



## EXHIBITS TO CITIZEN PETITION

Exhibit	Begin Bates	Document Description
1	BSCM13500000937	Robert Mullally asks, "How did all this resin end up in China if it was made in Texas?"
2	BSCM13500000440	ISF Form for Shipment of Marlex
3	BSCM11500006904	Counterfeit material from a supplier you use – ACTION REQUIRED
4	N/A	1/24/16 Order of the Honorable Judge Goodwin
5	BSCM07300068256	Cambridge Polymer Group Test Results
6	N/A	<a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm204199.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm204199.htm</a>
7	N/A	Marlex HGX-030-01 Property Data Page
8	BSCM00100000001	Relevant Portions of 510(k) packet for surgical mesh
9	BSCM04500000465	2004 Marlex HGX-030-01 MSDS
10	BSCM06701713798	In 2005, BSC purchased 8,800lbs of Marlex from Channel Prime Alliance
11	BSCM06700722854	BSC ran short of Marlex in 2011, creating a fire drill inside BSC
12	BSCM13000000033	History, Accomplishments, Actions, Lessons Learned Slide
13	BSCM06701713768	BSC did not think the FDA would approve a material change; McCaslin also considered a distributor who could not produce a COA high risk
14	BSCM04700235069	Phillips was not interested in doing business with BSC at any price
15	BSCM13800009460	BSC designed tests which would allow them to claim equivalency to certified Marlex quickly
16	BSCM13000000037	Marlex background, update slides
17	BSCM11200014917	Impending Marlex shortage would cost BSC \$120,000,000 in annual profits
18	BSCM05700089220	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.
19	BSCM13800009800	BSC hid the intended purpose of the Marlex because the information might scare away the Chinese sellers.

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20	BSCM13800008924	Zhao detailed visits to 5 Chinese distributors of Marlex found on alibaba.com
21	N/A	“There’s no end in sight for Alibaba’s counterfeit problem” published in Fortune Magazine at <a href="http://fortune.com/2015/05/18/theres-no-end-in-sight-for-alibabas-counterfeit-problem/">http://fortune.com/2015/05/18/theres-no-end-in-sight-for-alibabas-counterfeit-problem/</a> .
22	BSCM13800008343	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
23	BSCM06701715868	Zhao sent a picture of the counterfeit Marlex bags containing EMAI resin, showing a lot number. McCaslin told Zhao, “Very nice work!”
24	BSCM13500000010	BSC checked with 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
25	BSCM07700157280	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.
26	BSCM13500000465	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
27	BSCM11500004626	BSC declared to the relevant U.S. and Belgium authorities the product was Phillips Marlex made in Texas
28	BSCM12900000074	Zhao discussion regarding over-bagging, and inspection of shipped resin
29	BSCM11500006697	The shipper of the 4,400 lbs by air was not "over-cautious"
30	BSCM11500006979	Even though BSC’s chance of being audited was low, BSC played it safe and split the resin into 4 separate shipments
31	N/A	Letters to doctors in response to allegations that BSC is using counterfeit resin
32	BSCM11500005941	Burrill Report - Equivalency Testing
33	BSCM11500006588	Cuddy thought it was a clever solution to move to the ASTM standard, but Burrill said there was never an acceptance criteria

34	BSCM11500006055	Mechanical Testing Protocol
35	BSCM07300046915	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.
36	BSCM07700280496	An early test of the filament made from the counterfeit resin broke on the spinneret
37	BSCM07300073860	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.
38	BSCM07700280332	BSC decided to use the counterfeit resin and was designing tests to confirm its conclusion, it had a “difficult time establishing acceptance criteria.”