JEANNE SHAHEEN
NEW HAMPSHIRE

SUITE SH-506
HART BUILDING
WASHINGTON, DC 20510
(202) 224-2841

United States Senate

WASHINGTON, DC 20510

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The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

In light of recent press reports relating to litigation surrounding patient safety issues associated with transvaginal mesh products used to treat urinary incontinence, I write to seek answers to troubling questions regarding federal oversight of the supply chain and production processes for implantable medical devices.

As you know, recent reporting from *60 Minutes*, the Boston Globe and other outlets revealed that as a transvaginal mesh manufacturer, Boston Scientific Corporation continued to produce transvaginal mesh sling products using the chemical resin known as polypropylene, despite warnings in 2004 from the major domestic supplier of polypropylene indicating that it was unsafe to use polypropylene resin in products designed for implantation in the human body.[1] Subsequent complaints from patients who have the surgically-implanted mesh device suggest that severe irritation, inflammatory reactions and pain are prevalent symptoms stemming from sustained use of the device.[2] According to the *60 Minutes* report, more than 100,000 women have filed civil suits against Boston Scientific to seek restitution for damages caused by the effects of this device. Given that transvaginal mesh is a medical device, the Food and Drug Administration (FDA) oversaw the approval of the product and is responsible for ongoing post-market oversight of the safety of the device.

The reports further indicate that the warnings from the domestic supplier of polypropylene, Chevron Phillips Chemical Company, were not heeded by Boston Scientific. Instead, the device manufacturer successfully obtained polypropylene from other sources in China after Chevron Phillips reportedly refused to continue to supply Boston Scientific with the polypropylene resin that is used to produce the plastic mesh for the transvaginal mesh sling product. According to the reports, the Chinese supplier, EMAI Plastic Raw Materials, Inc., represented that the polypropylene sold to Boston Scientific was "Marlex" polypropylene product that was originally produced by Chevron Phillips and subsequently acquired by EMAI.

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[1] Pelley, Scott, "Gynecological Mesh: The Medical Device that has 100,000 Women Suing," 60 Minutes Report, CBS News, May 13, 2018. Available online at: https://www.cbsnews.com/news/boston-scientific-gynecological-mesh-the-medical-device-that-has-100000-women-suing/ ; *See also* Capelouto, J.D., "60 Minutes Looks at Lawsuits Against Boston Scientific," Boston Globe, May 14, 2018. Available online at: https://www.bostonglobe.com/metro/2018/05/13/lawsuits-filed-against-boston-scientific-featured-minutes/PRpJAgD3ByTsu7lHd3aHYM/story.html

[2] Pelley, Scott, "Gynecological Mesh: The Medical Device that has 100,000 Women Suing," 60 Minutes Report, CBS News, May 13, 2018. Available online at: https://www.cbsnews.com/news/boston-scientific-gynecological-mesh-the-medical-device-that-has-100000-women-suing/

However, chemical testing performed on behalf of the *60 Minutes* investigation suggests that the EMAI-supplied chemical compound is significantly different from samples of the Chevron Phillips Marlex polypropylene product that was originally used in the transvaginal mesh products.

Both the continued use of the original Marlex polypropylene product following warnings from Chevron Phillips and the subsequent use of the Chinese version of the polypropylene compound raise potential concerns relating to the FDA's oversight of Boston Scientific's production activities.

In order to be able to respond to concerns raised by patients and to be able to better understand the FDA's actions in monitoring the issue, I request answers to the following questions:

1. When did FDA officials become aware that Boston Scientific had switched polypropylene suppliers, from Chevron Phillips Chemical Company to Chinese suppliers, and were FDA officials aware at that time that the Chevron Phillips Chemical Company had raised concerns about the use of Marlex polypropylene products in implantable medical devices?

2. According to reporting from the Boston Globe, following notification of Boston Scientific's change in polypropylene suppliers, the FDA "conducted its own testing of the finished product for specific mechanical properties and physical characteristics and determined that all samples met the appropriate specifications."[3] Can you provide additional details on the scope of this finished product testing?

3. The FDA's response to the Boston Globe reporting indicates that "FDA concluded that the new resin does not raise new safety or effectiveness concerns." Did the FDA obtain samples of the new polypropylene resin that was used following the supplier change and compare the physical properties of the resin itself with the Marlex polypropylene resin that was previously used to produce the device?

4. The FDA's response also suggests that in its review of the adverse event reporting database, FDA "did not find any indication that the change in resin led to an increase in adverse events." Can you provide additional details on the types of patient circumstances that rise to the level of being included as "adverse events" for the purposes of adverse event reporting in the database?

I appreciate your ongoing commitment to ensuring that drugs and medical devices are safe and effective for human use, both at the time of original FDA approval and during the ongoing subsequent periods of drug and device production and medical use. Your attention to this issue will help to make certain that the FDA has the necessary processes in place to help avoid harm to patients.

Sincerely,

Jeanne Shaheen
United States Senator

[3] Capelouto, J.D., "60 Minutes Looks at Lawsuits Against Boston Scientific," Boston Globe, May 14, 2018. Available online at: https://www.bostonglobe.com/metro/2018/05/13/lawsuits-filed-against-boston-scientific-featured-minutes/PRpJAgD3ByTsu7IHd3aHYM/story.html