exception is that the Chinese resin had failed an important residuals test in the Cambridge/Burrill assessment. There, the approved test used hexane as a solvent. The Chinese resin failed this test. So, BSC re-did the "test" using water as a solvent. This bears repeating for all of you holding a plastic water bottle in your hand: the test for degradation of plastic using hexane as a solvent was repeated using water as a solvent. Not surprisingly, the new test results produced residuals in an acceptable (to BSC) range. Yet again, BSC knew it was failing the tests on this Chinese resin, so it just changed them until they passed. Facts are stubborn things. BSC could ignore them and change the tests to manipulate them, but should not be allowed to escape them as women suffer the consequences.

To avoid any misunderstanding, the Biocompatibility assessment lists a number of tests conducted by WuXi labs.

All of the tests were conducted on known samples of certified Marlex and the actual technical standards from Phillips were not consulted. None of the tests were performed on the Chinese resin, and most of the tests were performed before the 4,400 pounds was even purchased. This practice was deemed acceptable because the Chinese resin is "Marlex" based upon the Burrill Report. Because BSC had simply drifted off into a land where it was ignoring its own policies and procedures, where it had essentially decided to use the counterfeit resin and was designing tests to confirm its conclusion, it had a "difficult time establishing acceptance criteria."[86]

Table 9 of the Biocompatibility Assessment identifies the testing requirements BSC used to determine whether the Chinese resin is safe to use in human bodies. The form shows that no tests were run on the Chinese resin except for the hexane/water test.[87] Perhaps a little perspective is in order here. BSC knows it bought this resin from China from a known counterfeiter, EMAI. BSC knows it went to the heart of China's counterfeiting region, Guangdong, to just happen upon 37,400 pounds of "Marlex" that somehow made its way from around the world (La Porte, Texas). BSC knows this Chinese resin has no Certificate of Analysis (in violation of BSC's own material specifications), nor any documentation showing how it ended up in Guangdong from just east of Houston, Texas. And BSC is *reducing* its standard tests to wave it all on through? Red flag after red flag flew in the face of BSC executives and engineers—BSC employees blinded by the impending destruction of their $120,000,000 in annual revenue and, more pertinent to them, their own jobs. One does not buy from a known counterfeiter and *decrease* testing—not one sincerely trying to protect patients and comply with the law.

e. BSC failed to comply with FDA standards, its own internal policies, and dozens of its own Standard Operating Procedures

FDA standards, the FDA observed Good Manufacturing Practices standards, the ISO Standards for Quality Management Systems (such as ISO 13485:2300) and even BSC's own

[86] Exhibit 38, BSCM07700280332.
[87] Exhibit 32, BSCM11500005941.

internal standards and Standard Operating Procedures all require BSC to have a Certificate of Analysis. There is no exception to this requirement.

BSC's Material Specification for Polypropylene Resin requires BSC to have a Certificate of Analysis with supporting information.[88]

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 Defendant McCaslin. Defendant McCaslin acknowledged the need and asked if all would be dead without a C of C.[89]
- 8/5/11 – Defendant McCaslin stated that a distributor without a C of C is high risk.[90]
- 8/15/11 – Todd McCaslin stated that they needed to work on getting a C of A.[91]
- 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!"[92] McCaslin told Zhao to push a bit on getting a C of A.[93]
- 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.[94]
- 8/25/11 – Charles Smith pressed the importance of pursuing all avenues to determine lot number traceability.[95]

BSC knows that it should have the Certificate of Analysis and the data, yet it admittedly has neither. EMAI is only a distributor of the Chinese, counterfeit resin—not the manufacturer. (The speculation inside BSC is that EMAI itself gathered the counterfeit resin from multiple sources).

[88] BSCM13600002581, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.
[89] Exhibit 22, BSCM13800008343.
[90] Exhibit 13, BSCM06701713768.
[91] Exhibit 28, BSCM12900000090.
[92] Exhibit 23 at BSCM06701715875.
[93] *Id.*
[94] Exhibit 24, BSCM13500000015
[95] BSCM07700182055, which cannot be attached to this Citizen Petition, as it was marked confidential in bad faith by BSC.

f. BSC is violating medical device export law by exporting mesh made from counterfeit resin to other countries.

There are numerous federal and state laws, and of course FDA rules and regulations, that prohibit smuggling products out of China and into the United States. Even BSC concedes smuggling would be against its own internal policies. Yet the BSC emails discuss in detail the method that would be used and, in fact, was used to smuggle the Chinese resin out of the China and into the U.S. and Belgium. The smuggling from one of the world's leading counterfeiting regions, standing alone, is more than adequate grounds to cause a recall of the Chinese resin products. See, for example, the Class I recall and warning initiated by the FDA over a counterfeit Bard mesh. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm.

Storage and transportation of the Chinese Resin failed all known standards.

All known standards require that component materials be stored to reasonable standards and protected against contamination. The BSC Material Specification for Polypropylene Resin is one such standard. Yet BSC has no record of how the Chinese resin was stored except to note in occasional emails that the counterfeit resin should be moved to better storage facilities to because the existing storage was substandard. Whether this product, which is going to be permanently inserted into women's bodies, was stored in conditions that accelerate degradation or were subject to rats or vermin is simply unknown.

Exporting mesh made from counterfeit mesh violates 21 U.S.C. § 382 (f)

Section 382 (f)(1) prohibits the exportation from the United States of a medical device that is not manufactured in conformity with good manufacturing practices or does not meet international standards. Creating Advantage mesh from counterfeit resin and exporting it violates both standards. BSC exports mesh made from counterfeit resin in violation of subsection (f)(1).

Subsection (f)(2) prohibits the exportation of adulterated products. Creating Advantage mesh from counterfeit resin and exporting it violates this standard. BSC exports adulterated products in violation of subsection (f)(2).

Subsection (f)(5) prohibits the exportation of improperly labelled products. Selling counterfeit Advantage mesh and exporting it violates this subsection.

All mesh manufactured with Chinese Resin is adulterated and other violations of the Federal Food, Drug and Cosmetic Act (the Act).

Mesh made from Chinese resin and not made from certified Marlex is adulterated under the circumstances described in this Petition. *See* 21 U.S.C. § 351(h).

Mesh made from Chinese resin and not made from certified Marlex is misbranded within the meaning of the Act.

13. Using any Marlex with a Certificate of Analysis would require a new 510(k) and be a breach of contract with Phillips.

The last contract BSC had with Phillips for the purchase of Marlex HGX-030-01 expired on September 30, 2005.

The contract provides an express warranty by BSC that it will stop using Marlex in its mesh products except for mesh made from Marlex in the possession of BSC as of September 30, 2005 (a provision that doesn't apply to the Chinese resin) or purchased from a list of recognized distributors of Marlex who might have some run off left (EMAI is not on the list of approved distributors).

Since this contractual provision was going to require a change in materials from Marlex to something else a new 510(k) should have been submitted then (and wasn't).

To the extent that BSC now claims the Chinese resin is "Marlex" it lacks proof that EMAI is a certified distributor and it lacks proof that the Chinese resin was made on or before September 30, 2005. If the Chinese resin is made on or before September 30, 2005 then it has outlived its shelf life since BSC internals documents claim the shelf life of the product is seven years.

Since even BSC now concedes the resin is "China Sourced" BSC is in breach of its warranty to not use Marlex in its mesh products.

Further, Phillips changed the formula for Marlex HGX-030-01 in 2006. The performance qualifications for Marlex also changed. If BSC is claiming it is using China Sourced Resin matching the pre-2006 performance standards then those standards are no longer applicable to Marlex. If BSC is claiming it is using Chinese sourced resin that meet Marlex standards put in place in 2006 then BSC should have submitted a new 510(k) or documented why it concluded a new 510(k) was not required.

Conclusion

For all of these reasons and more the undersigned respectfully requests for the relief discussed above. Thousands of women have received counterfeit Chinese mesh products since this matter was first brought to the attention of the FDA on February 19, 2016. Thousands of women received—permanently—into the most intimate parts of their bodies counterfeit, Chinese resin smuggled into this country by BSC. BSC smuggled this counterfeit, Chinese resin into this country so it could sustain $120,000,000 in annual revenue. Women's health—which was supposed to be BSC's primary goal—suffers immediate, irreparable injury each day this BSC mesh remains on the market. Today, another two hundred women will permanently receive, as BSC's own words describe it, "[G]od knows what" into their bodies. Please act promptly to guard against any further damage or injury.

C. Environmental Impact

The actions requested in this petition are subject to categorical exclusion under § 25.30.

D. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner per 21 C.F.R. § 10.30(b).

E. Certification

The undersigned certifies, that, to the best knowledge and belief, this Petition includes information and views on which the petition relies, and it includes representative data and information known to the Petitioner which is unfavorable to the Petition.

Respectfully submitted,

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